

Inventor Relations Are Complicated! Developing and Maintaining Good Inventor Relationships Is Key

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Know Your Inventor

In the Office of Technology Licensing (OTL) at Stanford, we believe that the inventor is the most important client, our customer. She is the source of our raw material, the person who gives us inventions to find homes for. Therefore, we need to establish good relationships with inventors who sometimes don't really understand the commercialization process. Other inventors do not want to be bothered or educated with the legal and commercial details—especially prior to having inventions; some want to be very closely involved. Still other inventions are, frankly, not of commercial interest, but the inventor, as the creator with little objective perspective, often has unrealistic expectations.

The ideal inventor is someone who is involved and interested in giving input but is willing to rely on, and learn from, the experienced judgment of the licensing professional. On the other hand, sometimes the inventor has important insights that can help the licensing office make a better decision. The inventor, understandably, wants the technology developed and usually wants the licensing office to “get the best deal possible.” Inventors often think we undervalue their technology.

Inventors come in all flavors! They do not always speak with one voice. Inventors are faculty, staff scientists, graduate students, post-docs, or undergraduate students. Sometimes, one inventor wants the technology to be licensed nonexclusively but his joint inventor wants to start a company. Sometimes inventors don't get along with their co-inventors. Sometimes student inventors are afraid to speak their mind. Sometimes an “inventor” is not really an inventor in the patent sense and appears on invention disclosures because she is the principal investigator (or worse, a chairperson). Sometimes

inventors are at different institutions. The licensing office must be aware and sensitive to all these relationships to make reasonable decisions for all the effected parties.

The biggest challenge, but the greatest requirement for good inventor relationships, is to keep *all* inventors informed, not just the faculty inventor. This can be very difficult when the number of inventors is high and their status is different. We try to meet with all inventors for the initial meeting to explain the process and set realistic time, patenting and/or licensing, and monetary expectations (another important aspect to maintaining good inventor relationships). Although often one inventor is more interested than the others, or speaks for the others, we try to keep all inventors informed on general patenting and marketing correspondence so that they each have the opportunity to have input.

Lastly, sometimes inventors actually do know best. We have had inventions that we clearly thought were unpatentable and unenforceable but around which a company was created. We have wanted to drop inventions for good reasons, but inventors have persuaded us to continue with patent applications that eventually led to licensing activity. So, inventors' opinions should always be given serious consideration. We get their input on licensing strategies (nonexclusive/exclusive, startup/existing company) and their perspective on pricing (so as to see if our expectations are similar to theirs). Inventors do not dictate licensing to the licensing office, but we are very generous with asking for their input and reactions.

In general, our licensing teams work very closely with inventors—students and faculty alike—and are in regular communication with them. Working well with inventors ensures that the office will have repeaters whose second and third inventions may end up to be more valuable than the first. If a first-time inventor has a bad experience, the office may not get the opportunity to work on those second and third valuable ideas.

Outreach to New Inventors

Like other university inventors, Stanford researchers vary tremendously with regard to commercialization of their inventions—from disinterested inventors to very interested researchers, from experienced inventors to inexperienced. We have various informal activities to reach to new inventors: taking faculty to lunch; participation in new faculty orientation, attending speaking engagements at the laboratory or departmental level; hosting seminars for students, grad students, and post-docs as well as for faculty only; and exploiting speaking opportunities at Stanford entrepreneurial organizations. We have had barbeques and box-lunch occasions to attract student interest in the licensing office. But the OTL has been in business for long enough (more 37 years), that we are fairly confident that a new inventor will be encouraged by colleagues to contact us if there is a discovery that is has commercial potential.

For universities that are trying to build their technology transfer program, we believe that inviting successful inventors who can share their stories with colleagues is a good way to generate positive publicity. Often university researchers are more interested in hearing from external “experts,” such as patent attorneys, venture capitalists, and well-known entrepreneurs, about the their roles in the commercialization process. Any kind of interesting seminar on aspects of technology transfer is a chance to educate the community about the opportunities and challenges of university licensing.

We also caution, however, against overselling technology transfer because disillusioned inventors can be a very negative influence on colleagues. The best way to encourage disclosures is to have a good reputation among researchers.

We believe in providing abundant information via many sources: the Internet, brochures, pamphlets, annual reports, a newsletter, and an *Inventors Handbook*. We are willing to meet with new inventors (or potentially new recruits to Stanford) whenever they call so that we can establish a relationship early on. We find that it helps to calibrate future inventions if we can start to understand an area of research before inventions are disclosed to the office, when at all possible. If the OTL is aware of large research grants that may produce inventions, licensing staff can easily meet with faculty and staff to encourage disclosures.

However, if an office is swamped, getting new disclosures/the best disclosures may not be a priority. You have to prove yourself with what you get, not what you don't get.

Outreach to Current Inventors

As mentioned in the first section on our philosophy, we try to maintain regular communication with our inventors. We have an Inventor Portal, which is one of the most effective ways to allow the inventor to keep abreast of her invention activity without having to call/write the office all the time. The Inventor Portal, a Web-based, confidential system, provides a real-time, continuous status report on all invention disclosures, all patents filed, expenses associated with the filings, all licenses, and all royalty income past and current.

We also survey our inventors, six months and one year after the disclosure is submitted. The questions, about 8 to 10, are specific to the events related to the timing of the survey. For a new disclosure, we ask the inventor if she has met with the licensing staff and understands the process. For an older disclosure, we ask if he has been kept informed. If the customer survey indicates that there is an issue or unanswered questions, we respond right away to the inventor. The customer survey is a great way to keep in touch with inventors and resolve issues as soon as possible. The most common complaint, if there is one, is that an inventor is not kept as informed as she would like to be so it is very important to keep inventors informed. If we discover this, we call him right away.

We assign inventors to various licensing professionals based mostly on technical area of the invention. For repeat inventors, we try to keep the same licensing representative to enable people to establish a relationship, but there are times when the invention involves a different discipline or there are several inventors who have worked with different licensing staff so it's not a hard-and-fast rule. Very rarely, an inventor does not get along with a licensing person and we will change assignments, but inventors do not generally get to choose the licensing person.

Summary

The ability of office staff to manage inventor relationships well is one of the most important keys to success. Regular communication with and respect for the inventor will go a long way to contributing to good inventor relationships, some of which may last for years and many inventions and licenses.

The Southern Paradigm: Communications around the Production of Invention Disclosures

Odd Bres, PhD, Fred Munson, and Garold G. Breit

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Academic technology transfer is generally perceived as the process that conveys useful intellectual properties from academe to the larger community, thereby providing optimal utility to the economy. One key step of technology transfer is the new invention disclosure process, and the successful technology transfer program yields the optimal number of high-quality disclosures. Good disclosures are the beginning of successful patent prosecution, effective marketing, licensing, and dissemination of university innovation.

This article provides a method and organizational plan that has heretofore been informally known by its proponents as the *southern paradigm*. We have used this term to refer to an approach to technology transfer that includes proactive technology disclosure mining and aggressive marketing techniques. We believe that Bob MacWright (University of Virginia Patent Foundation), David Dey (University of Florida), and the University of Texas system have used some of these techniques.

The invention disclosure process has been recognized as an important aspect of the technology transfer process because it represents the key point of contact, the presentation of the germ of the technology, and the initiation of the transfer from idea to commercial product. Quite simply, experienced technology management professionals view new disclosures as the lifeblood of the successful program. Over the past decade, the growth rate of new technology disclosures as a function of research funding has been marginal (see *AUTM Licensing Surveys*™, 1995-2005); and there is an opportunity to do better.

To meet the need, a new method of mining, marketing, and managing technologies, known as the *southern paradigm*, has emerged. The methodology has been developed

by technology transfer professionals in universities of the Southern tier of the United States over the past fifteen years. It has proven to generate an increased number of new invention disclosures. More important, those disclosures are of better quality and, thus, a better experience for faculty inventors as well as for technology managers.

This chapter presents a detailed methodological description of the new approach as it pertains to mining intellectual assets to garner more and higher quality disclosures. Proven technology transfer manager Patricia Weeks has said that technology transfer is essentially a relationship-building process, but the key to success is to take a planned and disciplined approach.¹ As with all sales and marketing activity, a predictable percentage of the activities will lead to a predictable flow of deals. The southern paradigm approach provides a well-managed, highly interactive flow of information between the faculty inventor and the technology transfer manager.

We present here a scheduled series of interactions over a timeline of days, weeks, and months. The program includes a series of specific tasks, a timeline of interactions between faculty member and technology transfer manager, and anticipated time-labor demands. These assist in effective planning and will allow both the program director and technology transfer manager to measure and report their success. We focus on tactics, but digress at the outset to describe the underlying strategy.

How the Southern Paradigm Works: The Strategy

The basic underpinning of the southern paradigm is that there must be a close alignment between the science and technology embodied in an academic invention and the two other aspects of technology transfer: intellectual property (IP) protection and commercialization. The applicability and utility of university inventions are shaped to a great extent by the flow of information from industry back to the university research system, rather than a purely outward flow of scientific and technical knowledge. The resulting challenge for the technology management professional is to closely integrate the sales and marketing function with the academic faculty client's work. A series of communications are set to

- inform faculty members of the technology transfer process,

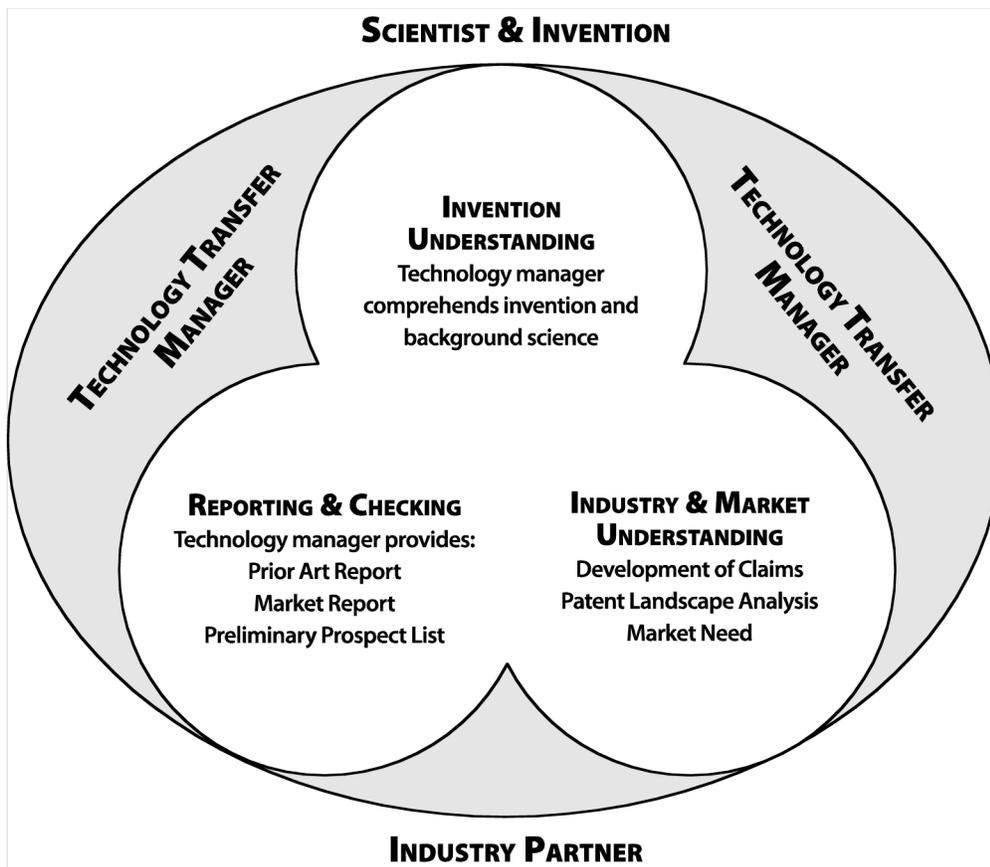
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- allow the technology manager to understand the technology invention knowledge (as akin to product knowledge of marketing parlance),
- allow inventor and technology manager to work together to navigate the IP landscape, and
- allow the technology manager to investigate and report market data to the inventor.

The southern paradigm therefore integrates the invention, IP protection, and marketing activities. Figure 1, presented as a cycle, describes the bi-directional information flow by which the technology manager understands the invention thoroughly and then relates back to the inventor the IP landscape and the state of the industry. The proper flow yields the most viable and valuable patent claims, a true prior art report, and a real prospects list.

Figure 1: Bi-directional Information Flow Management



Patent Prosecution Issues

Behind the southern paradigm method is a specific approach to patent prosecution. The close cooperative work builds on the concept of intellectual property as a developing process rather than an individual and static asset. Each technology is viewed as part of a developing patent family in which claims will evolve over time with ongoing research. Viewed in this way, the technology manager must understand and report to the researcher about the IP landscape and prior art. This can only be achieved by a collaborative ongoing approach.

At early stages of discussion it is worth informing academically oriented researchers of the meaning of publication patent bars and to tell them how patenting and publishing can be, with a small degree of planning, highly compatible. At a more detailed level, researchers can benefit from technology managers conducting patent searches, or at a greater level of sophistication, it may involve deciding on laboratory experiments aimed at providing information needed to broaden claims or to find ways to publish some negative results to forestall possible obviousness difficulties.

Market Considerations

Technology management professionals understand that market opportunities are just as important as patentability considerations when investing in IP protection. As with the IP landscape and prior art issues, the technology manager's analysis of industry's commercial needs can shape some aspects of ongoing research and new claims in follow-on provisional and continuing patent applications. This information can guide inventors.

For example, researchers pursuing novel discoveries in intracellular signal pathways may profitably consider industry's need for "druggable targets." Or they may keep in mind the relatively greater value of small molecules compared to biologics. The ongoing feedback and interactions with the faculty member gives the technology manager deeper insight as to the best commercial market prospects, and he or she gives the inventor new ideas about shaping the research to meet the greatest challenges and best opportunities in industry.

This works best if the technology manager has a chance to conduct—and report back on—market research rather than trying to accomplish the whole exchange at once. A draft market report is an invaluable focus of discussion.

Just-in-Time Technology Transfer

The southern paradigm is consistent with the just-in-time model of academic technology transfer, as suggested by MacWright.² In this deal-based model, the relatively inexpensive provisional patents are marketed aggressively long before they are converted to PCT (Patent Cooperation Treaty). That way the costs are transferred to the licensee, and it gives the licensee more input as to the claims structure of the patent. The just-in-time approach requires that the marketing activities happen quickly and efficiently.

The just-in-time model results in a greater number of technologies returned to the inventor (i.e., abandoned prior to PCT). Since the faculty member is so closely involved in the process, there is less of a negative surprise at this outcome. Instead it can be understood as a positive part of the invention process because the inventor has likely been directing scientific and technical energies at improvements and refinements that become the subject of follow-on disclosures. And the ongoing science is better informed by the patent landscape. This engages the researcher and leads directly to the next and the better disclosure. Truly the southern paradigm begins and ends with the scientist and the science.

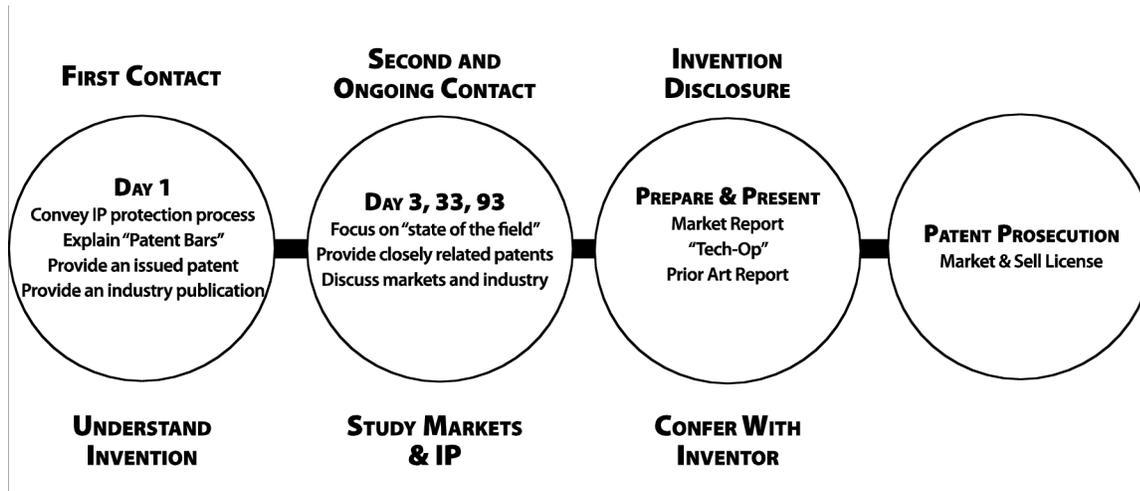
How the Southern Paradigm Works: A Description of the Process and Timeline

The southern paradigm is an interactive process that is conducted by technology managers and faculty-clients in a scheduled manner over days, weeks, and months. Figure 2 depicts the specific activities that are included in the new paradigm and a schematic of the labor demands on a technology manager (and intellectual property program) who adopts the new paradigm.

The Southern Paradigm: Communications around the Production of Invention Disclosures

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Figure 2: Flow of Specifically Scheduled Actions by the Technology Manager



As you observe, at first blush, the new paradigm seems to track traditional technology transfer practices. However, on closer examination, it becomes apparent that the new paradigm is more iterative, requires more direct, one-on-one communication, and places new service demands on technology managers involved in the process (and, on technology transfer offices).

The iterative aspect of the process reflects the basic value of the southern paradigm in promoting the two-way flow of information, mediated by the technology manager, between industry and the academic scientist. Also, by providing a schedule of planned actions and time investment (Figure 3), the paradigm aids in planning, monitoring, quality management, and consistent reporting of effort.

Schedule of Steps

Day 1

The technology manager schedules a one-hour face-to-face interview: On first contact with the faculty member, the technology manager provides information about the university technology transfer program and provides an overview of the concepts of technology transfer, with particular attention to the IP protection process and

Figure 3: The Labor Demands

Labor Demands		
1st Contact	2nd Contact	Invention Disclosure
5 hours	5 hours	10 hours

patent bars. The technology manager prepares for the meeting by researching the individual faculty member's background and should provide a related issued patent as an example and, also, based on an estimate, a relevant industry publication.

Technology managers should prepare for this first interview by considering the faculty member's specific scientific interests through a review of publications and through other sources. The disclosure process begins with this first meeting—a personal interview usually, and, preferably, in the faculty member's laboratory or office. During this meeting the technology manager seeks to understand the faculty member's field of study, specific scientific interests, publication history, academic standing, teaching responsibilities, and research budget.

Incidentally, while the faculty member may be aware of industrial applications of his or her work, there is much to be gained by asking about his or her academic peers (leading lights or even competitors) in the field. During this conversation, the technology manager provides the faculty member with an accurate description of the technology transfer processes, realistic expectations (including elements of quality), and a description of the mode of operation of the ongoing interactions for this professional relationship.

Further, the technology manager describes the steps involved in the just-in-time model of technology commercialization, including the fact that, while the technology transfer office invests in provisional patents, many technologies must be returned to the inventor after that first year of patent prosecution in favor of new developments. Behind Figure 1 lies the abovementioned mantra that the technology transfer process begins and ends with the scientist and science.

It should be noted that some important issues are relatively easy to discuss at this early point. Important groundwork is laid for the future challenges, under these relatively casual conditions, such questions as co-inventorship and royalty distribution expectations are explored. The just-in-time patent prosecution approach will result in the return or abandonment of a percentage of the new disclosures, this fact is much easier to explain and discuss right at the outset.

Day 3

Immediately after the initial interview (certainly within 72 hours), the technology manager will provide a specific article, reprint, published patent, or reference that directly relates to the specific scientific interest discussed earlier as an initial service to the faculty member. This may be in the form of a follow-up meeting or a communication. The information allows both parties to establish a commonality around an understanding of the central topic/science. If a misunderstanding exists, this is the appropriate time for a correction. This technology-related dialogue will be replicated many times over the next few months.

Day 33

As in day 3, the technology manager provides a contemporaneous article, reprint, reference, or preferably, issued patent that provides value to the faculty member and his or her associates. Again, this process of tracking technological development in the specific field of interest has the tendency to lead to critical thinking (compare-and-contrast exercises) related to a technology field and the latest technological development. At this point, the new paradigm suggests a focus on publication searches directed at the most active inventors and leading lights in the field, as well as key potential companies and key patents.

The combination of these patent searches and publication searches can effectively track the development of technology in broad (and narrow) fields of interest.

Day 93

A follow-up meeting is scheduled, located at the faculty member's office. As in day 33, the technology manager provides a current-day article, reprint, reference, or preferably, issued patent that provide value to the faculty member and his associates. Typically, at this point, the technology manager and the faculty member have established an understanding of the field, a good communication pattern, and the mutual respect that derives from (a) an expressed interest in the faculty member and her field of interest, (b) a relationship based on service, and (c) a notion of ongoing communication.

Beyond a basic service to faculty, it is predictable that, over time, inventive faculty members will produce new ideas and technologies that stem from this increasingly shared view of the state of the field. And, in our experience, when faculty members present these invention disclosures, the technologies tend to be

- distinct from prior art;
- clearly defined;
- more complete, with the information required of a quality specification;
- targeted at specific companies in the field; and
- marketable.

Disclosure Day

The actual invention disclosure can happen at any point during the background process. At this point the technology manager must, within days, produce the following.

1. A prior art search: This is a comprehensive review of the patent databases and is based on key-word, inventor, and assignee databases.
2. A market review: This perspective may include data from secondary and tertiary sources, market studies that are produced by consultants with experience in the field, and an internally constructed model.

Now, the technology manager has the necessary knowledge of the technology and the markets to make the strongest possible patent application, with commercially attractive claims. Also the technology manager has the product knowledge needed to begin the successful technology sales process. The faculty member is apprised of general progress and is involved again with industry presentations, industry visits, and the license process.

Labor and Time Management

The use of a timeline outlined below accomplishes two aims. First, a fast follow-up maintains the proper level of involvement and, second, it is a feasible time management method for the technology transfer manager. Under the just-in-time method, the technology manager typically sees 25 or more invention disclosures a year (with an aim to ten deals a year), so it is feasible to plan the work schedules along the schedules presented in Figure 2. This results in about 75 days of work, or one-third of the 240 work days per year; a proper balance with other sales, patent prosecution, deals, and license management duties.

The proposed times reflect the proper depth of effort for each step. It is all too easy to spend far too much time on “market analysis” while spending not enough time on personal faculty interviews.

Summary: Advantages of the Southern Paradigm

As has been noted above, initially, the new paradigm appears to be labor intensive (and, expensive). However, consider that

- we are meeting with relatively large numbers faculty members who have not been clients of the technology transfer program,
- we are investing in time-consuming explorations of diverse technology fields, and
- we are maintaining this rather-casual relationship over time.

However, in our experience, when that invention disclosure is produced, the technology manager is exquisitely prepared to move forward with alacrity. Much of the anticipatory work has been completed (and is perceived by the faculty client as faculty service), and the technology manager proceeds directly to secure intellectual property protections (with an understanding of the prior art) and promotion of the technology (with some knowledge of the competitive landscape of the marketplace).

The basic underpinnings of the southern paradigm: the efficient flow of information through iteration will continue to guide the technology transfer process from here. The process of investigating the scientific literature, the market review, and the prior art

searches will, if done properly, necessarily provide a sophisticated understanding of the invention.

The faculty meetings at which this progress is reported and discussed will further solidify in the technology manager's mind the product knowledge without which effective commercialization cannot happen. This includes knowledge needed for effective patent prosecution, well-focused marketing, and then selling the licenses. And this goes on the future ongoing work with the commercial licensee.

This process has produced:

- new levels of service (of a different scope) to faculty,
- an increased number of invention disclosures,
- faculty satisfaction,
- an accelerated technology promotion,
- office efficiency/economy in the long-term, and
- improved productivity.

Finally, the successful technology transfer office, and the successful manager will keep documented summaries of their results; numbers of faculty contacts and calls; how many disclosures result; and the percentages of disclosures leading to patents, deals, and dollars. The southern paradigm provides a structured series of actions and steps to maximize successful disclosures—the first and basic step of successful technology transfer.

Notes

1. The disclosure process should, as with any successful sales effort, be strongly oriented to clear, meaningful metrics, and the southern paradigm provides the basis for measuring the time and effort involved in garnering new disclosures.
2. MacWright, R. S., Esq. A Pragmatic, “Just in Time” Business Model for Academic Technology Transfer. *Les Nouvelles*, December 2007, pp 615–620. See also MacWright, R. S., Esq., “The University of Virginia Patent Foundation: A Midsized Technology Transfer Foundation Focused on Faculty Service, Operated Using a Deal-Based Business Model,” *AUTM Technology Transfer Practice Manual*, 3rd Edition, Vol. 2.

How to Protect Intellectual Property and Still Publish

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What Is a Publication?

A significant difference between academic and corporate research environments is reflected in publication. While most company inventors must have all publications reviewed and approved prior to submission, this is usually not the case in the academic setting. Although there may be agreements with corporate sponsors that require some prepublication review, compliance is imperfect. Outside of contractual obligations for prepublication review, most universities do not consistently review publications and, therefore, must often react quickly or after the fact to a disclosure that impacts on patentability. Accepting that academic freedom and publication rights are of paramount concern to academic researchers and their institutions, an understanding of what types of disclosures are novelty-destroying under U.S. and international patent laws is necessary.

An invention is not patentable if it was patented or described in a printed publication. United States law provides that an application must be filed within one year of the publication; however, any publication is a bar to patenting in most other countries.

Most researchers and technology transfer professionals understand that a peer-reviewed scientific paper published in a journal or textbook is a publication. Online publications are becoming common and often occur months before a journal is mailed. Therefore, it is necessary to know the journal and its publication practices. Usually this information is provided in publication guidelines available to authors or can be confirmed with the journal prior to submission. Authors are also usually, but not always, given warning through a galley-approval process or online notification of a publication date.

Abstracts, posters, and presentations for professional meetings or seminars should be evaluated as publications. Before widespread dissemination of information over the Internet, some materials were considered to be transitory and, therefore, not a publication. However, most patent offices view these types of materials as publications because they are publicly available and accessible to those skilled in the art to which the invention relates. Obtaining clear dates for publications of materials related to meetings can be very difficult depending on the size of the meeting and whether or not the meeting organizers are familiar with intellectual property (IP) issues. Unfortunately, it is not uncommon for a meeting representative to indicate that the abstracts will be online one date, only to have them show up days or weeks earlier. To be safe, some offices use the acceptance date of the meeting material as their warning for a potential online publication.

Theses or dissertations become publications once catalogued and shelved/made available online. The oral defense may be considered a publication if copies are provided to the audience, which includes anyone from outside the university.

Federal grant applications and abstracts become publications upon funding. This is because the grant application becomes publicly available at this point and may be requested under the Freedom of Information Act (FOIA). Unless information within the grant application is identified as confidential because it is a trade secret or commercial or financial information, it will be provided. While faculty members are sometimes reluctant to do so, unless information is marked as confidential, it is considered publicly available and will be considered as prior art as of the funding date. Abstracts of grants also are published online in a federal database. The content of the abstract, as well as the existence of the grant, will become public information and may elicit a FOIA request for detailed information about the technology.

Food and Drug Administration (FDA) applications also become available to the public upon approval and are available for review for prior art disclosures and admissions. There is often a wealth of data included that can show when and how an invention was made and when disclosures may have been made. Therefore, if data are to be included in an FDA submission, they should be reviewed for patentability before it is submitted to the

FDA so that there is a clear understanding of what is being disclosed and that it is consistent with patent filings.

Faculty members also make presentations either at companies or to visitors at their labs. If a confidentiality agreement is not in place, these disclosures will be considered public. Thesis and dissertation defenses where outside members are present also constitute public disclosures. E-mails with colleagues can constitute a public disclosure. In fact, any discussion of the technology outside of the university can constitute a disclosure from a prior art perspective; therefore, it is important that faculty understand that the first discussion of the technology should be with the technology transfer office.

The most frequent misconception is that any publication will destroy patentability. However, the law bars patenting only when the actual invention is patented or published. Therefore, careful analysis of a publication is required to assess what is actually being disclosed and what impact the disclosure could have on patentability.

A disclosure will be a bar to obtaining patent protection if the disclosure would be adequate to permit one of skill in the art to make and use the invention. In the U.S., this is referred to as an enabling disclosure. Other countries construe disclosures at least this broadly, with many limiting the publication to what is explicitly taught therein. It is often helpful to assess the impact of a potential publication from a prior art perspective, i.e., if it is published, how could it be cited in an anticipation or obviousness/lack of inventive step rejection? Clearly, if the publication teaches the basic invention, it will impact on patentability.

The typical case is not so clear because many early disclosures are incomplete and/or suggestive. The impact of the disclosure will depend on the nature of the invention, the state of the art, and the level of ordinary skill in the art. United States and international law are now much more closely aligned with respect to what would be obvious to one of skill. However, many countries do not have the same requirements as the U.S. concerning written description and enablement. Therefore, the impact of the disclosure may vary by country.

A conservative approach is suggested. It is important to review the publication as an examiner, not as the inventor or institution advocate. Review the disclosure objectively from the perspective of someone familiar, but not expert, in the art. Treat suggestions as at least an invitation to try. If a case can be made for anticipation or obviousness from this perspective, then it would be preferable to try and prevent the publication from becoming prior art.

There are a number of different tactics that can be employed to delay publication until a patent application can be filed: publication can be delayed; the publication can be revised, e.g., suggestions could be omitted and the publication focused on actual data only; or the audience could be limited to the university community (for a thesis or dissertation defense, for example). Explaining to inventors that their own suggestive or disparaging statements can later be their own worst prior art can often engender inventor cooperation. It is one thing to be scooped by a competitor, but quite another to destroy one's own opportunity for patenting. It can be disheartening when the worst prior art is the inventors' own publication. While there may be initial resistance to conferring with the technology transfer office about the timing and/or scope of disclosures, when options and consequences are explained and discussed, cooperation often follows.

When writing a grant application, faculty members review and follow the rules and requirements for the grant submission or they understand they may not receive funding. Manuscripts are written in accordance with the requirements of the journal. Faculty members understand that top peer-reviewed journals have specific requirements that they must follow if they hope to be published in the journal. If they wish to present at a meeting, they follow the procedures to submit a proposal or abstract. When the rules and requirements of patenting are explained in a similar manner, faculty understand what is required to successfully maneuver through the patenting process. An inventor's guide, invention disclosure meetings, or a review of a patentability analysis with the inventor are helpful tools.

Is There Anything Ready for Patenting?

There are two elements for invention: conception and reduction to practice. Conception is complete when the inventor has a definite and permanent idea reflecting a specific approach to the problem at hand. It must also be sufficiently definite that one of skill could practice the invention without undue experimentation. Reduction to practice can be achieved when the invention is shown to be suitable for its intended purpose by either actually making the invention or by filing a patent application, which would enable one of skill to make and use the invention.

A publication should be reviewed to identify possible inventions. This requires an assessment of the subject matter. Under U.S. law, patentable inventions include processes, machines, manufactures, and compositions of matter. The focus is on the essential characteristics of the subject matter and its practical utility and includes anything touched by the hand of man. Other countries define patentable subject matter eligibility, such as the European Patent Convention. Under the EPC, positive and negative definitions of patentable subject matter are explicitly provided.

For example, diagnostic methods and software are specifically not eligible for patentability. Oftentimes scientific publications disclose very early research results or confirmatory data. In these cases, there may be nothing ready or appropriate for patenting. For example, if a composition and a use are known (such as treating cancer), the mechanism of action would not be patentable. Alternatively, discovery of a new pathway or mechanism of action may be patentable as a method for screening for drugs.

In addition to identifying patentable subject matter by statutory class, an assessment must also be made concerning the adequacy of the disclosure to support a claim to that subject matter. The disclosure must enable one of skill to make and use the invention. If the publication concerns identification of a novel pathway, it would not necessarily support claims for treating disease or therapeutic agents. Also, publication of a composition and its use for one indication does not necessarily preclude patenting other uses. The challenge is often in determining how enabling or suggestive a disclosure could be. Again, the perspective of a conservative patent examiner is very useful. For patentability

purposes, the person of ordinary skill is often quite perceptive when determining obviousness but requires significantly more disclosure to make and use the invention from a written description standpoint. Although one of ordinary skill should be one in the same for both analyses, often they are not treated as such and even the slightest disclosure can render an invention obvious. This is especially true outside the U.S., where much less is required in terms of written description and one of ordinary skill is usually accomplished.

The amount of disclosure required depends on the type of invention. For a mechanical invention, a drawing can be adequate. For a biotechnology invention, much more is required. The challenge is to identify the point at which enough has been disclosed that the next disclosure would be damaging. Close coordination and good communication between the inventor and the technology transfer office are crucial so that patenting opportunities are not misjudged or missed.

Universities have different procedures for dealing with the inventor-patent attorney relationship. In some cases, direct access and communication are permitted. In other cases, communication is through the technology transfer office. Both can work well so long as someone is communicating effectively with the inventors. E-mail can be helpful. Inventor comments can be provided very effectively via e-mail. Conference calls can also be helpful. The most important factor is having a patent attorney/agent who understands the technology and the art or who is able to quickly learn what he or she needs to know from the inventor and/or technology transfer professional. It is also helpful if the patent attorney/agent is aware of the university's procedures, policies, and budget for patenting.

An effective strategy is to review all publications coming from an inventor or research group prior to submission as early as possible so that the relevance of the publication to the desired subject matter for patenting can be assessed. The point is to evaluate the disclosure in light of patentable subject matter, rather than filing something and then trying to figure out what could be patentable subject matter. Determining readiness to patent depends on defining what the claimed invention would be.

How to Assess the Impact of a Disclosure

There are two aspects to evaluating publication impact on patentability. In the first case, the determination focuses on what rights would be lost if an application is not filed prior to publication. In the second case, the evaluation focuses on what could be patented in light of a prior art disclosure. In both cases, an assessment of the prior art, what is disclosed in the publication, and differences between the prior art and publication must be made. When patentability is being evaluated, the adequacy of the disclosure to support a desired claim is required, i.e., is there sufficient information or data to enable one of skill to make and use the invention.

In the second case, the evaluation focuses on whether what is being disclosed is sufficiently different from the prior art to be patentable. It is helpful to actually draft a claim set at this point that reflects what is actually disclosed in the context of the prior art and decide whether the scope of the possible claims is worth patenting. Often it will not be because the information available when realistically assessed may not support the type of claim that may be of commercial interest. The U.S. written description requirements in particular will limit the types of claims that can be obtained based upon basic research results.

A patent attorney can generally come up with a way to claim subject matter, however, the technology transfer professional must decide if the patent protection would be of any value. Managing expectations at the outset can be challenging, but sometimes deciding not to file anything is the best choice. In cases such as this, however, it is a good strategy to maintain a relationship with the inventor and continue to follow his or her work and publications. It is also helpful to discuss with the inventor what results would be helpful for filing an application directed to desirable claims.

It is important to understand that there must be an adequate written description to enable one of skill in the art to make and use the invention as of the filing date. A section-112, first-paragraph problem cannot be solved later. If data are not available, there must be at least an adequate prophetic disclosure or the priority date may be meaningless. Filing a quick provisional is often not the best solution because the priority

date is only as good as the disclosure, and a provisional is subject to the identical 112 standards as a nonprovisional application.

Filing an application to prevent a publication from becoming prior art is justified when the disclosure would preclude or limit the patentability of an invention one wishes to claim. However, one must still have a clear idea of what the claimed invention will be and understand what disclosure will be required to support the claim. Filing a series of provisional applications to track ongoing, competitive research may be justifiable so long as it is understood what needs to be in the application that will be ultimately prosecuted. This may be a good strategy if there are going to be publications that are not quite ready for patenting but which could be used to make a strong case of obviousness. Ultimately, the value of a priority date and the applicability of prior art depend upon the quality of the disclosure. When patenting, it is wisest to file when adequate disclosure has been developed. Filing too early can preclude patentability because the claim cannot be adequately supported. The same publication can then become a fatal prior art reference because enough is disclosed to make a case for anticipation or obviousness, but not enough to support a claim to the invention.

Deciding What and When to Publish

Deciding what and when to file will depend on resources. In a case of limited resources, determinations will have to be made about the types of inventions and applications that should be filed. Most universities are not in a position to pursue international filings without a licensee. Deferring prosecution costs by filing a provisional application has limited utility. The one-year period for filing a nonprovisional U.S. application and foreign applications passes quickly, and a priority date is only valid if the disclosure provided is adequate to support the claimed invention.

It is challenging to review a publication and evaluate with certainty whether patent protection is feasible. Identifying areas of licensing interest and filing applications that meet basic patenting requirements can help manage expectations and conserve resources. Setting thresholds for patent applications in terms of adequacy of disclosure and advances in the art is important. If inventors understand what can and cannot be

achieved based on the publication being evaluated, they are less likely to be disappointed and more likely to work with the technology transfer office to create additional data or information toward what would be needed to obtain a desired patent claim.

There is a delicate balance between academic freedom and the value of the intellectual property. It is not feasible, or necessary, to protect every publication. Most publications can go forward without filing patent protection to cover the scope of the publication. This sometimes requires a provisional filing with a few general claims that can be followed up by a more complete disclosure. This prevents the publication from becoming troublesome prior art and also permits securing a valid priority date for the desired claim.

It is reasonable for the technology transfer office to be as demanding as a reviewer for a peer-reviewed publication. If a publication does not meet the basic requirements for patentability in terms of written description, enablement, and as an advance in the art, it is not ready for patenting just as it would not be ready for publication in a journal if reviewers raised issues about the research results, completeness of the manuscript, or significance of the results to the field. Papers are often turned down for publication for these reasons. Filing a patent application when the basic requirements for patentability are not met should be equally acceptable.

It is important that the technology transfer office explains the patenting process to its faculty, researchers, and students. Patenting has very different requirements from grant or manuscript drafting. The patent prosecution process is not the same as grant or publication review. The standards for patentability are quite different than funding or journal guidelines. If a researcher understands what is needed, he or she can more realistically assess his or her ability to provide the needed information and cooperation. There are specific requirements for filing and prosecuting a patent, just as there are for writing and obtaining grant funding or publication in a top peer-reviewed journal. As it takes years of experience, and often several failed attempts to meet grant and publication goals, patenting should be understood to require much the same experience level. Educating the researcher about the process can go a long way in managing expectations.

How to Deal with Unexpected Publications

The first step in evaluating the impact of an unexpected publication is to understand what has actually been disclosed and its contribution to the prior art. Oftentimes there is minimal or no impact from journal articles. This is because most peer-reviewed scientific publications are focused on research results that do not translate easily into invention. Presentations, posters, abstracts, and other public disclosures may be more problematic. While the results could be incorporated into a patent application, it would be necessary for the patent attorney to craft a patent disclosure that explains and develops the result into a patentable invention. For example, discovering a mechanism of action may or may not be an invention. If it could be developed into a drug-screening assay, perhaps a method patent would be feasible. However, figuring out how a known agent works will not likely be patentable.

On its own, the publication may become a reference that could raise an obviousness issue or preclude patentability on some aspect of a future invention; however, in the area of academic research, the full range of an invention is often not disclosed in a single publication. Since publication is of paramount importance to academic researchers and their institutions, the patenting process should work within the publication process and not impede it. There will almost always be a way to work around an unexpected publication. Given that filing too early is just as dangerous as filing too late, all that often changes is the timing for an application. Too little disclosure is just as deadly as an unexpected publication in many cases.

Damage control and mitigation can be helpful if there are research sponsors involved. If the prepublication provisions have been violated, they are likely to be upset. However, understanding the impact of the publication and explaining it to the sponsor will be very helpful in managing the situation. There is usually a way to work around the publication, whether it is just pursuing U.S. rights by taking advantage of the one-year grace period or filing international applications that work around the actual disclosure.

It is key to focus on the invention, and not the publication. The information in the publication may be helpful in providing the disclosure necessary to support a claim but rarely

will the publication on its own be adequate to meet the requirements of patentability. By focusing on the claimed invention, and not the publication, it will be easier to find a solution that will be workable for the sponsor and the institution.

Sometimes, there is a preexisting patent portfolio that can be relied upon, either for arguing that the invention was disclosed therein and, therefore, the publication was not novelty-destroying and/or as the basis for a U.S. continuation-in-part application to cover the disclosure. If a researcher has changed institutions, it is wise to understand the intellectual property that was created at the prior institution and to create an interinstitutional agreement to cover follow-on work at the new institution. This can help smooth the transition of the research and help prevent publications from falling through the cracks since publications are often written some time after the work is completed. If the researcher is aware of what is claimed in the patent portfolio, he or she can be helpful in identifying new subject matter and placing it in the context of prior work. This can help avoid the situation of creating his or her own worst prior art.

The philosophy of doing the best that can be done under the circumstances comes in handy when dealing with unexpected publication. Only after coming to an understanding of the circumstances, e.g., what was published and when, assessing the publication in the context of the prior art and an existing patent portfolio, and assessing the impact on patentability, can the damage be assessed and dealt with. Assuming damage and launching immediately into damage-control mode usually is not helpful. Realistically calculating the loss and then determining what could be done and at what cost is a much better approach. Filing a provisional application based on undefined fear is usually the worst option. It is better to only file when there is an invention at stake. Creating a quick review process to assess the nature and scope of the invention should always be the first step. Only if and when an invention is identified and quickly assessed as an asset to the university patent portfolio should the patenting process be started. Having a patent attorney or agent involved in the preliminary assessment can save time and money and posture the case for quick filing, if necessary.

However, it is crucial that the attorney or agent not be asked if a patent application could be filed because the answer will almost always be yes. That is what patent attorneys and agents are trained to do, i.e., figure out how to package information as an invention. Rather, they should be asked to do a quick patentability assessment, which should include drafting a few broad claims that are supported by the publication and outside of the prior art based on a quick patentability search.

Once this information is on the table, it can be assessed from a legal and business perspective and a rational filing decision made. Just because a patent application could be filed does not mean it should be. The claims could have no commercial value because of subject matter or scope; there could be significant written description, enablement, or prior art issues identified that impact on the likelihood of patenting success; the researcher may not be cooperative; or there may be third-party rights involved. Multiple factors need to be considered and weighed and, more often than not, in the final analysis, the publication will not be fatal.

Keeping a realistic perspective on the impact of a single publication can only improve the decision-making process for patenting. And it should be a decision-making process, not a reactionary process. In reality, there are many more bad filing decisions than truly damaging publications. Keeping this in mind will reduce anxiety about unexpected publications and result in better patenting decisions.

Ownership of University Inventions in the United States

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Introduction

In the United States, the inventors of technology claimed by a patent or patent application have the original legal title (ownership) to the patent/application.¹ Because title vests in the inventor, the inventor must personally authorize the original application for a patent, with some exceptions for unavailable inventors.²

A university's³ ownership of a patent/application comes through assignment from the inventor and is limited to the ownership interest of the inventor. Multiple inventors can lead to joint inventorship situations where each inventor has legal title vested in the patent application. If an inventor is employed by someone other than the university, his or her employer's interest along with the university's may be vested in the patent/application.⁴ This, in turn, means final ownership may be composed of a combination of inventors and/or their employers.

Inventorship

Basic Guidelines

The starting point for securing university ownership in patents is finding out who the inventors are. This should be done at the invention disclosure stage and then reviewed as the claims of the patent application change during prosecution and at least prior to issuance. The key questions to ask are: (1) What is new in this disclosure that constitutes patentable subject matter verses what was already known or done? and (2) Who came up with the new idea?

The broadest collection of potential contributors and their roles should be detailed early while memories are fresh. Once a patent application is drafted, the claims can then be mapped back to the various potential inventors' contributions to derive the inventor list for the patent application. This can be done at the level of each claim element. See the example inventorship grid in the Exhibit. Such a grid can be invaluable in cases where, sometimes many years later, continuation and divisional patent applications are filed or significant claim amendments are required for issuance. It is common for an original patent application to be dissected by a restriction requirement into multiple distinct inventions. This divides the original claim set into multiple subgroups corresponding to these separate "inventions." It is not proper to simply keep the same list of inventors on a patent application, or any divisional patent applications, when less than all the original named inventors actually contributed to a specific claim set subgroup from the original application.

Frequently, the original patent application filing in the U.S. is a provisional patent application.⁵ Under U.S. law, a later patent application may claim the benefit of the provisional application's filing date as long as one named inventor is the same on both applications.⁶ An initial U.S. provisional patent application listing all potential candidate inventors, or the subset known with certainty to be inventors. This provisional patent application can thus serve as a buffer between the provisional filing, and the inventorship listing in a subsequent utility application for the same invention.

Exhibit: Inventorship Grid

Claim 1	Inventor A	Inventor B	Inventor C
A vector for producing a biologic comprising			
a transcription initiation element (Seq ID No.: 1),	X	X	
a sequence encoding the biologic polypeptide (Seq ID No.: 2), and			X
a polyadenylation signal sequence (Seq ID No.: 3).		X	
Claim 2	Inventor A	Inventor B	Inventor C
The vector of claim 1, further comprising an origin of replication having Seq ID No.: 4).	X		X
Claim 3	Inventor A	Inventor B	Inventor C
A vector for producing a biologic comprising			
a transcription initiation element (Seq ID No.: 4) and	X	X	
a polyadenylation signal sequence (Seq ID No.: 5).		X	

Example restriction requirement: Group I = claims 1-2 and Group II = claim 3. If you elect to pursue Group I, inventors A-C stay on the patent application. If you elect to pursue Group II, inventor C should be dropped from the inventor list.

Detailed Discussion

Correctly identifying inventors is critical to ownership and validity of a patent because a patent may be invalid under 35 U.S.C. § 102(f) if the inventorship is incorrect⁷ and ownership in a U.S. patent flows from the inventors.⁸

Who is an inventor?

Conception is the touchstone of inventorship, the completion of the mental part of invention. ... [T]he test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention; the inventor must prove his conception by corroborating evidence, preferably by showing a contemporaneous disclosure. An idea is definite and permanent when the Inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue. The conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he can do so, he cannot prove possession of the complete mental picture of the invention. These rules ensure that patent rights attach only when an idea is so far developed that the Inventor can point to a definite, particular invention.

A joint invention is the product of a collaboration between two or more persons working together to solve the problem addressed. People may be joint inventors even though they do not physically work on the invention together or at the same time, and even though each does not make the same type or amount of contribution. 35 U.S.C. § 116. The statute does not set forth the minimum quality or quantity of contribution required for joint inventorship.⁹ [Emphasis added.]

An inventor is, thus, anyone who contributes to the conception of the invention. This is an inherently fact-specific standard that may be difficult to apply in some cases. The title or position of a person is not controlling and may not even be relevant. For example, a medical student doing a one-semester research project in an established faculty member's laboratory may qualify as an inventor of subject matter developed during the research project.¹⁰

Transfer of Title

Basic Guidelines

Patent ownership in the United States starts with the inventors. The inventors are presumed to own their inventions. A written contract, usually called an assignment, is required to transfer title of any patent or patent application to the university.

The first contract transferring ownership to the university should be the university employment agreement or other contract allowing someone to do research at the university (e.g., a visiting researcher agreement). In these contracts, the ownership of any patentable inventions should be prospectively assigned to the university as a condition of employment, permission to use university facilities, etc. An example of the assignment clause in an employment agreement is:

[In exchange for good and valuable consideration, the receipt and sufficiency of which I hereby acknowledge,] I agree to assign, and hereby do assign, to UNIVERSITY all right, title and interest in and to inventions, including all intellectual and tangible rights therein, whether or not patentable, which I have reduced to practice or conceived, or which I may hereafter reduce to practice or conceive, either solely or jointly with others, i) in the course of my employment, ii) with the use of the time, material or facilities of UNIVERSITY, or iii) relating to the research which I perform at the UNIVERSITY during my employment.¹¹ I further agree to execute documents confirming and memorializing the above assignment at the UNIVERSITY's request, regardless of whether such request is made during or after the termination of my relationship with the UNIVERSITY.

The bracketed text or its equivalent should be elsewhere in an employment agreement and should apply to the terms of the agreement generally. If the assignment provision is, e.g., added as a standalone addendum, it would be helpful to include the bracketed text.

A confirming assignment should be included with the invention disclosure documents. The disclosing individuals should all execute this confirmation assignment. Upon full elu-

cidation of the inventorship per the previous section, additional confirmation assignments should be secured as necessary.

Finally, a third confirmation assignment should be executed along with or after filing a patent application. This document should specify the serial numbers of the applications for clarity or provide that the attorney may add such information when available. This third assignment should then be filed with the U.S. Patent and Trademark Office (USPTO), preferably within three months of the patent application filing date.¹²

For an example assignment, see the Appendix.

Uncooperative Inventors

What do you do if you do not have any of the foregoing contracts and one or more inventors refuses to sign over title to an invention? This can happen, for example, with former faculty who clearly conceived an invention while at the university, but did not reduce it to practice until after the end of employment. These situations can be very difficult, especially when another institution provided the resources for reducing the invention to practice and, therefore, believes it is entitled to own the invention. Usually these matters are resolved by negotiation. Legal counsel should be consulted to evaluate the facts and evidence to determine what rights the university has and the prospects of enforcing those rights from a practical perspective.

Detailed Discussion

Once an institution has identified the inventors, the next step is to secure transfer of title from the inventors. Transfers of title are governed by contract law. Generally, the contract must expressly state that ownership of the invention is being transferred. There are limited circumstances where an implied contract term¹³ or a fiduciary obligation¹⁴ may be asserted to transfer patent ownership.

Even where an unwritten basis is invoked to effect transfer of title, a writing must be executed or legal title remains with the inventor.¹⁵ An assignment document need not be recorded with the USPTO to be valid. However, failure to record the assignment can result in loss of ownership if a later party, unaware of the prior assignment, buys a patent/application from an inventor.¹⁶

Recording the assignment of a base application at the USPTO, which by the assignment's terms applies to later continuing applications, is effective for constructive notice purposes for continuations or divisional applications of that base application.¹⁷ Exceptions are provisional patent applications where the subsequent application includes additional material not common with subject matter of the provisional application and continuations-in-part applications, which by definition include subject matter that is not in common with the application from which it continues.¹⁸ A recorded assignment of a provisional patent application is not effective notice for applications claiming the benefit of the provisional if the subsequent application includes new matter relative to the provisional application.¹⁹ A continuation-in-part application (CIP) should have the base application's assignment rerecorded for the CIP or a new assignment executed and recorded, depending on the terms of the base application's assignment.²⁰

The Bayh-Dole Act

Much of academic research is supported at least in part with federal research money. There is an emerging body of law suggesting that the Bayh-Dole Act may, in effect, alter the way ownership and title is determined when federal money supported the underlying research. The Bayh-Dole Act provides for ownership of such inventions on the following general terms:

Each nonprofit organization or small-business firm may, within a reasonable time after disclosure [to the funding agency], elect to retain title to any subject invention.

If a contractor does not elect to retain title to a subject invention, the federal agency may consider and, after consultation with the contractor, grant requests for retention of rights by the inventor.

The plain language of the Bayh-Dole Act creates a statutory right to university ownership of inventions from federally sponsored research upon following the procedures required by the act. Implicit in this is the fact that the federal government otherwise has title to any such inventions.²¹ If the recipient of federal funds fails to elect title to a federally funded invention within timeframes specified in the Bayh-Dole Act, title to the invention

does not automatically by default rest with the federal government. The federal government must request title from the contractor in writing in the event that a federal contractor fails to elect title and it must do so within sixty days of learning of the contractor's failure (37 CFR 401.14 (d)). Under this statutory scheme, one could easily conclude that the inventor does not own such an invention by virtue of inventorship and can only obtain ownership if the university declines title and the funding federal agency consents.²² This has been the basis for some district courts voiding an assignment by an academic inventor to a private company.²³

Patent title is transferred from the federal government to a university upon meeting the requirements of the Bayh-Dole Act (35 U.S.C. § 202). The inventor can only secure title from the federal government after it is declined by the university.

Creating Contractual Ownership Rights: Employees

A university should have a written assignment and an enforceable contractual obligation to execute further documents to memorialize such an assignment.

Prospective Assignment

Ideally, an inventor should prospectively assign all inventions to the university such that, upon conception, legal title (and any patent/application thereon) instantly vests in the university. Traditionally, this prospective assignment mechanism has been viewed as an untested and, therefore, unreliable means of transferring title. This was further complicated because state contract law is applied to determine an assignment's validity. Thus, a prospective assignment provision might be enforceable in Texas but not enforceable in California. The law has changed significantly in this area in the past few years.²⁴ The current law is summarized in the recently decided *DDB Technologies L.L.C. v. MLB Advanced Media L.P.*, 517 F.3d 1284, 1290 (Fed. Cir. 2008):

Although state law governs the interpretation of contracts generally, the question of whether a patent assignment clause creates an automatic assignment or merely an obligation to assign is intimately bound up with the question of standing in patent cases. We have accordingly treated it as a matter of federal law. Applying

federal law, we have held that whether an assignment of patent rights in an agreement such as the one in this case is automatic, requiring no further act on the part of the assignee, or merely a promise to assign depends on the contractual language. *If the contract expressly grants rights in future inventions, “no further act [is] required once an invention [comes] into being,” and “the transfer of title [occurs] by operation of law.”* Contracts that merely obligate the inventor to grant rights in the future, by contrast, “may vest the promisee with equitable rights in those inventions once made,” but do not by themselves “vest legal title to patents on the inventions in the promisee.” [Emphasis added.]

Because the enforceability and effect of a prospective patent assignment is now nationally uniform, contractual language should be written to effect such transfers.²⁵ In addition, there should be language obligating the inventor to execute patent application-specific documents to facilitate recordation of assignments (sample language above).

Obligation to Assign

Some contracts do not effect transfer of title *per se*, but obligate the inventor to execute an assignment. If assignment does not happen by operation of a prospective contract provision, a postinvention assignment should be executed at the earliest possible point. A convenient way to secure assignments is to make a standard form assignment part of the invention disclosure paperwork. Risks in using an obligation-to-assign clause include prior sale by an inventor to an innocent purchaser or by probate to one or more heirs. These situations raise difficult legal questions such as the nature of the university’s rights and under what circumstances such rights may be enforced against persons not a party to the employment agreement. However, universities generally encounter such circumstances on a very infrequent basis.

Postfiling Assignment Confirmation

Postfiling assignment confirmations are useful for at least three reasons. First, a university may not want to publicly record an employment agreement. Second, a prospective assignment necessarily lacks specific identification information for any resulting patent applications. Third, assignment confirmations help ensure that an inventor does not later

assert that an invention was somehow not conceived and/or reduced to practice during a period of employment, and, thus, not assigned by operation of an employment agreement. Thus, inventors should be obligated to execute an assignment confirmation document, identifying any application by title and serial number.

Integrating Intellectual Property Policies with Contractual Agreements

Most universities use institutional regulations, commonly in the form of intellectual property (IP) policies, to determine invention ownership. These policies should be included in an employment agreement as an appendix or by specific reference.

What if the intellectual property policy is not expressly made part of an employment contract? If not included in an employment agreement, a university IP policy may or may not be enforceable as an implied contract, depending on state contract law.²⁶ The general rule is that a contract, once formed, may not be modified except by further mutual agreement. There is also a general presumption that a written agreement is the complete agreement. In cases where a written employment or other agreement exists, there will often be an integration clause. This integration clause explicitly disallows implying additional contractual terms into the employment agreement. Asserting that an IP policy forms implied contractual terms of an employment agreement may not be possible in such circumstances. It is, thus, important that employment agreements incorporate an IP policy explicitly.

What happens if the IP policy changes? The default assumption should be that a unilateral change in a university IP policy will not be effective for pre-existing contracts. Rather, the terms of the IP policy when the contract was executed should be assumed to still apply. This is because contract terms generally are modified by mutual consent of the contracting parties. In many modern contracts, there is also an explicit integration clause that precludes modifying the terms of a contract except by a written document signed by both parties. A rewritten IP policy posted on the university Web site and mailed to faculty, for example, would not qualify.

One may still try to bind an employee to any modifications of the IP policy by expressly allowing modification by the university with notice to the employee. Any integration clause should be modified to accommodate this. There is a divergence of opinion as to whether an employee can be bound by a unilateral change of such terms, even when expressly agreed to in a contract. To ensure the maximum likelihood of enforceability, an employment agreement should condition continued employment and access/use of university resources on acceptance by a university employee of any modified IP policy upon notice to the employee. The result of such an approach is dependent on state law and should be vetted with counsel before being relied upon. The same analysis applies when amending an existing employment agreement to add on a university IP policy.

Creating Contractual Ownership Rights without a Written Agreement

As discussed above, anyone contributing to the conception of an invention may be deemed an inventor. Consequently, nonemployees may end up being joint inventors with university employees, possibly resulting in a split of ownership. Visiting scientists, students, or fellows performing research with faculty should be required to execute agreements transferring ownership of any resulting inventions to the university. If no agreement is executed, a university IP policy may not be sufficient to ensure transfer of ownership. In one Federal Circuit case on point, a university IP policy was enforced as a binding contract. The facts and circumstances of this case are informative. *Regents of Univ. of N.M. v. Knight*, 321 F.3d 1111 (Fed. Cir. 2003):

- State law allowed for the possibility that the IP policy could be an implied contractual term of employment.
- The inventors had knowledge of the existence of the IP policy.
- The inventors evidenced an intent to be bound by the IP policy by the execution of documents and/or other actions pursuant to the requirements of the IP policy.²⁷

As shown above, implied contracts are based on facts in evidence showing an unwritten contractual agreement among the parties. This would be the type of evidence needed to have a reasonable basis for asserting an IP policy against, e.g., an undergraduate student.

Notes

1. E.g., 35 U.S.C. § 152 (United States Patent and Trademark Office (USPTO) *Manual of Patent Examining Procedure* (MPEP), Appendix L, through September 30, 2007) (Issue of patent to assignee).
2. 35 U.S.C. § 111 (“An application for patent shall be made, or authorized to be made, by the inventor, except as otherwise provided in this title. ...”); the Patent Cooperation Treaty allows an international patent application to be filed by an owner as the applicant. This allows entry into most countries’ patent systems in national stage applications. A national stage application in the United States must comply with the same inventorship requirements as a regular domestic patent filing. 35 U.S.C. § 371(c)(4).
3. The term *university* is used to refer generally to 503(c) organizations dedicated to research and/or educational activities.
4. 35 U.S.C. § 116 (USPTO MPEP, Appendix L, through September 30, 2007).
5. 35 U.S.C. § 111(b) (USPTO MPEP, Appendix L, through September 30, 2007).
6. 35 U.S.C. § 119(e) (USPTO MPEP, Appendix L, through September 30, 2007).
7. *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1349-50 (Fed. Cir. 1998); correction for an honest mistake is available under 35 U.S.C. § 256.
8. While this article focuses on U.S. legal requirements, inventorship is an issue for ownership of patents in many other jurisdictions. See, e.g., Convention on the Grant of European Patents (European Patent Convention), Art. 60 Right to a European patent, (1) The right to a European patent shall belong to the inventor or his successor in title. If the inventor is an employee, the right to a European patent shall be determined in accordance with the law of the state in which the employee is mainly employed; if the state in which the employee is mainly employed cannot be determined, the law to be applied shall be that of the state in which the employer has the place of business to which the employee is attached. Canada, Patent Act (R.S., 1985, c. P-4), section 27, (1) The commissioner shall grant a patent for an invention to the inventor or the inventor’s legal representative if an application for the patent in Canada is filed in accordance with this act and all other requirements for the issuance of a patent under this act are met. Japan, Patent Act (Act No. 121 of 1959 through the revisions of Act No.75 of 2005(Effective November 1, 2005)), Article

- 123 (Trial for patent invalidation), (1) Where a patent falls under any of the following, a request for a trial for patent invalidation may be filed. In the event of two or more claims, a request for a trial for patent invalidation may be filed for each claim... (vi) where the patent has been granted on a patent application filed by a person who is not the inventor and has not succeeded to the right to obtain a patent for the said invention..... *Cf.* Peoples Republic of China, Patent law of the People's Republic of China (as revised by the 17th Session of the Standing Committee of the Ninth National People's Congress on August 25, 2000), Chapter 1: General Provisions, Article 6. An invention-creation, made by a person in execution of the tasks of the entity to which he belongs, or made by him by mainly using the material and technical means of the entity is a service invention. For a service invention-creation, the right to apply for a patent belongs to the entity. After the application is approved, the entity shall be the patentee. For a nonservice invention-creation, the right to apply for a patent belongs to the inventor or creator. After the application is approved, the inventor or creator shall be the patentee. For an invention-creation, made by a person by using the material and technical means of the entity to which he belongs, and where the entity and the inventor or creator has entered into an agreement under which there is provision on who has right to apply for a patent and to whom the patent right belongs, the provisions of the agreement shall prevail.
9. *Burroughs Wellcome Co. v. Barr Lab.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994); *Stern v. Trs. of Columbia Univ.*, 434 F.3d 1375, 1378 (Fed. Cir. 2006) (“Because ‘conception is the touchstone of inventorship,’ each joint inventor must generally contribute to the conception of the invention.”).
 10. *Stern*, 434 F.3d at 1377; inventorship is discussed further at Vol. 1, Part 1, Chapter 15.4 (3rd ed.).
 11. Derived from language held enforceable in *Imatec, Ltd. v. Apple Computer, Inc.*, 15 Fed. Appx. 887, 2001 U.S. App. LEXIS 16841 (Fed. Cir. 2001).
 12. 35 U.S.C. § 261 (USPTO MPEP, Appendix L, through September 30, 2007).
 13. *Banks v. Unisys Corp.*, 228 F.3d 1357, 2000 U.S. App. LEXIS 23907, 56 U.S.P.Q.2d (BNA) 1222 (Fed. Cir. 2000) (“[W]here an employee is hired to invent something or solve a particular problem, the property of the invention related to this effort may belong to the employer. ... When applying the ‘employed to invent’ exception, a

court must examine the employment relationship at the time of the inventive work to determine if the parties entered an implied-in-fact contract to assign patent rights. State contract principles provide the rules for identifying and enforcing implied-in-fact contracts.”) [internal quotes and citations omitted]. Standardized contract language often includes an integration clause. If a faculty employment agreement has such a provision, it likely will preclude implied-in-fact contract terms. Some cite a North Carolina state court ruling as creating a per se rule that university faculty are hired to invent under North Carolina law. *Speck v. North Carolina Dairy Foundation Inc. et. al.*, 311 N.C. 679, 319 S.E. 2d 139 (1984). This is not a patent case. *Id.* at 687 (“The secret process developed by the plaintiffs was not patentable, and this fact was recognized by the plaintiffs at the time they discovered the process.”) Any application of this ruling to the patent realm is speculative.

14. An executive-level employee (e.g., a university president) with responsibility for a particular area, may be held to a general fiduciary obligation and required to assign patent rights for inventions related to the executive’s area of responsibility. E.g., *Davis v. Alwac International Inc.*, 369 S.W.2d 797 (Tex. Civ. App. — Beaumont 1963, reh’g denied).
15. 35 U.S.C. § 261 (USPTO MPEP, Appendix L, through September 30, 2007).
16. *Id.* (“An assignment, grant, or conveyance shall be void as against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the Patent and Trademark Office within three months from its date or prior to the date of such subsequent purchase or mortgage.”).
17. M.P.E.P. § 306 (USPTO MPEP through September 30, 2007).
18. *Id.* M.P.E.P. § 306.01 (USPTO MPEP through September 30, 2007).
19. *Id.*
20. M.P.E.P. § 306 (USPTO MPEP through September 30, 2007).
21. *TM Patents L.P. v. IBM*, 121 F. Supp. 2d 349, 368 (SDNY 2000):

The United States has title to all “subject inventions” made in performing work under a funding agreement with a research organization such as M.I.T. By statute, “subject invention” is defined as “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.” 35 U.S.C. § 201(e).

22. *Fenn v. Yale Univ.*, 184 Fed. Appx. 21 (Fed. Cir. 2006) (“[P]ursuant to the Bayh-Dole Act, a federal agency such as the NIH may only grant an inventor’s request to retain rights to an invention subject to the Act when the contractor (in this case Yale) has elected not to retain rights to the invention.”).
23. *TM Patents, L.P.*, 121 F. Supp. 2d at 368; *Bd. of Trs. v. Roche Molecular Sys.*, 487 F. Supp. 2d 1099, 1117-19 (NDCA 2007) (“The VCA effectively assigned any rights that Holodniy had in the patented invention to Cetus. This does not end the inquiry, however, as Stanford claims that Holodniy had no interest to assign based on the Bayh-Dole Act. Holodniy’s purported assignment to Cetus conflicted with the legal requirements of the Bayh-Dole Act, which mandated that Stanford be given a superior right to retain title to the patents. ... Because Stanford exercised its right and obtained title in the patents, Holodniy had no interest to assign to Cetus. The assignment provision in the VCA is therefore void ...”).
24. *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1253 (Fed. Cir. 2000); *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1580-81 (Fed. Cir. 1991); *FilmTec Corp. v. Allied-Signal Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991).
25. *FilmTec*, 939 F.2d at 1573 (Contract provided that inventor “agrees to grant and does hereby grant” all rights in future inventions.); *Speedplay*, 211 F.3d at 1253 (Contract provided that employee’s inventions within the scope of the agreement “shall belong exclusively to [employer] and [employee] hereby conveys, transfers, and assigns to [employer] . . . all right, title and interest in and to Inventions.”).
26. *Regents of Univ. of N.M. v. Knight*, 321 F.3d 1111, 1122 (Fed. Cir. 2003) (“Although Knight, as a faculty staff member, had no employment contract with UNM, he too was bound by the Patent Policy. Under New Mexico law, a written personnel policy may form an implied employment contract. The 1983 UNM Patent Policy thus created an implied contract between Knight and UNM that governed the relationship between Knight and UNM. Thus, we agree with the district court’s conclusion that both Scallen and Knight were bound by the Patent Policy.”). See also:
 - *Univ. of W. Va. v. VanVoorhies*, 278 F.3d 1288, 1298 (Fed. Cir. 2002): The Federal Circuit summarized the effect of the IP policy at issue thusly, “Under the policy, WVU owns all inventions that are made by University personnel or made

with substantial use of University resources. The policy states nothing about WVU's ownership interest being subject to the election of University personnel. Thus, any inventions made by VanVoorhies pursuant to his graduate studies rightfully belong to WVU." Taken out of context, this seems to be a blanket endorsement of the enforceability of an IP policy as a binding contract. One problem with relying on the quoted language as a general rule is that the enforceability of an IP policy as a contract is determined by state contract law, not federal law. Thus, at best, the above quote is specific to West Virginia. The second problem with the quoted language is that it is dicta, that is, it is not a determination of the law used to decide the case. In the case, a written assignment agreement was in place that included any continuing applications from the application specifically assigned. *University of West Virginia Bd. of Trustees v. VanVoorhies*, 84 F. Supp. 2d 759, 773-774 (ND WV 2000). The university IP policy was at issue in VanVoorhies' related fraud claims, where the inventor actually relied on the IP policy. *Id.* at 771. Because the above quote was dicta and pertains specifically to West Virginia, it does not create a federal rule deeming university IP policies as contractually binding for patent ownership determinations.

- *Chou v. Univ. of Chi.*, 254 F.3d 1347, 1357 (Fed. Cir. 2001): The inventor in this case accepted a position with the university. "The basic terms and conditions of the employment agreement are set out in the letter of appointment received from the Provost's Office." The letter of appointment incorporated the administrative policies of the university, which included an obligation to assign inventions to the university. "The inventor accepted her appointment, thereby assuming the obligations set out in the University's policies." Contracts, while usually formed by countersignatures to a written document, may also be formed by such actions in response to an offer of employment. The inventor accepted employment under the express terms of her letter of appointment by the act of assuming her duties under the appointment. The terms of her employment expressly incorporated the university patent policy. This is, therefore, not a case where an IP policy was enforced as an implied contract, the policy was expressly incorporated as a term of the employment agreement.

27. *Regents of Univ. of N.M.*, 321 F.3d at 1120 (Fed. Cir. 2003) (“Moreover, both Scallen and Knight acted as though they intended to be bound by the Patent Policy. ... Until that point, Scallen and Knight had acted as though they were obligated to assign their inventions to UNM and to cooperate in the prosecution of related patent applications.”)
28. Derived from language held enforceable in *Imatec, Ltd. v. Apple Computer Inc.*, 15 Fed. Appx. 887, 2001 U.S. App. LEXIS 16841 (Fed. Cir. 2001).

Appendix

Intellectual Property Assignment Agreement

The following are exemplary in nature in the context of the various agreements specified and reflect a general approach for securing ownership.

Example Clauses for Employment Contracts

Intellectual Property

Inventions

[In exchange for good and valuable consideration, the receipt and sufficiency of which I hereby acknowledge,] I agree to assign, and hereby do assign, to UNIVERSITY all right, title and interest in and to inventions, including all intellectual and tangible rights therein, whether or not patentable, which I have reduced to practice or conceived, or which I may hereafter reduce to practice or conceive, either solely or jointly with others,¹⁾ in the course of my employment,²⁾ with the use of the time, material or facilities of UNIVERSITY, or³⁾ relating to the research which I perform at the UNIVERSITY during my employment.²⁸ I further agree to execute documents confirming and memorializing the above assignment at the UNIVERSITY's request, regardless of whether such request is made during or after the termination of my relationship with the UNIVERSITY.

The bracketed text or its equivalent should be elsewhere in an employment agreement and should apply to the terms of the agreement generally. If the assignment provision is, e.g., added as a standalone addendum, it would be helpful to include the bracketed text.

Works of Authorship

I acknowledge that all works of authorship I create within the scope of my employment shall be the exclusive property of UNIVERSITY for all purposes. I further acknowledge that any copyrights in these works shall be the exclusive property of UNIVERSITY as a “work-for-hire” pursuant to 17 U.S.C. § 201(b). To the extent a work of authorship I create within the scope of my employment is deemed not to be a “work-for-hire,” I hereby

irrevocably and exclusively assign and grant to UNIVERSITY all of my right, title and interest, in such works of authorship. I further agree to execute documents confirming and memorializing the above assignment at the UNIVERSITY's request.

University Intellectual Property Policy

I acknowledge that the University Intellectual Property policy (attached as appendix X) forms a part of this employment agreement. I agree to follow the procedures and requirements of the Intellectual Property policy, including, but not limited to, the requirements for prompt disclosure of any inventions. I further acknowledge that the University may modify the Intellectual Property policy during my employment, with notice to me by [mail, posting, email]. I agree that any such modification the Intellectual Property policy shall be binding on me to the maximum extent permitted by law. I acknowledge my continued employment will be contingent on acceptance of such Intellectual Property policy modifications and that my continued activities as an employee, after notice of the modification(s), shall constitute my acceptance of such modifications. I expressly waive and agree to be estopped from raising any issue of lack of separate consideration for any such modification to the Intellectual Property policy in effect at the time of this agreement. In case of conflict between this agreement and the Intellectual Property policy, I agree the Intellectual Property policy (and any modifications thereto) shall be controlling.

Example Clause for Invention Disclosure Forms

For UNIVERSITY employees, visiting researchers and students: I agree that all research materials, notes and records generated during my [employment with UNIVERSITY] [research activities at UNIVERSITY] are the property of UNIVERSITY, including specifically any such materials related to the subject matter of this invention disclosure. I hereby assign all of my rights in this invention to UNIVERSITY for good and valuable consideration, the receipt of which is acknowledged by me.

Example Standalone Patent Assignment Contract

Assignment

For good and valuable consideration, the receipt and sufficiency of which are hereby

acknowledged, each undersigned inventor has sold and assigned, and by these presents hereby sells and assigns, unto UNIVERSITY, (hereinafter ASSIGNEE) all right, title, and interest in and to his invention relating to

[TITLE HERE]

as set forth in the United States and/or PCT patent application(s)

Serial No. filed _____ filed _____

executed concurrently herewith

executed on _____

[Repeat for each application assigned.]

in and to said United States and/or PCT Patent Applications, including any and all divisions and continuations or National Stage applications, respectively, thereof and in and to any and all Letters Patent of the United States which may issue on any such application or for said invention, including any and all reissues or extensions thereof and all applications for Letters Patent which may hereafter be filed for said invention in any country or countries foreign to the United States, and all Letters Patent which may be granted for said invention in any country or countries foreign to the United States and all divisions, continuations, continuations-in-part, additions, extensions, renewals, re-examinations and/or reissues thereof and all rights of priority in any such country or countries based upon the filing of the said application for Letters Patent of the United States, and/or said PCT Patent Application, which are created by any law, treaty or international convention; to be held and enjoyed by said ASSIGNEE, its successors, legal representatives and assigns to the full end of the term or terms for which any and all such Letters Patent may be granted as fully and entirely as would have been held and enjoyed by the undersigned had this Assignment not been made;

Each of the undersigned hereby authorizes and requests the U.S. Commissioner of Patents and Trademarks, and any and all foreign patent issuing authorities, to issue such Letters Patent to said ASSIGNEE, its successors or assigns in accordance herewith;

Each of the undersigned warrants and covenants that he has the full and unencumbered right to sell and assign the interests herein sold and assigned and that he has not executed and will not execute any document or instrument in conflict herewith;

Each of the undersigned further covenants and agrees that at any time upon request of said ASSIGNEE, its successors, legal representatives or assigns he will communicate to said ASSIGNEE, its successors, legal representatives or assigns all information known to him relating to said invention or patent application and that he will execute and deliver any papers, make all rightful oaths, testify in any legal proceedings and perform all other lawful acts deemed necessary or desirable by said ASSIGNEE, its successors, legal representatives or assigns to perfect title to said invention, to said application(s) including divisions, continuations, reissues, extensions, additions and renewals thereof and to any and all Letters Patent which may be granted therefor or thereon, in said ASSIGNEE, its successors, or assigns or to assist said ASSIGNEE, its successors, legal representatives or assigns in obtaining, reissuing or enforcing Letters Patent for said invention;

Each of the undersigned hereby grants to all practitioners associated with U.S. Patent and Trademark Office customer number XXXXX, including specifically [Name of Attorney] (USPTO registration number) and including specifically [Name of Attorney] (USPTO registration number) the power to insert in this Assignment any further identification which may be necessary or desirable to comply with the rules of the U.S. Patent and Trademark Office or any foreign patent issuing authority for recordation of this Assignment.

Names and Signatures of Inventors:

 _____ Date _____ Date _____

 _____ Date _____ Date _____

Names and Signatures of Witnesses:

 _____ Date _____ Date _____

 _____ Date _____ Date _____

Executed this ____ day of _____, 2007, at _____.

(Signature)

Optional Notarization:

State of _____ County of _____
 Before me personally appeared _____, and
 acknowledged the foregoing instrument to be his free act and
 deed this day of _____, 2007.
 Seal

(Notary Public)

Innovation Disclosure

Page Heller

During the writing of this chapter, Page Heller was a senior licensing manager at The Texas A&M University System in College Station. He is now president of Hopes Creek Consulting, based in College Station, Texas.

Introducing the Innovation Disclosure

The launching pad for technical evaluations, market analyses, and strategies for statutory protection is a single document commonly called the *invention disclosure*. The word *invention*, however, implies that the subject matter of the disclosure only includes patents. If it were necessary to broaden the scope of the disclosure document to take in copyrights, it might lead to a decision to include a second type of documentation called the *software disclosure* or *copyright disclosure*. There might even be a third type for trademarks. To discuss all of these forms generically, they will be referred to as *innovation disclosures*. These are alternately referred to as *disclosures of innovation*, which you may occasionally see abbreviated as DOI. Let's examine what an innovation disclosure is and what it is not.

What an Innovation Disclosure Is

An innovation disclosure is a document typically prepared by the inventor or innovator and submitted to the technology transfer office to notify it of an innovation. Most often, forms provided to the innovator by the technology transfer office guide the preparation of the document by posing a series of questions. The questions address the technical aspects, as well as the contractual and commercial aspects of the innovation. Fundamentally crucial questions that may impact statutory protection are often also included. By answering a series of questions, the innovator can submit a disclosure with assurance that he or she is addressing the fundamental questions pertinent to the evaluation.

To encourage the innovator to submit this document to the office for review, the forms should be simple. If they can be limited to one or two pages when printed, they will be more likely to be completed by the innovator. If the innovator must spend as much time

filling out the innovation disclosure form as he or she would authoring a technical paper, then he or she will likely opt for the paper.

The innovation disclosure is used to begin the commercial evaluation of the innovation. Information gleaned from the document will be used by an intellectual property manager to learn enough about the market for the innovation to formulate questions he or she can ask during the first interview with the innovator.

The innovation disclosure also aids the patent attorney in becoming familiar with the innovation, if patent protection is sought. Accordingly, the invention must be described in enough detail that someone skilled in the art could understand and make the invention.¹

What an Innovation Disclosure Is *Not*

An innovation disclosure is not a patent application. There will be times when those unfamiliar with the technology transfer process will submit an innovation disclosure to your office and then call to find out how their patent application is proceeding, thinking they have just filed a patent application. Or, worse, an inventor may submit an innovation disclosure to your office just prior to a public disclosure, thinking he or she has filed an application.

It is important to know that an innovation disclosure does not stand alone. You must always contact the innovator to get the full picture. Treat the innovation disclosure as a tool to assist you in the early discussions with the innovator. Ensure that standard operating procedures exist in your office that result in immediate review of such documents as soon as they are received. Immediately upon receipt, study the document to ascertain whether or not public disclosure is imminent. If this is indeed the case, it may be necessary to contact the innovator to file the necessary paperwork in a short timeframe.

An innovation disclosure is not a dissertation. It is not intended for peer review, nor is it expected to rise to the level of a journal article. It should be much more concise than either of these types of documents. It should teach the whole innovation in language that is understandable by someone skilled in the art. In terms relating to patent law, that

means someone who is considered to have normal skills and knowledge in a particular technical field.

If a technical paper is used to describe the innovation, then ask the innovator which portions refer specifically to the innovative part of the overall technology described. Sometimes it is not evident to someone who is not a specialist in the specific field of the innovation; for example, the licensing manager reviewing the disclosure.

An innovation disclosure is not a public disclosure. Yes, the names are similar; and, yes, this sometimes causes confusion. Assure the innovator that the innovation disclosure is kept confidential. (Check your state law if you are a public entity to make sure the document is exempt from a public request for information.) Sometimes the document is requested by a potential licensee during negotiations. You may wish to remove the answers to questions relating to funding contracts and public disclosures before sharing the document, even under a nondisclosure agreement.

Parts of the Innovation Disclosure

Although tempting, it just isn't practical to include all the possible questions you may want to ask of an innovator in the innovation disclosure form. This would result in a form so lengthy it would deter the innovator from taking the time to fill it out. There are certain subjects, however, for which you must ascertain the answers to determine whether the innovation is worth pursuing. The following sections address information that is fundamental to a disclosure. Some offices will want to add areas beyond these by adding questions. Others may wish to stick to the basics in order to get the disclosure in the door.

Technology Description

Most often the innovator will be able to provide a complete and extensive technical description of the innovation; after all, he or she is the creative source behind the technology. The innovator is trained to write in great detail and provide ample background and citations. Thus, as you would expect, the technology description is usually the best portion of the innovation disclosure. It is often constructed from technical papers, in fact.

Unfortunately, you are not necessarily looking for a full, detailed technical understanding of all aspects of a technical area of research in the same level of detail as is offered. You might prefer a more concise description that doesn't delve into adjacent fields of research. You may wish to encourage the innovator to identify specific sections of an attached technical paper that more specifically address the innovation.

In any event, it is desirable that the innovator describes the best mode for using the device or operating the process.² In other words, you do not want the innovator to hide the best way of operating in an attempt to thwart others from using the innovation. If patent protection is being considered, it will be important to describe the best mode known at the time. Should a competitor discover that the inventor has failed to disclose the best mode of operation, the patent could be invalidated. Even if patent protection is not an option, you will want to base your analysis of commercial potential on the best mode.

Market

Some innovators are market savvy; that is, they know the problems industry is facing and they know how their innovation works as a solution to a certain subset of those problems. In these cases, this knowledge should be used to your advantage to get a head start in transferring the technology for public benefit. Put more simply, you would like to know what your innovators know.

Accordingly, the innovation disclosure should include questions related to identifying companies most likely to be interested in the technology. This information on potential licensees and competitors will facilitate your commercial analysis and shed light on how competitive the field is.

In contrast, there are innovators who don't have a clue as to what industry is doing. It is also important for you to know this fact about them. The same questions are likely to have terse answers or be left blank. This will also be a factor in your evaluation. Do you, as the licensing associate, know the market? How hard will it be to discover what problems

industry is having in the area of the innovation? Is it easy to determine how the innovation solves a problem? If you can't answer these questions, then you have the proverbial solution-looking-for-a-problem, and it will be very difficult to transfer the technology.

Public Disclosure

It is imperative that your office be made aware of any past or future public disclosures when considering filing for patent protection. Since many innovators don't know what to consider when reporting a public disclosure, it is best to ask for information relating to technical papers, posters, dissertations, and meetings. When you interview the innovator, ask about anyone he or she may have talked to about the innovation. Sometimes this will bring out a casual conversation with colleagues at another institution that you may wish to consider.

As mentioned above, when a disclosure is received in my office, I immediately assess whether a public disclosure has or is about to occur. If the inventor filled out the form on her way to a conference, you may have very little time to make a rather important decision to file a patent application or forego it. These are the stressful situations that make the job so interesting.

Don't forget to ask about future plans for public disclosures. Sometimes a report to a funding agency is coming up and could have confidential material identified and extracted to an appendix. Sometimes you will learn of a poster session in the near future. One of the services you can provide to your innovators is the coordination of such events with commercialization efforts.

Funding

When an innovation is conceived, it is often conceived as a piece of a larger body of work. The funding provided for that scope of work may be governed by a contract. Funding contracts may be a complicating factor in managing an innovation, so it is important to know what is contained in the contract before committing to any action. I cannot count the number of times a professor has come to me with a company interested in licensing his or her technology only to find that the funding contract stipulates rights to other parties.

Ask the innovator for contract numbers for the funding agreements they cite in their disclosure. Get to know your contracts office personnel so you will get expedient service from them when you ask for copies of the contracts.

Ask the innovator what his or her plans are for upcoming funding. Sometimes you can head off a problem. For instance, if the conception of a portion of the technology occurred under an industry consortium agreement, then refined and improved under a private contract, it may be better to separate the originally conceived invention from the improvement and work with each under separate innovation disclosures.

Contribution

The innovation disclosure should identify all the innovators who have conceived any part of the innovation. You will need to have an idea of how many inventors may be cited on a patent application or how many authors are to be included in a copyright registration. This will impact your evaluation, since it is harder to manage an innovation with twelve inventors than an innovation with two inventors. You will also find it necessary to have the contact information for each person involved to facilitate execution of the necessary papers associated with such filings.

It is also a good idea to ask the innovators to identify their level of contribution to the innovation at the time of disclosure. It is far easier to get agreement on this point when the innovators are submitting the innovation than it is after revenues start to flow. If you bundle technologies, the split might change, but it is still good practice to know the level of contribution of each innovator at the outset.

Predisclosure Meetings

Too many technology transfer offices get in a mode of being 100 percent responsive rather than being proactive. By this I mean that they wait for disclosures to show up at their door to begin work. It is easy to do, after all, since there are typically many more disclosures coming in the door than can be effectively managed. But, that is no excuse for becoming a fully reactive (and, thus, less effective) office. This can only result in some good technologies languishing and being forgotten in the labs.

Ideally, your office would receive only high-quality innovation disclosures. To get those, you will need to meet with the potential innovator before they disclose. You can actually guide the process by helping the innovator know how you evaluate technologies and what to look for when making the election to send a disclosure with your office. In your discussions with potential innovators, you might even discover how a technology could solve an industry problem and ask for a specific technology.

Some technology transfer offices are actively going to industry partners to find out what problems they face, then coming back and searching for the solution among known innovators. This aggressive tactic can lead to innovation disclosures coming into your office with the licensee in hand.

Duty to Report

If the innovation disclosure cites a United States federal funding agreement, there is likely to be a reporting requirement back to the funding source. Most often, either your office or the contracts and grants office performs this function. It may be necessary to coordinate with different offices to ensure that these reporting requirements are met within a set timeframe. It is imperative to review the contracts so you are aware of all reporting requirements outside your office. The USA Code of Federal Regulations (37 CFR 401.14) implementing the Bayh-Dole Act stipulates, for instance, that the agency must be notified of the innovation disclosure within sixty days of your receipt.

Reporting requirements may be different for innovations you intend to protect under copyright law rather than patent law. There is no election of title, for instance, for copyright works. The title is immediate and resides with the author unless governed specifically by contract. Once again, the wording of the funding agreement is critical.

For federally funded inventions you intend to patent, you will make a decision to elect title within a two-year period after reporting the invention. The government retains certain intellectual property rights.³ The initial notification, election to title, and status changes can all be electronically transmitted to the federal agency through iEdison, a secure interagency, interactive, Web-based system for reporting.

Troubleshooting

You might run into a few stumbling blocks when getting your innovators to disclose to your office. Here are some of the more common problems you may face.

When an Innovator Is Withholding

Occasionally, you will find an innovator who is intent on “gaming” the system; that is, playing a mental game designed to get around the policy requirements. An innovator like this may send an innovation disclosure to your office in strict accordance with the letter of your policy, but withhold critical information in an effort to circumvent the spirit of the policy.

For instance, an innovator may write the technical portion of the disclosure in a way that makes an invention appear to be a minor improvement over the state of the art, indicating to you that it would be hard to protect and that it would carry a low value. He or she may also withhold mention of an important company representative who has contacted him or her wanting to learn more about the invention. The innovator may seek a release of rights from your office so he or she may own the resulting invention (and presumably license it personally to the interested party).

It is hard to protect against such game playing, but it is possible to make the game harder to play by making sure the innovator’s department head or superior sees the disclosures. The department head may recognize the understatement or know of the company interest. Another safeguard would be to have a reporting requirement for license agreements secured for technologies that have been released to an innovator. This functions as a good check for conflict of interest.

When an Innovator Doesn’t Have Time

You may know of commercially viable innovations resulting from a research project, but can’t get the innovator to disclose it to your office because he or she just doesn’t have time. If the technology seems important enough, many licensing professionals will fill out an innovation disclosure form themselves through a process of interviewing the innovator

and then simply get the innovator to edit and sign it. The interview might even be with a graduate student of the innovator or a subordinate to the lead innovator so his or her time is not compromised.

This method of getting a disclosure on file is an easy way to keep a busy and important innovator happy with your office. He or she, of course, will benefit if you are right and the innovation proves to be commercially viable.

When Questions Are Unanswered

You will find that some innovators leave questions on the innovation disclosure form blank. Thus, you might not know, for instance, whether there was an enabling public disclosure or whether there was none if the answer to the question regarding publications is left blank.

Technology transfer offices handle these cases differently. If you are struggling to get a good flow of innovation disclosures into your office, you may accept the disclosure and fill in the blanks yourself during the upcoming personal interview.

On the other hand, you may have more innovation disclosures coming in the door than you can handle with your current resources. In that case, you may wish to notify the innovator that the innovation disclosure has not been accepted because it is incomplete and that you will be glad to log it when the innovator answers all questions. By taking this approach, you will be working with the innovators who most want to work with your office.

Sample Innovation Disclosure Forms

Here are some links to examples of innovation disclosure forms from various universities. You will see that each carries a different style; yet, they each address the same fundamental areas. They may provide some insight into the various ways of designing your own form.

- [TTP_V3__P2_disclosetamu.pdf](#)
- [TTP_V3__P2_discloseTampere.pdf](#)
- [TTP_V3__P2_disclosePSU.pdf](#)
- [TTP_V3__P2_discloseAustralian.pdf](#)

Notes

1. MPEP 2164.05(b) Specification must be enabling to persons skilled in the art: The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to which the claimed invention pertains at the time the application was filed. Where different arts are involved in the invention, the specification is enabling if it enables persons skilled in each art to carry out the aspect of the invention applicable to their specialty. *In re Naquin*, 398 F.2d 863, 866, 158 USPQ 317, 319 (CCPA 1968).

When an invention, in its different aspects, involves distinct arts the specification is enabling if it enables those skilled in each art, to carry out the aspect proper to their specialty. “If two distinct technologies are relevant to an invention, then the disclosure will be adequate if a person of ordinary skill in each of the two technologies could practice the invention from the disclosures.” *Technicon Instruments Corp. v. Alpkem Corp.*, 664 F. Supp. 1558, 1578, 2 USPQ2d 1729, 1742 (D. Ore. 1986), aff’d in part, vacated in part, rev’d in part, 837 F. 2d 1097 (Fed. Cir. 1987) (unpublished opinion), appeal after remand, 866 F. 2d 417, 9 USPQ 2d 1540 (Fed. Cir. 1989). *In Ex parte Zechnall*, 194 USPQ 461 (Bd. App. 1973), the board stated “appellants’ disclosure must be held sufficient if it would enable a person skilled in the electronic computer art, in cooperation with a person skilled in the fuel injection art, to make and use appellants’ invention.” 194 USPQ at 461.

2. MPEP 2165 The best mode requirement: The specification. . . shall set forth the best mode contemplated by the inventor of carrying out his invention.

“The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention.” *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 963, 58 USPQ2d 1865, 1874 (Fed. Cir. 2001).

The best mode requirement is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. The requirement does not permit inventors to disclose only what they know to be their second-best embodiment, while retaining the best for themselves. In *re Nelson*, 280 F.2d 172, 126 USPQ 242 (CCPA 1960).

3. For more, see the Council on Governmental Relations Web site at <http://www.cogr.edu/>.

Patentable Inventions Versus Unpatentable: How to Assess and Decide

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Introduction

When a technology transfer office receives an invention disclosure, the technology must be assessed for its potential marketability and patentability. Patentability opinions prepared by patent lawyers can be quite expensive, and the opinions are usually not guarantees that a technology is either patentable or unpatentable. Therefore, in most cases, the initial assessment is performed by the technology transfer office. If the technology passes initial scrutiny, an application can be filed or a patent attorney can be consulted if a more expert opinion is needed. This chapter summarizes some of the laws governing patentability and how they can be applied during an assessment of a new invention disclosure. Included at the end of this chapter is a glossary of commonly used patent or related terms, particularly terms used in this chapter.

What Is Patentable?

The requirements for patentability are regulated by federal law. The U.S. Constitution gives the Congress power to enact laws relating to patents. There are three major requirements for patentability: novelty, usefulness, and nonobviousness. Secondary requirements include adequate written description, enablement, and best mode. The primary statutory requirements of patentability are encompassed by 35 U.S.C. §§ 101, 102, 103, and 112. These laws and their application in assessing patentability are reviewed below.

Statutory Subject Matter

The United States Code summarizes the categories of subject matter that are patentable and further requires that the invention must be new and it must be useful.¹ As the

Supreme Court has recognized, Congress chose the expansive language of 35 U.S.C. § 101 so as to include “anything under the sun that is made by man” as statutory subject matter.² In that case, the Supreme Court held that a genetically engineered microorganism is not excluded from patentability under 35 U.S.C. § 101.

As long as an invention falls within the general categories of a new machine/device, a process/method, or a composition of matter, it generally meets the statutory constraints of 35 U.S.C. § 101. However, if there is no clearly defined use for the invention, the U. S. Patent and Trademark Office (PTO) may issue a lack of utility/usefulness rejection. For example, inventions such as novel chemical compounds for which no useful purpose has been found may be rejected as unpatentable for lack of utility. The threshold for usefulness is usually not very high and does not, for example, equate to commercial marketability. Fortunately, these rejections are not issued very often.

Although the typical technology transfer office may not receive such a disclosure, an invention that is immoral cannot be patented on the ground that it lacks utility. Inventions that are not patentable subject matter under 35 U.S.C. § 101 are also discussed below in the section entitled “What Is Not Patentable.”

Conditions for Patentability, Novelty, and Loss of Right to Patent

35 U.S.C. §102 requires that an invention must be novel.³ The assessment of novelty is based on an objective standard. An invention that is not novel is said to be *anticipated*. When reviewing a technology for novelty, 35 U.S.C. §§ 102(a) and 102(b) encompass the heart of the analysis. The main concerns are whether *someone else* invented before your inventor did or that your inventor published or disclosed the invention more than one year ago. The new technology will not be novel if the invention was (a) patented, published, or known to the public before the technology under evaluation was invented or (b) described in a publication, used publicly, or offered for sale to the public more than one year prior to the filing date (or tentative filing date) of the technology under evaluation.

The one-year bar is called a *statutory bar* and is absolutely unforgiving in its application against an invention. However, it is also referred to as a *one-year grace period*, because

if an inventor does publish or disclose the invention any U.S. rights that might exist may still be protected as long as an application is filed no more than one year after the publication or disclosure.

Usually, the date of invention is considered to be the date a patent application is filed, but in certain circumstances, a more specific determination of the actual invention date is necessary. In these circumstances, evidence must be provided to demonstrate when conception occurred. Such an analysis does not usually arise until an application is undergoing prosecution and requires specific evidence of *conception* and reduction to practice, such as copies of dated laboratory notebook pages.

A prior art search can be performed to help determine if an invention is novel, but even an extremely thorough search of all available scientific and patent databases is no guarantee that there is not problematic or relevant art out there. For example, a similar invention may be in use (i.e., known) elsewhere in the United States, but its use is not presently searchable in any of the databases. Federal grant applications that are funded are also not searchable by typical electronic searches. Federal grant applications under review are considered confidential, but once the grant is awarded, only the abstract is published. Therefore, information in the application itself is not searchable by standard search methods.

However, the entire grant application does become available to the public for inspection under the Freedom of Information Act (FOIA) once the grant is awarded. In fact, the courts have held that once a federal grant is allowed, it is now public and can be used as prior art.⁴ Additionally, another inventor or entity may have already filed a patent application encompassing the same invention as the new disclosure under evaluation, but the application is not available in any of the searchable databases because it has not yet published. Therefore, even if the most thorough art search possible is performed, more art may be out there that is difficult to find using standard search methods because it is not yet searchable. This is one of the reasons that warranties regarding patentability should not be included in a license agreement.

Even if a thorough prior art search is performed, the inventor(s) should be questioned regarding what is known by others and whether the inventor(s) has in any way disclosed the invention publicly or published the invention.

When a prior art reference is found that appears to anticipate the invention encompassed in the new disclosure, do not discard the new invention until it is determined that the prior art reference teaches each and every element of the new invention. If the new invention has even one aspect that is novel over the prior art, then the new invention may still satisfy the novelty requirement.

Conditions for Patentability, Nonobvious Subject Matter

35 U.S.C. § 103 requires that for an invention to be patentable, it must be nonobvious.⁵ Even if a technology is novel, it may not be patentable if it is too similar to the prior art, a situation known as *obviousness*.

An analysis of obviousness is not as straightforward as a novelty analysis, and, in fact, can be one of the more difficult determinations in patent law. An invention must not be an obvious development over what is known in the art, as judged by one of ordinary skill in the art. Although most obviousness determinations are not simple, a mere change in color, change in materials, or a change in size relative to the prior art is probably obvious.

An obviousness rejection is usually couched in terms of a combination of references either teaching or suggesting to one of ordinary skill in the art all the features of the claimed invention. Therefore, when assessing a technology, some consideration of how the claims will be written is usually required.

When a technology is one that is in a very crowded field of research and is not a ground-breaking technology, but is instead a small advancement or minor improvement over the art, the likelihood of an obviousness rejection greatly increases. The more art there is, the greater likelihood that the invention may be obvious or that an examiner will at least use the art to issue an obviousness rejection. Additionally, because the grounds used by examiners for obviousness rejections are often in a gray area relative to the law and

because examiners have a fair amount of latitude in making such a rejection, it can be difficult for a patent lawyer to overcome the rejection.

If the art teaches or suggests a result that is the opposite of the results disclosed by the present technology or the art suggests that the present approach would not work, then the new technology is probably not obvious. Additionally, if the new discovery was an unexpected result, it is probably not obvious. Those topics can be discussed with the inventor if the initial analysis demonstrates a lot of art in the field of the new technology and there is a concern that the invention might be obvious.

Regardless of how many prior art references are found, there must be something in those references that would cause one of ordinary skill in the art to link the references together. That is, there must be something in the art or the references that teaches or suggests that the references be combined or modified to arrive at the present invention or would motivate one of ordinary skill in the art to make the invention as claimed. Furthermore, the combination of the references must teach or imply every element of the new invention.

Adequate Written Description and Enablement

35 U.S.C. § 112 includes six paragraphs, the most important of which for this review of patentability is the first paragraph. The first paragraph encompasses the written description, enablement, and best mode requirements of patentability.⁶

An adequate written description is one that fully describes the claimed invention, meaning that the inventor actually invented and disclosed in the specification that which is recited in the claims. Written description is relevant to the breadth of a claim. Rejections for inadequate written description are usually phrased as *not in possession of the invention as claimed* and most often mean that more is being claimed than was actually invented and described in the specification. Possession may be shown in a variety of ways including description of an actual reduction to practice or by showing that the invention was *ready for patenting*, such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

For example, a common scenario seen in invention disclosures is when it demonstrates that drug X can kill breast cancer cells in vitro, but the inventor has only tested a single breast-cancer cell line. Although the inventor suggests that the drug can be used for all cancers, a claim for *treating cancer using drug X* would be rejected as lacking adequate written description because the application does not demonstrate that *all* cancers can be treated. The claim would probably have to be amended to recite treating *breast cancer using drug X*.

To obtain a broad claim of treatment of more than one kind of cancer, the inventor must have data where multiple kinds of cancer had been tested successfully or must be able to demonstrate or explain why the mechanism by which drug X works is common to the types of cancers being claimed. It should be noted that in what are called the *unpredictable arts*, such as biotechnology, the PTO has greater written description requirements than for other technologies such as engineering. In fact, the PTO has issued an expanded set of written description guidelines devoted exclusively to biotechnology.

When the analysis suggests that the technology is good but is too narrow, it can be suggested to the inventor that additional experiments be performed to broaden the scope of the invention. Determining whether to file a provisional application based on the data that is available or waiting for additional experiments to be performed is not always an easy task and is beyond the scope of this chapter.

However, things to be considered include marketability of the technology in its present state, whether the inventor has the willingness or resources to do additional experiments, and whether any new data added later if the provisional application is converted and filed as a PCT or nonprovisional U.S. application would be supported by the provisional application as filed. If the provisional application is too brief or is filed using only the limited data available in the disclosure, the benefit of the provisional filing date could be lost if the examiner asserts that the provisional application does not support that which is claimed in the nonprovisional application where a lot more data or broader use data are added.

Rejections for lack of enablement may sometimes seem similar to a written description rejection but are supposed to be based on providing enough information in the specification that one of ordinary skill in the art could read it and reproduce and practice the invention. The amount of information required may vary by technology, but a series of factors are taken into consideration when enablement is being determined and revolve around the issue of how easily one of ordinary skill in the art could make and use the invention as claimed. The factors used when determining whether undue experimentation would be required to reproduce the invention include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

For example, if the mouse cancer cell line or mouse cancer model described above did not have a good human counterpart or was not very representative of similar human cancers or the drug used was so new that it is not easy to speculate about how much drug would have to be given to humans or at what intervals or the equivalent human cancer was known to be notoriously nonresponsive to chemotherapy, a reasonable examiner might reject the claims asserting that undue experimentation would be required to translate the mouse model to humans. Gene therapy claims are also rejected for lack of enablement, but the nuance in those rejections is usually that the field of gene therapy is unpredictable. Unpredictability is probably asserted most often in biotechnology cases.

Although analyses of adequate written description and enablement are sometimes difficult when an invention disclosure is first received and may not seem as important as novelty and obviousness analyses, some thought should be given to the requirements of 35 U.S.C. § 112 because the value of a patent is usually diminished if the claims have to be narrowed for any reason to be allowed.

If the invention disclosure being assessed is particularly sparse in its content, be sure not to overlook 35 U.S.C. § 112 considerations. Furthermore, if an application is to be filed, express your concerns about 35 U.S.C. § 112 issues to the person writing the application,

but realize that the more work the patent attorney has to do to expand the scope of the invention, the higher the bill will be. The more detailed and complete the disclosure is when it is sent to the attorney, the easier it will be for the attorney to write a good patent application.

What Is Not Patentable?

As summarized above, patent law provides for what is patentable and for what is not patentable. Additionally, guidelines and court cases have further construed what is not patentable (i.e., *nonstatutory* subject matter).

An invention is not patentable if it falls into one of the following categories:

- perpetual motion device;
- antigravity device;
- abstract ideas or mental processes;
- laws of nature or scientific principles;
- naturally occurring substances;
- an invention disclosed publicly more than 12 months ago (includes sale, offer to sell, exhibit at a trade show, publication);
- substituting superior material for inferior material;
- a mere change in size, form, or shape;
- literary, dramatic, musical, and artistic works (these are subject to copyright laws);
- data structures or programs per se;
- mere mathematical algorithms;
- nonfunctional descriptive material;
- electromagnetic signals;
- gene therapy;
- human beings;
- an invention that is inoperative;
- an invention that can only be used for illegal purposes (such as a torture device); and
- an invention solely useful in making atomic weapons.

Mere discoveries are not patentable; however, the terms *discovery* and *invention* are quite often used interchangeably, even by the courts. A discovery can be thought of as

something that adds to human knowledge but does so by observation. Discoveries include such things as identification of a new species of plant, a new biochemical pathway, naturally occurring substances, or laws of nature. Nonetheless, once a discovery is made, a modification or new use of the discovery might be patentable. An invention encompasses a creative concept or suggestion of an act to solve a problem, followed by an act that results in, for example, new products, results, or processes or improvements of known products, results, or processes or a new combination for producing products, results, or processes.

Gray areas do exist when ascertaining if something is a discovery or invention. Although one may discover a gene, a protein, or even a drug in a species of plant, each of these is patentable once isolated. Similarly, a method of treating a disease by regulating a newly discovered biochemical pathway is patentable, even though discovery of the biochemical pathway itself is not patentable.

Although mathematical algorithms and software cannot be patented, if a claim recites a process or step using the algorithm or the software, the claim may not be rejected as directed to nonstatutory subject matter.

A new appreciation (e.g., discovery) of the properties of a composition or a process is not patentable. For example, discovering the mechanism by which something works is not patentable if the process or composition was known and the result of the process or effect of the composition were already known.

For example, what if it was known that drug X cures breast cancer (but it was not known how drug X worked) and there was an issued patent claiming treating breast cancer with drug X. If at some point an inventor discovers that drug X works by inhibiting a particular enzyme, a new patent could not be obtained claiming a method of treating breast cancer with drug X by inhibiting the enzyme. This newly discovered mechanism of action would merely be a new appreciation of the drug's properties. However, discovering a new use of a compound or process might still be patentable.

Patent Myths

A few of the common misconceptions about patents are summarized below because many have been perpetuated by those who are ill-informed and/or misinterpret relevant case law. These misconceptions can adversely impact one's views on patentability.

- **Myth #1:** *An inventor needs to know how an invention works.* When assessing the details of an invention, trying to determine whether to file a patent application, and how to market to a potential licensee, remember that the inventor does not need to understand how or why his or her invention works. In fact, the PTO does not examine applications based on such information. For example, if an inventor discovers a new method of curing cancer, it does not matter how the method works, just that it works.
- **Myth #2:** *An inventor needs a prototype.* An application need only describe the invention in sufficient detail to allow one of ordinary skill in the art to make or practice the invention, based on what is disclosed in the specification. If the invention is such a simple device that drawings and a description will allow one of ordinary skill in the art to make or practice the invention, that is all that is needed. In fact, if the invention is simple enough, actual reduction to practice may not be necessary.
- **Myth #3:** *An idea is not patentable.* An idea may not be patentable; however, if that idea has been formulated in such detail that it can be so clearly described in the specification that one of ordinary skill in the art could make or practice the invention based on the details provided in the specification, then it might be possible to get a patent on the idea. Few technologies other than simple machines or simple processes probably fall into this category. For most technologies, the standards of written description and enablement are so high it is difficult to get a patent even where there is substantial data and reduction to practice.
- **Myth #4:** *The preferred way of practicing an invention can be kept secret by exclusion from a patent application.* Patent law requires that the best mode of practicing the invention be included in the application, if a best mode is known.

Failure to comply can result in invalidation of a patent. If secrets are to be kept, then they must be protected as a trade secret and are not allowed in patent law.

International Patent Laws

The requirements of patentability are similar in most countries, but not identical. Novelty is required, a new invention must not be obvious (sometimes referred to as *lack of inventive step*), and it must have utility. Even when similar requirements are in place, laws may vary slightly from one country to the other, as well as the terminology used.

One notable difference between U.S. patent law and the rest of the world is that U.S. patent law provides that a patent can be obtained by the *first to invent*, while the rest of the world uses a *first-to-file* system. This knowledge might be useful during prosecution in the United States and when marketing a technology that may have lost out on filing dates in one or more foreign countries. There have been persistent efforts by various groups to have this part of U.S. patent law changed to better harmonize U. S. law with that of the rest of the world.

The one-year grace period for filing a patent application in the U.S. under 35 U.S.C. §102 (b) is rare in most other countries. In most countries, publication, public use, or sale of an invention is an absolute bar to obtaining patent protection. However, a few countries have exceptions to the absolute bar and even have one-year grace periods, most notably Canada and Australia. There are a few more arcane rules and shorter grace periods in some countries, so all is not lost if a technology is publicly disclosed.

If it is suspected that a technology has publication or disclosure problems, a patent attorney should be consulted to determine the specific rules for filing in each country of interest, because the application may have to be filed directly in the country of interest without the benefit of filing as an international application under the Patent Cooperation Treaty (PCT). The benefit of filing a PCT application is that it provides a mechanism by which an applicant can file a single application that, when certain requirements have been fulfilled, is equivalent to a regular national filing in each designated contracting state of the treaty (more than 100 countries are contracting states).

Changes in Patent Law

Patent laws in the United States and other countries are changed or amended from time to time. At the time of this writing, a number of substantial changes to U.S. patent law are being proposed by Congress and the PTO that could alter some of the analyses provided above. Therefore, it is important to stay abreast of changes in both U.S. and foreign patent law because the changes may affect the patentability of inventions, as well as the prosecution of applications.

Glossary of Patent Terms for Interpreting “Patentese”

Below is a glossary of some of the more common patenting terms.

Anticipation: A term used when an invention is allegedly not novel (see *Novelty*).

Claim: One of the numbered paragraphs that appear at the end of a patent and that defines the scope of protection given to the owner of the patent; a claim may be directed toward an apparatus, a method, a product, or composition of matter, as well as new and useful improvements thereof.

Composition of matter: Also referred to simply as *composition*; typically encompasses things such as compounds, formulas, drugs, proteins, nucleic acids, and mixtures thereof.

Conception: The formation in the mind of the inventor(s) of a definite and permanent idea of the complete and operative invention, as it is to be applied in practice. Conception is completed only when the idea is so clearly defined in the mind of the inventor(s) that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.

Embodiments: Versions or variations on the invention.

Enablement: The requirement that the specification adequately describe how to make and how to use the invention.

Experimental use: Statutory bars prevent one from filing a U.S. patent application more than one year after placing an invention on sale, publication, or public use of an invention. However, if the use was experimental, and for the purpose of testing, improving, or refining the invention, rather than public or commercial purposes, that use may not be counted as starting the one-year grace period.

Invention: Any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof. That is, an invention must be useful, novel, and unobvious to one skilled in the art at the time it was made (i.e., the filing date of the application).

Inventor: Person who conceived the invention; inventorship is not the same as authorship.

Novelty: Where no single piece of prior art discloses *every element* of the claimed invention. If an invention is not novel, it is said to be *anticipated*.

Obviousness: Whether an invention is obvious to one of ordinary skill in the art to which the invention pertains; if the invention could readily be deduced at the time the invention was made from prior art by a person of ordinary skill in that art, it is said to be obvious.

Office action: The document prepared and provided by the examiner to explain why the application is rejected or is allowable.

One of ordinary skill in the art: The hypothetical/mythical person who is presumed to know the entire prior art to which the invention pertains; sometimes referred to by the acronym PHOSITA, meaning a *person having ordinary skill in the art*.

Patent Cooperation Treaty (PCT): International treaty allowing a national or resident of a member country to file an international application designating all national and regional patent offices that are members of the PCT. The applicant can then choose at a later date (normally 30 or 31 months from the first filing date) to file the application in any member country.

Printed publication: May include books, magazines, journal articles, posters presented at meetings (but not slide presentations), Web-based publications, newspapers, patents, patent publications, and catalogued dissertations.

Prior art: The existing body of technological information (publications, earlier patents, public use, sales, presentations at scientific conferences, etc.) known at the time an application is filed, against which the claimed invention is judged to determine if it is patentable as being novel and nonobvious.

Provisional patent application: A special form of U.S. application that reserves a filing date for the material in the application, but which will never be examined or become a patent. Provisional applications are automatically abandoned one year after filing, unless a U.S. nonprovisional (also called *utility*) or PCT application is filed within that year, claiming benefit of the provisional application to preserve the filing date. The provisional application does not have to contain claims, but there are circumstances when it is preferable that it does have claims.

Reduction to practice: There are two kinds of reduction of practice: *actual reduction to practice* occurs when the invention is built or practiced, and *constructive reduction to practice* occurs when an application is filed that adequately discloses the invention.

Restriction requirement: An office action in which the examiner asserts that there is more than one invention in the application. Generally, the rule is one invention to a patent, but when a restriction requirement is issued, you must elect only one invention for prosecution in the pending parent application as outlined by the examiner. However, the nonelected inventions can be pursued by filing one or more divisional applications at any time until the parent application issues as a patent.

Specification: The part of the patent application that precedes the claims and in which the inventor specifies, describes, illustrates, and discloses the invention in detail.

USPTO: United States Patent and Trademark Office, also referred to as PTO.

Utility (usefulness): Some definable use, no matter how trivial.

Written description: Description in the specification of sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention at the time the application was filed.

Notes

1. 35 U.S.C. § 101 states: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”
2. *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09, 206 USPQ 193, 197 (1980).
3. 35 U.S.C. § 102 provides that a person shall be entitled to a patent unless
 - (a) the invention was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent; or
 - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States; or
 - (c) he has abandoned the invention; or
 - (d) the invention was first patented or caused to be patented, or was the subject of an inventor’s certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor’s certificate filed more than twelve months before the filing of the application in the United States; or
 - (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application desig-

nated the United States and was published under Article 21(2) of such treaty in the English language; or

- (f) he did not himself invent the subject matter sought to be patented; or
- (g) (1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

4. *E.I. du Pont de Nemours & Co. v. Cetus Corp.*, 19 USPQ 2d 1174 (N.D. CA 1990).
5. 35 U.S.C. § 103(a) states: "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

The rest of 35 U.S.C. § 103 is not provided here, but note that 35 U.S.C. § 103(b) refers specifically to biotechnology and that 35 U.S.C. § 103(c) refers to prior art and to joint research agreements as provided in the CREATE Act (Collaborative Research and Technology Enhancement Act of 2004).

6. The first paragraph of 35 U.S.C. § 112 states: "The specification shall contain a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable* any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the *best mode* contemplated by the inventor of carrying out his invention" [emphasis added].

Determining Inventorship

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Why Worry about Inventorship?

When an invention is made at an institution, chances are the institution doesn't own it.¹ The inventors do. The institution must affirmatively acquire ownership from the inventors. Since the technology transfer manager's business is licensing—a privilege of ownership—identifying the inventors is job one. Some guidance follows.

Inventions, Patentable Inventions, and Inventorship

Governments issue patents on inventions that meet objective standards of novelty and nonobviousness. A patent conveys to the patentee (that is, the inventor) the power to constrain the use of the invention by others. It also discloses the invention, complete with instructions on how to make and use it, to innovative minds everywhere. Both the reward to the inventor and the disclosure of the invention to other innovative minds "...promote the progress of the useful arts..." [Art 1 §8 U.S. Constitution].²

Ownership has its privileges, but duties also attach. In addition to the duty of full disclosure, the inventor(s) must declare (under penalty of perjury for intentional falsification):

I believe the inventor(s) *named below* to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought in the invention ... the specification of which is attached hereto...[and]...have reviewed and understood [its] contents, including the claims. [emphasis added]

All individuals claiming to have contributed to at least one element of one of the claims are to be named below. Everyone named declares that he or she—and each of the others—is an inventor. Given the consequences of declaring falsely and the difficulty of grasping

what is inventive, signing this form ought to evoke apprehension. Unfortunately, especially in academic settings, it usually occasions great misapprehension. Among the misunderstandings are as follows:

- *Inventorship by illusion:* Inventors may be nominated by reason of social status, appealing personality, or intellectual acumen, irrespective of their actual contribution to any claimed invention.
- *Inventorship by dictum:* When a principal investigator (PI) functions as ruler of his or her principality, with a king (department chair) or pontiff (dean) backing him or her up, the PI tends to feel entitled to overrule institutional policies and public laws, especially the patent law. Signatures dutifully affixed to declarations at this PI's dictation are dangerous. Even more dangerous is the signature that does not appear, due to the PI's veto.
- *Inventorship by courtesy:* A group, or a benevolent PI, may wish to include a noninventor as a courtesy or because the noninventor "deserves" royalties. Some institutional policies provide royalties to noninventors, but the patent law does not.
- *Inventorship by authorship:* *Author* describes a person who has written something. Authorship has nothing to do with inventorship. An author, being more than an amanuensis, writes down his or her own thoughts, but their patentability rests solely with the patent laws. In academia, where publications are the coin of the realm, authorship may seem more important than inventorship. It is, therefore, easy to see why academics have such difficulty disentangling the two concepts.
- *Inventorship by effort:* Occasionally, an inventor forms a "definite idea of the complete and operative invention" in a single moment and, when the invention is made and used, it works exactly as expected. More often, the idea doesn't work. If the fault was in the idea itself, the conception was illusory—there was no invention. But if the fault was in the implementation, efforts to get it right may eventually vindicate the original concept. Technicians, students, and others often do the work that proves the principle. But, if the work only validates the concept, none are inventors.
- *Inventorship by enablement:* A patent claim will not issue if the application does not sufficiently describe how to make and use the invention claimed. The claim is not "enabled." Since the patent must describe at least one procedure that would actually

make the claimed concept work, making and using a working prototype might seem to constitute an inventive contribution. But it does not.³ On the other hand, when a worker's effort to enable a concept reveals a fault in the concept and the worker helps formulate a truly valid concept, he or she may be an inventor of the corrected concept, not because of his or her work but because of his or her insight.

- *Inventorship by materials*: If a patent owner wishes, and is not otherwise obligated, he or she can convey rights of *ownership* in the patent to a party who contributed materials in the course of reducing the invention to practice, but a contributor of materials, biological or otherwise, without more, is *not* an inventor. Nor is a contributor of money, equipment, or other facilities.

A Special Note on Reduction to Practice

It is said that “ownership runs to conception.” In fact, ownership runs to *complete* conception. When a “...definite and permanent idea of an operative invention including every feature of the subject matter sought to be patented is known...” [*Coleman v. Dines*, 754 F.2d 353, 359 (Fed Cir. 1985)] so that “...one of ordinary skill in the art could construct the apparatus, perform the process, or make the composition without unduly extensive research or experimentation...” [*Trovan*, 299 F.3d at 1302], conception is complete. Invention is also said to comprise a two-step process of conception and reduction to practice, suggesting that conception is not *complete* until the inventor converts his or her idea into a physical reality. In fact, such proof is not necessary. At the first moment the inventor can describe his or her invention with particularity, including how to make and use it, reduction to practice has occurred. By convention, just as all racehorses are born on January 1, the date the law assigns to that moment is the date a patent application claiming the concept is filed. The statement “filing a patent application is constructive reduction to practice” is a misnomer. Filing a patent application gets you a date to use for legal purposes.

Joint Inventorship

If an individual is, in fact, the sole inventor of a concept, all that remains is to determine the concept's patentability.⁴ But if two or more parties assert a mutual contribution to a concept, the law must determine not only patentability (novelty and nonobviousness) but

also membership in the inventive entity. The relevant law (35 USC §116) seems only to make the inventorship determination more difficult by stating that “Inventors may apply for a patent jointly even though (1) they did not physically work together at the same time,⁵ (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.” Parsing which subject matter is inventive and which is not is exceedingly difficult.

Nevertheless, the law demands accuracy, and violation of the law has consequences, at least when a dispute arises. Any sign that a discloser of an invention harbors any of the foregoing misconceptions about inventorship forewarns of a dispute that may play out badly in the patent office or in litigation. The section “What? When? Where? Who? Why?” outlines an approach to searching for the seeds of dispute in an invention disclosure.

Hazards of Misjoinder, Nonjoinder

Misjoinder, Common Assignee

The law recognizes only actual inventors who are the “first originators of the invention upon which a patent is sought.” When all the prospective inventors have an obligation to assign to one institution, naming too many inventors (misjoinder) is a lesser error than naming too few (nonjoinder). The legal standard for joint inventorship is quite low [*Canon Computer Systems Inc. v. Nu-Kote International Inc.*, 134 F.3d 1085, 1087-88 (Fed. Cir. 1998)], and misjoinder is (usually) easy to correct. It is better to guard against misjoinder by adding claims that recite minor contributions by persons who would otherwise not qualify as inventors. Adding only elements that contribute nothing to the overall invention, however, isn’t inventive and could amount to inequitable conduct.⁶ Should that happen, the aforementioned easy correction mechanism is unavailable [*Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.*, 45 F.3d 1550, 1556-57, 33 USPQ2d 1496, 1500 (Fed. Cir. 1995)].

Other thorny issues can arise. Suppose three joint inventors agree to split evenly any royalties, but prosecution eliminates an inventor, freeing up one-third of the royalties. If institutional policy doesn’t spell out how to distribute this portion, the inventors’ agreement ought to. Or, suppose several patents with potentially different inventive entities

spring from one invention disclosure, or a series of invention disclosures mature into interrelated patents that must remain bundled for proper licensing. To add even more spice to the hash, the technology manager must bear in mind that a royalty-splitting agreement among inventors, being a private contract, is probably none of the technology manager's business!

The manager can at least keep the inventors apprised of the status of the claims and serve as a sounding board (NB: avoid becoming an arbiter!). The healthiest deliberations on royalty splits include a neutral party who keeps the focus on weighing the scientific contributions to the inventive concept(s). More formulaic approaches, such as splitting royalties in proportion to the number of claims each inventor contributed, tend to be inequitable.

Misjoinder, Different Assignees

As interinstitutional collaborations proliferate, so does uncertainty about inventors and assignees: inventorship determinations necessarily take place across cultural, political, and power gaps that inevitably separate institutions. And, since inventorship affects ownership, everything from a misunderstanding to a cynical plot can undermine the privileges of ownership. For example, in the United States, all joint owners of a patent must voluntarily join any suit for infringement on that patent. If a joint owner refuses to join, the suit fails. On the other hand, any joint owner may unilaterally license or assign the whole patent (albeit nonexclusively) to a third party without accounting to the other owners. Thus does a misjoined "inventor," named perhaps simply to make peace, end up making war.

Nonjoinder

If the technology manager is unaware that an undeclared but bona fide joint inventor exists, a patent may issue and be licensed exclusively to a party who relies on it to make investment decisions. Unfortunately, the patent is susceptible to invalidation unless the inventive entity can be corrected. If the nonjoined party must assign his or her rights to the institution,⁷ correction is usually possible. But a nonjoined true inventor having no such obligation⁸ is a grave danger. He or she can (with clear and convincing evidence)

invalidate the patent. If, to avoid invalidation, he or she is joined, he or she can destroy the exclusivity of a license or prevent your institution or your licensee from bringing suit against an infringer.

Although often overlooked when collaborations begin, a written patent plan is essential. A well-crafted plan that includes a representative from each side, charged with jointly tracking the collaboration's inventions,⁹ can help preserve rights to legitimately co-invented technology. It can prevent noninventors from being named, keep parties from deriving an invention from a joint project and claiming it as an independent invention, and prevent forfeiting benefits of the CREATE (Cooperative Research and Technology Enhancement) Act.¹⁰ A carefully drawn plan will exclude conceptions made before the collaborative effort began and concepts developed during but not under the collaboration. Conversely, the plan can spell out how, and if, an invention conceived prior to or outside the collaboration might be pooled with collaboration inventions.

What? When? Where? Who? Why?

To keep incorrect inventorship from clouding title to a patent, one should¹¹ make a good-faith effort to get inventorship right. Patent attorneys generally regard this as the client's duty. Fortunately, a technology manager who is conversant with the science and follows the prosecution of the claims can usually identify the inventive entity and keep track of changes in it. This may not be enough, however. For example, if the original inventive entity spans two institutions but prosecution eliminates one institution's inventor, what rights and duties do the institutions then have to one another? Should they continue to share attorney-client privileged information? If exchanges of technical information continue, are the exchanges confidential or are they public disclosures having implications for patentability?

What Is the Invention?

Probing inventorship requires, first, knowing what the invention is. An invention, unlike a discovery, is always a solution to a problem. Playing "20 Questions" with witnesses, including but not limited to the inventor,¹² will generally identify the invention (and, usually, the true inventors).

Determining Inventorship*John S. Roberts, PhD, MBA*

1. What is the problem with the current state of the art? (Too much heat? Not enough? Too slow, fast, weak, strong, big, small...?)
2. How has everybody managed to get by up to now?
3. Why hasn't the problem already been solved (or solved well enough)?
4. What is the inventor's solution?
5. Has the inventor written that down?
6. Can I see what he or she wrote? (And, if necessary, why not?)
7. What are the individual elements (parts, components, steps) of that solution?
8. In drawings, how would the inventor depict those elements and their interactions?
9. Where can one get the materials needed to make and use what is in the drawings?
10. How should one put the materials together so they'll work?
11. What does the inventor think is the best way of making and using the invention?
12. What's the difference between this and the devices/methods described in the second question?
13. Why didn't anybody who dealt with this problem up to now hit upon the inventor's way of solving the problem?
14. Has the inventor or anyone else tried it?
15. What were the results?
16. Can I see the results? (And, if necessary, why not?)
17. Did the inventor's first ideas have to be modified to get good results?
18. How did the inventor hit upon the modification?
19. Does the inventor have data on the versions that failed?
20. If the inventive solution becomes available, why will the public adopt it?

Who Was Involved?

The inventors, technicians who worked on an underlying discovery or tested prototypes, individuals who witnessed notebook entries or work in progress, or wrote or received reports, or consulted or attended lab meetings are all potential sources of evidence to ascertain who contributed to the complete conception (inventors) and who merely followed directions, suggested a problem in need of a solution, explained how the invention works mechanistically, or provided resources (noninventors).

Where Is Everyone and Everything?

This includes written records, reports, and drawings of the invention, witnesses and inventors, where the invention was made, and where it was first reduced to actual practice.

When Did it Happen?

Both inventorship and ownership can depend upon the developmental history of the invention.

Why Did it Happen the Way it Did?

“Why” questions are aggressive and, therefore, dangerous. On the other hand, they may produce highly revealing answers.

1. Why did/didn't the inventor work with others to develop the invention?
2. Why didn't the inventor keep notebooks or records?
3. Why did the inventor (or another party) tell X he or she should/should not be named as an inventor?
4. Why should/shouldn't X be named as an inventor?

Disputes: Misjoinder or Misunderstanding?

Disputes over who invented first (priority) are different from disputes over who contributed (joinder). When two parties *independently* conceive of a single invention, or so allege, only one of the two can legitimately have a patent on it. In foreign jurisdictions, title goes to the first party to apply for the patent.¹³ In the United States, two applications for the same invention can interfere with one another. To resolve an interference,¹⁴ objective evidence, supported by affidavits or depositions, is essential. A technology manager confronted with such a dispute cannot typically demand evidence from the contending parties and is unlikely to get any information at all from a party at a different institution. The possibility also lurks that instead of two inventors there is one inventor and one thief! Priority disputes cry out for expert legal assistance.

Resolution of joinder disputes depends upon how thoroughly the investigator is able to characterize the contributions made to the conception of the invention. Typically, pieces

of the concept spring independently to several minds. The weight of each piece is irrelevant—only quality counts. Eventually, the pieces are fitted together, perhaps in one brief conversation among less than all of the contributors or perhaps over several years and continents.

Interview the Named Inventors

The investigator must reconstruct the inventive process, annotating each recalled event with hard evidence if possible (notebooks, drawings, manuscripts, abstracts, telephone notes, e-mails, faxes, letters, notes taken at meetings, etc.) by (1) questioning at least the named inventor(s) closest to the development of the invention to understand what they believe the invention is and (2) getting a narrative of the invention's genesis, with an emphasis on who did (said, drew, calculated, looked up, talked with, went to see, tried in the lab) what, when, where, and why.

Interview the Misjoined or Nonjoined Inventors

Remember, this is a dispute. Everyone connected to the situation is potentially an inventor. *Cautionary note:* Investigation of inventorship disputes requires authority. Your knowledge of patent law and the relevant science will help, as will an attitude of objectivity, but if you do not have clear authority to investigate, petition your superiors for the funds to retain a qualified patent attorney for the purpose.

Making Corrections: Who Has to Do What?

Inventorship may change because of

- a canceled claim (loss of inventor),
- a withdrawn claim (e.g., to satisfy restriction requirement),
- an amended claim (loss or gain of inventor),
- an interference (leads to canceled claim),
- new evidence, new view of invention (no change in claims), or
- re-issue.

Under U.S. Patent Law, an attorney, the inventive entity itself, the assignee(s), the U. S. Patent and Trademark Office, or a court, all depending on specific circumstances, can correct inventorship.

When Canceling or Narrowing a Claim by Amendment during Prosecution Cancels an Inventor

Usually, the attorney of record simply files (with a fee) an amendment (by way of a petition) requesting correction because of the cancellation. The assignee is also eligible to do this,¹⁵ and, if the assignee hasn't acted, the inventors (*all* of them) who originally declared themselves inventors—including the canceled inventor—can file the amendment (but any assignee must consent).

When Adding a New Claim during Prosecution Creates an Inventor

A request (with a fee) to correct inventorship must be made, together with a statement from the added inventor(s) that they themselves intended no deception. Since an inventor-come-lately would not have signed the original declaration of inventorship, all members of the new inventive entity must sign a new declaration, and any assignees must consent.

When a Change in the Story, not in the Claims, Changes the Inventors during Prosecution

If an error in naming inventors arises without any deceptive intention during prosecution, the error is easily corrected. The attorney of record files a petition to correct, setting forth the change(s) sought. Also, each person added (or deleted) contributes a statement declaring that he or her himself or herself intended no deception in not joining (or misjoining) the inventive entity.¹⁶ Since correction changes the inventive entity, each member of the new entity must sign a declaration of inventorship. None of this is effective without the written consent of assignees¹⁷ and payment of a fee.

The foregoing steps are formalities if all parties are available to the prosecutor and the proposed change in inventorship doesn't give rise to a dispute or activate a hidden agenda. True inventors who resist an invitation to join the inventive entity, or nonjoined parties who believe they have a right to join, or misjoined parties who resist being removed, cause disputes—and problems.

When a true inventor refuses to join or cannot be reached, a problem of getting a viable declaration of inventorship arises. The other inventor(s) may file a new declaration that names the omitted inventor. According to 35 USC §116, "...the Director, on proof of the pertinent facts and after such notice to the omitted inventor as [the Director] prescribes, may grant a patent to the inventor(s) making the application, subject to the same rights which the omitted inventor would have had if he had been joined. The omitted inventor may subsequently join in the application." If all the inventors refuse to execute the declaration, the institution can step in if at least one has assigned his or her invention to the institution or has agreed in *writing* to do so. The institution, on proof of the pertinent facts, may serve as agent for all. Even without any assignment, a party who shows sufficient proprietary interest can exert the right of agency. The standard for proving sufficient proprietary interest, set out in MPEP 409.03(f), is substantial.¹⁸

During prosecution, a nonjoined party seeking joinder has little recourse via the patent office. As a member of the public, he or she can file a protest against the pending application if he or she can identify the application in question for the patent office.¹⁹ Subject to several rules, the patent office enters the protest into the record, but takes no other action.²⁰ True inventors should not, against their true belief, admit a party to the entity. If they do, the patent can fall because it names an inventor who did not actually invent [35 USC §102(f)] and/or because the entity or some other party in interest deceptively withheld material information from the patent office.

A misjoined party who, in order to remain joined, denies contrary facts is only making a case for deceptive intent. He or she will enjoy, at most, a Pyrrhic victory. His or her continued presence in the inventive entity would render invalid and unenforceable any patent that issues [35 USC §102(f)], thus destroying his or her asset. Fortunately, his or her assignee can remove him or her once the patent has issued (see below).

Interference

A nonjoined party with no obligation of assignment to your institution can provoke an interference in the patent office by filing the patent application (or some of its claims) a second time, this time naming himself or herself and any others he or she believes are

also true contributors. This is one reason to take care about returning rights to a discloser of what a technology manager views as a noninvention. Should the manager later see worthiness in a related invention disclosed to him or her by others, the noninvention, no longer in your institution's control, may rise up in an interference against the case the technology manager thinks is worthy.

Changing the Inventive Entity after Issuance under 35 USC §256

A nonjoined party can make his or her way onto the patent through the patent office or a court. According to the decision in *Stark v. Advanced Magnetics Inc.*, No. 95-1233 (Fed. Cir. 1997), §256 changes the old practice of summarily invalidating a patent that acquires any odor of deception whatsoever. Stark avers that §256 should operate to preserve the patent for all—but only—the true inventors. Although §256 prevents joinder of a true inventor who was deceptive about not joining (probably always a *non sequitur*), it does not invalidate a patent simply because the named inventors weren't honest when they denied entry to the nonjoined inventor. The rule that implements §256 (37 CFR §1.324) does require a statement by all parties to the effect that they agree to the correction. The correction proceeding can also take place under the aegis of a court. The commissioner issues a certificate of correction upon order of the court.

Changing the Inventive Entity by Re-issue

Misjoined noninventors may not wish to remove themselves from the inventive entity. However, according to MPEP 1412.04, if all co-owners of the patent join the proceeding and state that they believe “the original patent to be wholly or partly inoperative or invalid through error of a person being incorrectly named in an issued patent as the inventor, or through error of an inventor incorrectly not named in an issued patent, and that such error arose without any deceptive intention on the part of the applicant.” [Note: *applicant* here refers to the applicant for re-issue, i.e., the assignee(s).] The MPEP continues: “...an assignee of the entire interest can add or delete the name of an inventor by reissue (e.g., correct inventorship from inventor A to inventors A and B) without the original inventor's consent. Thus, the assignee of the entire interest can file a reissue to change the inventorship to one the assignee believes is correct, even though an inventor might disagree.”

Conclusion

The foregoing provides an annotated index of actions that a technology transfer manager can take in managing particular issues surrounding inventorship. Perhaps the most trying job, particular in academic settings, is determining who is *not* an inventor. The most unnerving is finding the hidden or forgotten inventor, i.e., the “destroyer.” The most put-off-until-later job is the most urgent one: get the declarations of inventorship, powers of attorney, and assignment documents executed *now!* And, by all means, complete that interinstitutional agreement. Also, while the inventors are in the mood, get joint inventors to agree, in writing, to their royalty splits. All of these actions reduce the likelihood of a dispute, which nobody wants because it’ll usually require a lawyer to resolve. Know the laws and policies that convey rights to the institution—technology managers typically think they know them, but don’t. Finally, enjoy the inventors. Trying as they may sometimes be, they are the best part of the job.

Notes

1. The intellectual property policy of some public institutions is statutory. If the statute explicitly provides for ownership a priori, an invention may be institutional property at the moment of conception. In general, however, the institution’s interest is secured only by the inventor’s promise to transfer ownership a posteriori.
2. In other jurisdictions, ownership falls to the applicant, who need not be an inventor.
3. The Bayh-Dole Act, and the language of many sponsored research agreements, confound the issue by stating that the sponsor enjoys certain rights to inventions “conceived or first *actually* reduced to practice” [emphasis added] during and under the contract. Individuals who first actually reduce to practice an already “complete” concept (see note 3) may not be inventors. Nevertheless, the institution where those individuals did the (noninventive) actual reduction to practice may have acquired an obligation to grant patent rights to a sponsor of the practical work, which rights it can’t obtain under any policy or law.
4. *Sole* inventor contrasts with *joint* inventor. A sole inventor may not be the *only* inventor. (See note 5.)

5. Joint inventors must communicate. If each made the same invention, unaware of the other's work (even if employed at the same place), the invention is not joint. The second to invent (under U.S. law) will not be granted a patent. Attempts to fix the situation by declaring the invention a joint effort will not be effective.
6. An intentionally concocted claim canceled during prosecution without removing its inventor from the application leaves behind a record of possible deception and a possibly fraudulent inventor declaration. One should always take care, therefore, that any such claim be a dependent claim: the standards of novelty and nonobviousness do not apply to the limitations one finds in the claim itself [*In re McCarn*, 212 F.2d 797, 101 U.S.P.Q. 411, 413 (C.C.P.A. 1954)].
7. *Chou v. University of Chicago* [254 F.3d 1344 (Fed Cir. 2001)] endorsed the view that the mere acceptance of an academic appointment, without any signed agreement at all, subjects the inventor to the administrative policies of the institution, at least under Illinois law. Even so, securing an actual executed assignment and recording it in the patent office as early as possible is preferable. Consider 37 CFR 3.71(a): "One or more assignees as defined in paragraph (b) of this section may, *after becoming of record* pursuant to paragraph (c) of this section, conduct prosecution of a national patent application or reexamination proceeding *to the exclusion of either the inventive entity, or the assignee(s) previously entitled to conduct prosecution.*" [emphasis added]
8. Be careful to understand the obligation of assignment (if any) that "lesser parties," particularly students, have at your institution. If a student invents and is not required to assign, persuade the student to execute an assignment as if subject to institutional policy.
9. In complex, large-scale collaborations, a joint steering committee serves this function.
10. The CREATE Act allows information to move among research collaborators at multiple institutions without precipitating a public disclosure and permits collaborating institutions to acquire patent rights that were unavailable to disparate assignees prior to its passage. Much depends, however, upon having a written collaboration agreement in place "on or before the date the claimed invention was made."
11. What the technology manager should do and is actually able to do are two different things. Carefully drawn license agreements, therefore, make no warranties or representations that any licensed patent is or will be held valid.

12. The questions are intended to flesh out the nature of the disclosed invention, not necessarily to probe its legal novelty or nonobviousness. An invention, whether or not it is patentable, is an invention.
13. The first to file must not have *stolen* (derived) the invention.
14. Interference practice is beyond the scope of this article.
15. One of the advantages of securing assignment early is the convenience it brings to prosecution. This benefit of ownership by assignment also extends to certain corrections made without canceling a claim.
16. Since 1997, no showing of facts or of diligent effort to correct is required.
17. Note that changes in inventorship may affect information disclosure statements: bringing a new party into an inventive entity may bring with it “secret prior art” to report [*OddzOn*]. A new party might also bring a new assignee, which could affect the protections of the CREATE Act.
18. A proprietary interest obtained other than by assignment or agreement to assign may be demonstrated by an appropriate legal memorandum to the effect that a court of competent jurisdiction (federal, state, or foreign) would by the weight of authority in that jurisdiction award title of the invention to the 37 CFR 1.47(b) applicant.
19. This is one reason to avoid disclosing the serial number and filing date of a patent application.
20. So-called opposition practice, where protesters may take a more active part in patent prosecution, as of this writing, is not practiced in the United States. It is commonplace in other jurisdictions.

Issues in Identifying Contributors to Inventions under U.S. Law

J. Peter Fasse and Erin Kaiser

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This chapter addresses inventorship and ownership issues, as may arise in a university or hospital setting. The chapter first defines inventorship and its legal background. Second, it addresses the complications that can arise when there are possible joint inventors and provides general guidelines for determining inventorship. Third, it describes the differences between inventorship and authorship. Fourth, it addresses the differences between inventorship and ownership. Finally, it discusses how to correct inventorship in the event of an error.

What Does it Take to be an Inventor?

Under U.S. law, only the first, original inventor(s) can obtain patent protection for an invention.¹ Inventorship is defined by statutory provisions of Chapter 35 of the U.S. Code (USC) as interpreted by case law. Despite these legal underpinnings, the process of determining inventorship is a very fact-specific endeavor. A first basic principle often misunderstood by inventors is that inventorship is determined in view of the claims at the end of a patent application that define the invention, not the content of the specification.

Once you understand the claims of a patent application, you review the process of invention in two parts: (1) conception and (2) reduction to practice. Conception is the key aspect for determining inventorship, i.e., to be an inventor, a person must make an intellectual contribution to the conception of the claimed invention.

In a 1994 biotechnology lawsuit, the Court of Appeals for the Federal Circuit took the opportunity to restate the long-standing principles of inventorship:

Conception is the touchstone of inventorship, the completion of the mental part of invention. It is “the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.” Conception is complete only when the idea is so clearly defined in the inventor’s mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation. Because it is a mental act, courts require corroborating evidence of a contemporaneous disclosure that would enable one skilled in the art to make the invention.

Thus, the test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention; the inventor must prove his conception by corroborating evidence, preferably by showing a contemporaneous disclosure. An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue. The conception analysis necessarily turns on the inventor’s ability to describe his invention with particularity. Until he can do so, he cannot prove possession of the complete mental picture of the invention. These rules ensure that patent rights attach only when an idea is so far developed that the inventor can point to a definite, particular invention.²

Conception is a mental act, but courts do not accept an inventor’s testimony alone to prove conception. Proof of conception requires corroborating evidence of a contemporaneous disclosure that is sufficient in scope and detail to enable one skilled in the art to make the invention.³ Thus, when you determine inventorship, it is important to have all potential inventors present laboratory notebook pages, charts, graphs, invention disclosure forms, e-mails, and any other documents that support their claim of inventorship. These materials should be collected and saved in the application file to support the decisions made on inventorship once the patent issues and for use during prosecution of the patent application or in litigation of the issued patent in the event it becomes necessary to prove dates of conception and/or reduction to practice.

The second part of the process of invention, reduction to practice, may be relevant to determining inventorship in that whether an individual is a co-inventor depends on whether his or her contribution constituted part of the conception or a mere reduction to practice. In this regard, one who does no more than reduce a completely conceived invention to practice is not an inventor.⁴ Reduction to practice can also become important if a date of invention must be proved, for example, in a declaration by the inventors to demonstrate a date of invention prior to the publication date of a reference published less than a year before the inventors' application filing date or in an interference proceeding.

Reduction to practice can be actual or constructive. An actual reduction to practice exists when, for example, a new device, composition, or machine is successfully made and tested, or a process is performed successfully. A constructive reduction to practice occurs when a patent application having a sufficient written description of the invention is filed, regardless of whether there has been an actual reduction to practice.

Conception and reduction to practice are normally, but not necessarily, distinct events separated in time. Nevertheless, courts have recognized for many years that simultaneous conception and actual reduction to practice can occur in some situations. For example, in *Smith v. Bousquet*, the Court of Customs and Patent Appeals (CCPA), a predecessor to the Federal Circuit, found conception and reduction to practice to be simultaneous. The CCPA explained, "we are in agreement with the views expressed by the Examiner of Interferences that the record in this case does not warrant a holding that either of the parties established conception ... prior to, or independent of, a reduction to practice."⁵ Elsewhere in its opinion, the CCPA quoted from the decision of the Examiner of Interferences (emphasis added):

[T]here is no known relation between chemical structure and insecticidal action, therefore, it is obviously impossible to predict or determine in advance of actual experiment whether or not any specific compound or group of compounds is a new and useful insecticide.

In the *experimental sciences of chemistry and biology the element of unpre-*

*dictability frequently prevents the conception separate from actual experimentation and test.*⁶

The doctrine of simultaneous conception and reduction to practice is alive and well, having been applied by the Federal Circuit in 1991 in *Amgen Inc. v. Chugai Pharmaceutical Co.*⁷ Regarding a claim to a “purified and isolated DNA sequence” encoding human erythropoietin (EPO), the Federal Circuit in *Amgen* stated, “[i]n some instances, an inventor is unable to establish a conception until he has reduced the invention to practice through a successful experiment. This situation results in simultaneous conception and reduction to practice.”⁸

In *Amgen*, the Federal Circuit linked its finding of simultaneous conception and reduction to practice to the unpredictability of cloning and sequencing genes:

[S]uccess in cloning the EPO gene was not assured until the gene was in fact isolated and its sequence known. Based on the uncertainties of the method and lack of information concerning the amino acid sequence of the EPO protein, the trial court was correct in concluding that neither party had an adequate conception of the DNA sequence until reduction to practice had been achieved⁹

Cases such as *Bousquet* and *Amgen*, however, do not stand for the proposition that, in an unpredictable art, someone who merely executes instructions and carries out experiments designed by the inventors to reduce an invention to practice becomes a co-inventor. Even though conception is not complete until the reduction to practice has occurred in this scenario, the person or persons who simply reduce the invention to practice based on the suggestion or instructions of others are not inventors.

Joint Inventorship: Who Are the True Inventors?

In many situations in academic or hospital settings, several people collaborate on a given research project. Are they all inventors? To answer this question, we start by looking to the law, which states that more than one person may contribute to the conception of an invention, thereby creating joint inventorship of that invention. Joint inventorship is

defined in 35 USC § 116 (2004), which provides in pertinent part:

When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

Thus, 35 USC § 116 provides three negative rules of joint inventorship. First, the inventors do not need to work together at the same physical location or at the same time. Therefore, the conception of the invention need not occur simultaneously amongst the joint inventors. Second, a person's contribution to the claimed invention must not be insignificant in quality and must do more than explain well-known concepts or the current state of the art (although no set type or amount of intellectual contribution is required).¹⁰ Third, a patent may issue with claims of a varying scope, such that each inventor need not make a contribution to the subject matter of every claim of the patent.¹¹

This sounds simple enough, but joint inventorship has been said to be “one of the murkiest concepts in the muddy metaphysics of patent law.”¹² In addition, the courts say that the determination of whether a person is a joint inventor is very fact-specific, with no bright-line standards sufficing for general use in every case.¹³ Nevertheless, if several individuals all assert that they should be named as inventors on a given patent application, you can use the following guidelines to help you to determine who contributed to the conception of the claimed invention.

First, despite the three negative rules provided in 35 USC § 116, there must be some minimum level of collaboration or connection between the joint inventors. On this issue, the Federal Circuit has stated:

The statutory word “jointly” is not merely surplusage. For persons to be joint inventors under § 116, there must be some element of joint behavior, such as col-

laboration or working under common direction, one inventor seeing a relevant report and building upon it or hearing another suggestion at a meeting. . . .

Individuals cannot be joint inventors if they are completely ignorant of what each other has done until years after their individual independent efforts. They cannot be totally independent of each other and be joint inventors.¹⁴

In other words, for joint inventorship there must be some evidence that information relating to conception of the invention was shared among the joint inventors. For example, one co-inventor's contribution to the conception may be shared with a second co-inventor more than one year prior to the second co-inventor's contribution without negating the conclusion that the parties were collaborating with one another.¹⁵

Second, as alluded to above, the contribution must be to the conception of the invention, not merely to the reduction to practice.¹⁶

Third, merely posing a problem to be solved or suggesting a desired result does not constitute inventorship.¹⁷ Thus, the head of a laboratory who poses a problem may not be an inventor if he or she has done nothing more. Similarly, one who merely funds the research of others, or provides laboratory space or materials, without more, is also not a co-inventor.

Fourth, merely following the instructions of others does not constitute invention.¹⁸ Thus, a researcher, e.g., a student, technician, or doctoral candidate, who is carrying out experiments designed or developed by his or her boss is not an inventor. Likewise, one who merely assists the actual inventor, without more, has not contributed to conception.¹⁹

Fifth, although a co-inventor's contribution may be relatively small compared to that of his or her co-inventor(s), the contribution must be "not insignificant in quality."²⁰ In some situations, a collaborator contributes to the conception of a minor point, but if that point merits inclusion in the claims, then the collaborator should be named as an inventor. On the other hand, if that minor point is covered in only one or a few claims, you may decide to omit those claims to exclude that collaborator from being listed as an inventor.

Sixth, once conception has occurred, the inventor may use the services, ideas, and aid of others in the process of perfecting an invention without diminishing his or her inventorship.²¹ On the other side of this issue, a person who supplies background data or general information does not, without more, become an inventor.²² Therefore, an inventor need not undertake all the steps necessary to reduce the invention to practice to be an inventor.²³

How are these guidelines applied in the following scenario? Assume that a laboratory technician or contract sequencer uses routine sequencing techniques to determine the sequence of a nucleic acid originally cloned by someone else. Is the technician a co-inventor on a claim to the sequenced nucleic acid? In the authors' view, the answer to this question is no, under a correct interpretation of the Federal Circuit's holding in *Fiers v. Revel*.²⁴

Of course, it is important to remember that, in this hypothetical, the person requesting the sequencing service has the clone in hand. In the *Fiers* case, Fiers did not. Fiers argued that his conception date was the date on which he had a workable *method for isolating the gene* (encoding beta-interferon). In denying Fiers the conception date, the Federal Circuit stated: "We conclude that the Board correctly decided that conception of the DNA of the count did not occur upon conception of a method for obtaining it."²⁵ Thus, the Federal Circuit in *Fiers* did not suggest that a technician who sequences a clone isolated by someone else is a co-inventor of claims to the nucleic acid sequence of that clone.

When Is an Author not an Inventor? Inventorship v. Authorship

An issue that often arises in a university or hospital setting is whether all of the authors of a journal article should be named as inventors of a patent application covering the subject matter of the article. As a general principle, inventorship on a patent (or patent application) and authorship on a research publication are two different things.

Understandably, this distinction is often lost on authors. It is not uncommon for a co-author on a journal article to be a thesis adviser, a colleague with whom general discus-

sions were held, a department or laboratory head, a graduate student, a technician or research collaborator who simply carried out instructions, or someone who supplied a component described in the article, e.g., an antibody, cell line, or nucleic acid vector. As discussed in detail above, such a co-author may or may not be a co-inventor, depending on what that co-author actually did and how the invention is defined in the claims.²⁶

At all times, it is incumbent upon you to be alert to inventorship issues. Although inventorship must be determined according to facts provided by the authors(s), the conclusion as to who among them is an inventor is a legal determination. You should always be prepared to provide to the authors a cogent explanation of the differences between inventorship and authorship, when the question arises.

When conducting in-house seminars or other training relating to patents, academic technology transfer offices should devote at least some time to a discussion of inventorship issues and the distinctions between inventorship and authorship determinations. Such a discussion will pay off in future avoidance of potential misunderstandings and discord among scientific colleagues and collaborators during the patenting process.²⁷ In addition, the final determination of inventorship can be assigned to outside counsel, who can then take the responsibility (and blame) for the decision, and deflect the potential anger of persons who were not named as inventors away from the technology transfer managers.

Who Owns my Invention? Inventorship v. Ownership

Inventorship and ownership of a patent can also be two different things. As a general rule, the named inventor is presumed to be the owner of the patent unless there is an assignment. As a result of this distinction, collaborative research between companies or between academic institutions, and between academic institutions and companies, can present difficult and complex patent considerations for inventorship as well as ownership.

Most academic institutions and companies require that employees assign to the institution or company all rights, title, and interest in inventions developed by the employee while an employee of the institution or company. Courts construe this obligation broadly and apply it to personnel who work at an institution, even if they are not exactly employ-

ees.²⁸ The Federal Circuit has found that assignment requirements can exist even in the absence of a signed contract.²⁹ As a result, a collaboration between two unrelated institutions raises issues as to ownership, because the collaborators, as inventors, will assign their rights to different entities.

Unless there is an agreement to the contrary, the rights of the several joint assignees of a patent are governed by 35 USC § 262, which provides in pertinent part:

[E]ach of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States without the consent of and without accounting to the other owners.

This means that one co-owner (or co-inventor) can sell the patented invention without having to pay anything to any other co-owner (or co-inventor). Similarly, one co-owner can grant a license to a company without the consent of the other co-owners and without having to give the other co-owners a share of the license royalties. It is important for an institution that has outside collaborations to consider ownership issues carefully, particularly when the institution is seeking to license the technology arising from such collaborations. A licensee may be less likely to take a license, or may offer a much lower royalty, if another co-owner has the ability to license the same technology to a competitor. Thus, all co-owners should consider contractual arrangements, e.g., interinstitutional agreements, to provide a consolidated front to potential licensees.

It is also important to consider the effect of research collaborations on inventorship in view of *Perceptive Biosystems v. Pharmacia Biotech*³⁰ In *Perceptive*, the district court concluded that the patent applicant had made a series of misrepresentations to the U.S. Patent and Trademark Office (USPTO) about a research collaboration, that the misrepresentations were material to inventorship and were designed to obfuscate the issue of correct inventorship, and that these misrepresentations constituted inequitable conduct before the USPTO. The Federal Circuit agreed. Thus, it is important for academic institutions and companies to be aware of research collaborations between their own inventors and third parties and properly characterize any such collaborations before the USPTO.

What if I Made a Mistake in Determining Inventorship?

If you catch an error in inventorship during prosecution of a patent application, you can correct this error under 35 USC § 116 if there was no deceptive intent in making the error. Section 116 states, in pertinent part:

Whenever through error a person is named in an application for patent as the inventor, or through an error an inventor is not named in an application, and such error arose without any deceptive intention on his part, the Director may permit the application to be amended accordingly, under such terms as he prescribes.

A simple petition that sets forth the facts, names the proper inventors, and asserts that there was no deceptive intention can be used to request the correction of inventorship under 37 CFR § 1.48.

Once a patent issues, the named inventors are presumed to be correct,³¹ and if the inventors named in a patent are incorrect, the patent is invalid. However, if an honest mistake was made in determining inventorship during prosecution of the application, all is not lost. In particular, if a court determines that there is clear and convincing proof of error, a patentee may invoke 35 USC § 256, entitled “Correction of Named Inventor,” to avoid patent invalidity.³² Section 256 states, in pertinent part:

Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.

This section addresses two varieties of error in inventorship—misjoinder and nonjoinder. The first clause of § 256 addresses misjoinder, where a person who is not an inventor is listed incorrectly. The second clause addresses nonjoinder, where an inventor was not listed. The question is what types of errors permit correction in each of these two cases.

The Federal Circuit in *Stark v. Advanced Magnetics* held that the misjoinder clause does not contain the “without any deceptive intention” language found in the second clause, and, thus, the term *error* must include all varieties of mistakes—both honest and dishonest.³³

Therefore, 35 USC § 256 allows deletion of a misjoined inventor whether that error occurred by deception or by innocent mistake. On the other hand, the nonjoinder clause expressly refers to an error “without any deceptive intention” by the unnamed inventor (even if any of named inventors, even if incorrectly named, had a deceptive intent). In addition, 35 USC § 256 allows the addition of an unnamed actual inventor, as long as this nonjoinder was without any deceptive intent by that inventor. Interestingly, the Federal Circuit reads §116 as requiring a lack of deceptive intent in both cases of misjoinder and nonjoinder.³⁴

Thus, given the appropriate facts, the error of omitting inventors or naming incorrect inventors will not necessarily invalidate the patent in which the error occurred. Instead, after a hearing of all concerned parties, the court can order correction of the patent and the USPTO then issues a certificate correcting inventorship. Of course, if some of the named inventors are not true inventors, and intentionally deceived the USPTO, then the patent, though valid, may be unenforceable for inequitable conduct, but that is an issue for another chapter.

Notes

1. The rigid requirement that U.S. patents name the inventor(s) and only the inventor(s) has its roots in the U.S. Constitution. Art. I, Sec. 8, Cl. 8 provides that “inventors” are to have “the exclusive right to their ... discoveries.”
2. *Burroughs Wellcome Co. v. Barr Laboratories Inc.*, 40 F.3d 1223, 1227-1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994) (citations omitted).
3. *Coleman v. Dines*, 754 F.2d 353, 224 USPQ 857 (Fed. Cir. 1985); *Mahurkar v. C.R. Bard*, 79 F.3d 1572 (Fed. Cir. 1996); *Price v. Symsek*, 988 F.2d 1187, 1195 (Fed. Cir., 1993).
4. *Sewall v. Walters*, 21 F.3d 411 (Fed. Cir. 1994).

5. *Smith v. Bousquet*, 111 F.2d 157, 162, 45 USPQ 347, 352 (CCPA 1940).
6. *Id.* at 159.
7. *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).
8. *Id.* at 1206.
9. *Id.* at 1207.
10. *Pannu v. Iolab Corp.*, 155 F.3d 1344, 47 USPQ2d 1657 (Fed. Cir. 1998); see also *Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 1466 (Fed. Cir. 1997) (“Each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice.”) (quoting *Burroughs*).
11. *Ethicon Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 45 USPQ2d 1545 (Fed. Cir. 1998).
12. *Mueller Brass Co. v. Reading Industries Inc.*, 176 USPQ 361, 372 (E.D. Pa 1972), *aff’d*, 180 USPQ 547 (3rd Cir., 1973).
13. *Fina Oil*, *supra* note 10 at 1473.
14. *Kimberly-Clark Corp. v. Proctor & Gamble Dist. Co. Inc.*, 973 F.2d 911, 23 USPQ2d 1921 (Fed. Cir. 1992).
15. *Pannu*, *supra* note 10.
16. The following Federal Circuit dictum in *Pannu* (155 F.3d at 1351) should not be read at face value (emphasis added): “All that is required of a joint inventor is that he or she (1) contribute in some significant manner to the conception *or reduction to practice* of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the full dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.” If taken at face value and out of context, this statement might be interpreted as a statement that a significant contribution to reduction to practice can substitute for a significant contribution to the conception. Such has never been the law, and neither the context of *Pannu* nor the cases cited by the *Pannu* court suggest that the court intended the statement to be so read. The authors do not understand the intended meaning of the statement, and can only suggest that it may represent a typographical error or an editing oversight.

17. *Pro-Mold and Tool Co. v. Great Lakes Plastics Inc.*, 75 F.3d 1568 (Fed. Cir. 1996).
18. *Stern v. Tr. of Columbia Univ.*, 434 F.3d 1375 (Fed. Cir. 2006) (holding that a medical student who simply carried out experiments that the professor suggested did not contribute to conception of the invention); see also, Burroughs, *supra* note 2.
19. *Bd. of Educ. ex rel. Bd. of Trustees of Fla. State Univ. v. Am. Bioscience Inc.*, 333 F.3d 1330 (Fed. Cir. 2003).
20. *Pannu*, *supra* note 10 at 1351; see also *Mass. Eye and Ear Infirmary v. Novartis Ophthalmics Inc.*, 199 Fed. Appx. 960, 964, 2006 WL 2860587, 4 (Fed. Cir. 2006), in which a doctor claimed that he was a co-inventor because he suggested to the named inventors that the upper limit of their range for the claimed irradiance range should be 900mW/cm (not 1200mW/cm). The court found that his contribution to conception was not sufficiently significant, because his suggested limit was contained within the previously conceived broader range.
21. *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613 (Fed. Cir. 1985).
22. *Liebel-Flarsheim Co. v. Medrad Inc.*, 481 F.3d 1371 (Fed. Cir. 2007) (holding that attendance at “brain-storming sessions” was insufficient evidence to prove contribution to conception); *Hess v. Advanced Cardiovascular Systems Inc.*, 106 F.3d 976 (Fed. Cir. 1997).
23. *Idacon Inc. v. Central Forest Products Inc.*, 3 USPQ2d 1079 (E.D. Okla. 1986).
24. *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993).
25. *Id.* at 1169.
26. *In re Katz*, 687 F.2d 450, 455 (C.C.P.A. 1982) (“[A]uthorship of an article by itself does not raise a presumption of inventorship with respect to the subject matter disclosed in the article. Thus, co-authors may not be presumed to be co-inventors merely from the fact of co-authorship.”)
27. See *Chou v. Univ. of Chicago*, 254 F.3d 1347 (Fed. Cir. 2001).
28. In *Regents of Univ. of N.M. v. Knight*, 321 F.3d 1111 (Fed. Cir. 2003), a faculty staff member without an employment contract was bound by an implied contract from the university’s patent policy, which was contained in the Faculty Handbook, to assign all inventions to the university. Similarly, in *Univ. of W. Va. Bd. of Tr. v. Vanvoorhies*, 278 F.3d 1288 (Fed. Cir. 2002), the court concluded that a graduate student was obligated to assign an invention to the university under its policy that provides the university owns all inventions made by university personnel or made with substantial use

of university resources.

29. *Chou*, supra note 27 (finding that a university's patent policy obligated a graduate student to assign her inventions to the university even though she never signed a contract mandating such an assignment).
30. *Perseptive Biosystems Inc. v. Pharmacia Biotech Inc.*, 225 F.3d 1315, 56 USPQ2d 1001 (Fed. Cir. 2000).
31. *Amax Fly Ash Corp. v. U.S.*, 514 F.2d 1041 (Ct. Cl. 1975).
32. *Checkpoint Sys., Inc. v. All-Tag Sec. S.A.*, 412 F.3d 1331 (Fed. Cir. 2005); see also *Stark v. Advanced Magnetics, Inc.*, 119 F.3d 1551, 1556 (Fed. Cir. 1997).
33. *Stark* at 1554.
34. *Id.* at 1555.

How to Identify Owners in the United States

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Introduction

In this chapter, we delve into the topic of ownership, including how to identify ownership of patent rights, the rights of co-owners, determining whether there is an obligation of researchers to assign ownership rights to universities, and how patent rights are typically transferred to the university. How the Bayh-Dole Act may impact ownership rights is also briefly covered. Finally, we arrive at our general conclusions and recommendations.

Though our focus here is on patent rights, technology property rights can be in other forms, for example, kept as a trade secret.¹ Keep in mind that the discussion contained in this chapter is for general educational purposes only. It is the opinion of the authors, and not of the authors' firm or clients. Further, the discussion contained in this chapter does not constitute legal advice and may not apply to specific fact situations. Advice of patent counsel is recommended for questions on specific situations.

Identifying Owners Starts with Identifying Inventors and Applicants

Under United States law, original ownership of patent rights is in the inventors. Absent some obligation or actual transfer of rights, the inventors hold the rights to apply for and obtain a patent on their invention.² Further, “[t]he validity of a patent requires that the inventors be correctly named.”³ Therefore, the question of ownership often starts with the determination: who are the inventors?

Who is included as an inventor or co-inventor of a given invention is a legal determination that is beyond the scope of this chapter. However, we shall address several basic principles of inventorship that—in the context of university research—are often the subject of confusion.

Co-authors Are often not Co-inventors

It does *not* follow that a co-author of a publication detailing the same work that is the subject of a patent application must also be a co-inventor. For example, to be an inventor, the researcher must contribute to the conception of at least one claim. Though inventions are often reduced to practice in laboratory, a researcher who *only* contributes to reduction to practice is generally not an inventor,⁴ though they may normally be included as an author on a scientific publication. Also, the main focus of a scientific article is often not the same as the focus of the claims of a patent application.

Co-inventor Must Be Co-applicants, but Co-applicants Need not Be Co-inventors

As noted above, in the United States, the inventors are the original owners of an invention and are originally entitled to apply for a patent on that invention in exchange for disclosing their invention to the public. To exercise their right to apply for a patent, all joint inventors *must* jointly apply for a patent application,⁵ and the “patent is applied for in the name or names of the actual inventor or inventors.”⁶

However, inventors *may* apply for a patent jointly (thus, be co-applicants) even though each inventor did not make a contribution to the subject matter of every claim of the application (i.e., are not co-inventors of the subject matter of every claim).⁷ When different inventions are closely related, this creates a frequent source of confusion. Consider the following hypothetical:

Professor A and Postdoctoral Researcher B, working in close collaboration, together conceive and reduce to practice a monoclonal antibody that binds to protein X. Further, they together conceive that the antibody has therapeutic uses in the treatment of cancer. Both are employed by Alpha University. After completing their laboratory notebook entries describing the foregoing, they write to their friend, Dr. C (employed at Gamma Corp.) and describe their findings. C then writes back and suggests the attractiveness of particular therapeutic group Y. A and B are excited about C’s suggestion because they had never heard of therapeutic group Y and call him back by phone. Continuing the discussion, A, B, and C together conceive of a specific molecular design in which Y is covalently coupled

to the monoclonal by linker Z. A and B then report all of this to their technology transfer officer at Alpha University, as C simultaneously reports all of this to his licensing executive at Gamma Corp.

Setting aside questions of prior art (potentially complicated in this situation), how can patent applications on these inventions be structured, and how would they then influence or alter ownership?

One approach, as shown in Table 1, is to file a single application. Four claims tracking key points in the genesis of the inventions are shown, with their corresponding inventors. A+B are clearly co-inventors of claims 1 and 2 and must apply together. C is considered the sole inventor of claim 3, but can be included in the application as a co-applicant. Likewise, A+B+C is a distinct inventive entity, but can be included in the application as well. Given the assignment obligations of each inventor, the application as a whole is co-owned by Alpha University and Gamma Corp.

Table 1: Single Filing

Application 1	
Inventors	Claims
A+B	1. A monoclonal antibody that specifically binds to protein X
A+B	2. The monoclonal antibody of claim 1 coupled to a therapeutic group
C	3. The monoclonal antibody of claim 1 coupled to therapeutic group Y
A+B+C	4. The monoclonal antibody of claim 3 covalently coupled to therapeutic group Y by linking group Z
Owners of 1: Alpha University and Gamma Corp.	

On reflection, Alpha University may decide its licensing position is significantly diluted by co-mingling claims 1 and 2 with claims 3 and 4. So, Alpha University may insist on partitioning the claims (perfectly legitimate) and filing a pair of applications, as set forth in Table 2.

Table 2: Pair of Filings

Application 1		Application 2	
Inventors	Claim	Inventors	Claim
A+B	1. A monoclonal antibody that specifically binds to protein X	C	1. A monoclonal antibody that specifically binds to protein X coupled to therapeutic group Y
A+B	2. The monoclonal antibody of claim 1 coupled to a therapeutic group	A+B+C	2. The monoclonal antibody of claim 2 covalently coupled to therapeutic group Y by linking group Z
Owner of 1: Alpha University		Owners of 2: Alpha University and Gamma Corp.	

Again, this can be a perfectly legitimate approach for the filing of applications in the United States. Of course, Gamma Corp. may have similar feelings about co-mingling its independently owned intellectual property with that of Alpha University and may request a further split of the filings, as set forth in Table 3.

Note that the same result in Table 3 can be achieved from an initial filing as in Table 1 by canceling claims in the single filing and then filing continuing applications with the partitioned claims. Inventorship, and consequently ownership, would then be updated accordingly. The importance of appropriately partitioning claims in such a situation is underlined by the discussion contained in the next section, which pertains to the rights of co-owners.

Table 3: Three Filings

Application 1		Application 2	
A+B	1. A monoclonal antibody that specifically binds to protein X	C	1. A monoclonal antibody that specifically binds to protein X coupled to therapeutic group Y
A+B	2. The monoclonal antibody of claim 1 coupled to a therapeutic group		
Owner of 1: Alpha University		Owner of 2: Gamma Corp.	

Application 3	
A+B+C	1. A monoclonal antibody that specifically binds to protein X covalently coupled to therapeutic group Y by linking group Z
Owners of 3: Alpha University and Gamma Corp.	

Co-owners Have an Equal and Undivided Interest and May Independently License Patent Rights

Under 35 U.S.C. § 116, each co-applicant, or the co-applicant's assignee, is a co-owner with equal and undivided interest in the entire patent if the inventor co-applicant contributed to the conception of *at least one claim* and may freely and independently license or sell his or her rights without accounting to the other co-owners.⁸ A co-owner may also refuse to join in an infringement suit, effectively impeding the other co-owners' ability to sue infringers.⁹

In *Ethicon Inc. v. United States Surgical Corp.*, CAFC 45 USPQ2d 1545, Ethicon filed suit in 1989 against U.S. Surgical for infringing two claims of its patent on surgical instruments (claims 34 and 50). The patent named InBae Yoon, MD, a medical doctor, as the sole inventor. While the case was pending, in 1992, U.S. Surgical became aware of Young Jae Choi, an electronics technician, who it claimed should have been listed as an inventor on the patent. U.S. Surgical then obtained a retroactive license from Choi to practice the

invention. The court found that Choi contributed to the conception of two of the 55 claims (claims 33 and 47), and, therefore, was a co-inventor and co-owner of the patent.

As a result, Choi, an inventor on 2 claims out of the 55 claims of a patent application and *different* claims than those that were being enforced, had the power to license rights in the entire patent and could effectively prevent another joint inventor from enforcing the patent against a potential infringer. Given the power of each co-owner over a patent, it is useful to determine at the outset of prosecution who the inventors are for each claim of the patent and tailor co-applicant filing strategies accordingly.

Researcher Inventors Are often under an Obligation to Assign Patent Rights to the University

Though under U.S. law an invention is originally owned by the inventors, often the inventors at a university are researcher employees acting under the duties of their employment and are under express and/or implied agreements to transfer any property rights arising from the invention to their employer, the university. Such agreements are normally governed by state law.

The basic principle that invention ownership originates in the inventor still applies in an employer-employee relationship. However, there are two exceptions and one limitation to the rule in this context.¹⁰ The first exception is an express agreement of the employee to assign patent rights to the employer. The second exception is when the employee was hired to solve a particular problem. The limitation is when the employer is entitled to shop rights in the invention.

Express Contract to Assign

Preferably, there is an express agreement in place detailing the rights and obligations of both the researcher and the university regarding patent rights. In many instances, patent rights are agreed by the researcher to be transferred to the university as an express condition of employment or continued employment.

An express written agreement that is a reasonable and legally binding contract and that

the employee has read, understood, and signed, is preferable. A general university policy to assign patent rights might also been effective to obligate the researcher to assign patent rights (depending upon state law),¹¹ and often universities have both in place.

Hired to Invent or Hired to Solve a Specific Problem

If there is no express agreement or general patent policy in place, the employee may still be obligated to assign patent rights to the university under a hired-to-invent theory.¹² Under this theory, the researcher is under an obligation to assign patent rights due to an implied contract because the researcher was hired or later directed to solve a specific problem and having solved the problem was simply part of the duties of employment.

However, the burden to show an employee was hired to invent is on the employer, and various factors are considered by a court to make this determination.¹³

Shop Rights

In the instance where an employer does not have the right to an assignment of patent rights, it may still be entitled to shop rights in the invention. This is a nonassignable and nonexclusive right to use employee's invention when the employee had used the employer's time, facilities, and materials to develop the invention.¹⁴

The Obligation of Nonemployee Inventors to Assign Patent Rights Is less Clear

Though professors, research assistants, and often postdoctoral researchers are generally hired as employees of a university, special situations may arise for others making use of the universities resources. For example, graduate students and undergraduates who may be contributing to research, but are not technically employees, may be inventors. A faculty member may be visiting from another university and conducting research without compensation from the host university.¹⁵

Though a general policy and signed agreements may be in place for employees, separate agreements and policies may be needed to clarify the rights of these nonemployee researchers in possible technology arising from their work.¹⁶

Assignments of Interest in Patent Rights

General Procedures during Patent Prosecution

During the normal course of prosecuting a patent application, an inventor who is obligated or otherwise agrees to assign patent rights to the university will be provided an assignment document to be signed and notarized. This document should clearly state that each inventor is assigning title to the invention to the university and detail the terms of the transfer of ownership rights.

Requirements for a Valid Assignment Are Governed by State Law

An assignment document, like an employment agreement, is a contract and must comply with contract law to be valid. In contrast to patent law, which is governed by federal law, contract law is primarily state law, and each state may differ in its interpretation and enforcement of the provisions contained in an assignment.

Nevertheless, there are general requirements for a valid contract that is commonly applied. Perhaps the most important is *consideration*, which is an exchange of value. In other words, in exchange for the researcher's assignment of patent rights to the university, the university is giving the researcher something valuable in return. In the case of a researcher hired to invent, this may be his or her salary or other compensation. Universities may also offer other incentives, such as profit sharing.

The Bona Fide Purchaser

Assignments should be promptly recorded at the U. S. Patent and Trademark Office (USPTO).¹⁷ Underlining the importance of acquiring and recording a valid assignment of patent rights is the concept of the *bona fide purchaser*.¹⁸ Under this concept, a previous assignment of property rights is void as against a subsequent bona fide purchaser of the property.

To be a bona fide purchaser, the purchase must be for value (e.g., not a gift or for a price well below market value) and the purchaser must not have notice of the prior assignment. Notice can be actual, where the purchaser knows that the rights have already been assigned, or constructive, where an assignment is publicly recorded.

Therefore, assignments should be duly executed and timely recorded at the USPTO to guard against the possible ownership claims of a bona fide purchaser.

Impact of the Bayh-Dole Act on Ownership

The Bayh-Dole Act of 1980 allows universities to elect title to inventions created in whole or part by research sponsored by the U. S. government (e.g., an National Institutes of Health grant).¹⁹ The act requires that inventors timely report inventions to the university and requires the university to timely report whether it will elect to pursue patent rights on an invention. If the university does not elect to receive patent rights and the government determines it also does not want to file a patent application, one or more of the inventors may request to retain ownership, but they must comply with the notification and reporting procedures of the act.

Under the Bayh-Dole Act, the government retains a nonexclusive, irrevocable, paid-up license to practice the invention throughout the world. The government also has march-in rights, where it may retrieve technology if it is not adequately developed and commercialized by the assignee.

Special Provisions that Apply to Nonprofit Organizations

Nonprofit organizations (e.g., universities) must further comply with certain provisions.²⁰ First, though normally patent rights are similar to other forms of property and are freely assignable,²¹ under the Bayh-Dole Act, a nonprofit organization (e.g., a university) *may not assign* patent rights to third parties, except to a patent management organization, without permission. Second, royalties must be shared with the inventors and the remainder used for scientific research and education. Third, licensing preference must be given to small businesses.

Conclusions and General Recommendations

Considering the general principles outlined above, it is recommended that ownership of patent rights be established at the outset of any university relationship, that assignments of interest to the university are executed and recorded early, and that there is no unnecessary co-mingling of the university's patent assets.

Get Future Ownership in Patent Rights Established up front by Express Agreements

Preferably systems and policies are in place to ensure that the agreement between the researcher and the university is clear and understood to all involved at the outset of the employment or other relationship. One practice is to hold the first paycheck until there is a signed employment agreement accepted by both an employee and the employer to ensure the employment is undertaken only when the relationship with respect to future patent rights is established.

Record Assignments Early

Researchers have a tendency to relocate, and documents requiring their signature are, therefore, preferably completed sooner rather than later during patent prosecution. Student and visiting researchers are expected to move on to other positions, and professors and research assistants also commonly move to other institutions or companies.

Having to track down an inventor to complete an assignment is much easier when the inventor is still at the university, rather than in another state or even another country. The ability to speak with the inventors in person may also be beneficial to answer any questions they may have regarding the assignment or other documents requiring their signature.

Remember to Distinguish Co-applicants from Co-inventors

As discussed, inventors *may* apply for a patent jointly (thus, be co-applicants) even though they are not co-inventors of the subject matter of every claim. Be sure to distinguish co-applicants from co-inventors to sort out filing strategies, as illustrated in the hypothetical above. Collaborators may seek to obfuscate the distinction between co-inventors and co-applicants when it is to their advantage—and to your disadvantage—to do so.

Avoid Co-mingling Ownership in a Single Application

Guard against overlapping ownership claims of patents. Investigate inventorship of each aspect of the invention, and, if possible, map out the claims. Co-mingle patent rights by strategy, not by default (e.g., have proper collaborative agreement in place under the Cooperative Research and Technology Enhancement [CREATE] Act).

Negotiate the terms of sponsored research contracts and consulting contracts and be clear on ownership of resulting inventions. Also beware of co-ownership claims hidden in material transfer agreements, for example, when certain material was used to make the invention.

Good Luck!

With these basic principles of determining patent ownership in mind, each university should develop programs that best suit its needs and promote innovation among its researchers. Consult your patent counsel for more information on any of these topics and for more tailored recommendations.

Acknowledgments

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Notes

1. See, e.g., *Speck v. N.C. Dairy Foundation Inc.*, 311 N.C. 679, 319 S.E.2d 139 (1984), which involved a dispute over a secret process for the use of lactobacillus acidophilus in dairy products.
2. 37 C.F.R. § 3.73(a): “The inventor is presumed to be the owner of a patent application, and any patent that may issue therefrom, unless there is an assignment.”
3. *Chou v. Univ. of Chicago*, 254 F.3d 1347 (Fed. Cir. 2001) (citing *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348-49, 47 USPQ2d 1657, 1661 (Fed. Cir. 1998)).

4. Though, of course, there may be exceptions, e.g., when an invention requires reduction to practice for conception to be complete, the so-called doctrine of “simultaneous conception and reduction to practice.”
5. 37 C.F.R. § 1.45.
6. 37 C.F.R. § 1.41(a). Therefore, the applicants of a patent application are normally the inventors, though they may have assigned their rights to apply for a patent to the university (§ 1.46). However, there are some exceptions provided for unavailable inventors, for example, dead, insane, or incapacitated inventors (§ 1.42, § 1.43). There is also an exception for inventors who refuse to join in an application or cannot be found or reached after diligent effort (§ 1.47). In these limited circumstances, other persons may apply for a patent on behalf of the inventor or inventors (e.g., the legal representative on behalf of a deceased inventor)(§ 1.41). In the U.S., only natural persons may apply for a patent, and not, for example, a university, corporation, etc. Another inventor, or a person who shows a pecuniary interest in the application, may file on behalf of the inventor or inventors. The inventors may subsequently join in the application. Therefore, while the applicants of a patent application are generally the inventors, this may not necessarily be the case. Further, though it may be more difficult to apply for a patent if an inventor is unavailable or refuses to cooperate, it is still possible to do so.
7. 35 U.S.C. § 116: “*When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.*” [emphasis added]; see also 37 C.F.R. § 1.45(b).
8. *Ethicon Inc. v. United States Surgical Corp.*, CAFC 45 USPQ2d 1545, 1552 (Fed. Cir. 1998) (“[A] joint inventor as to even one claim enjoys a presumption of ownership in the entire patent.”).
9. Unless, for example, co-owners have granted each other a unilateral right to sue. See *Ethicon*, 45 USPQ2d at 1554.

10. *University Patents Inc. v. Klingman*, 762 F. Supp. 1212, 1919-20, 20 USPQ2d 1401, 1406 (E.D. Pa. 1991). Aside from the rights and obligations arising from an employer-employee relationship, an inventor who is an officer, director, or other high-level employee may also have an obligation to assign patent rights under a fiduciary duty to the employer.
11. See, e.g., *Chou v. Univ. of Chicago*, 254 F.3d 1347 (Fed. Cir. 2001) (holding that under Illinois law, Chou was obligated to assign inventions pursuant to patent policy in university handbooks). Cf. *Liggett Group Inc. v. Sunas*, 437 S.E.2d 674, 30 USPQ2d (BNA) 1678 (N.C. App. 1993) (holding that under North Carolina law, “unilaterally promulgated employment manuals or policies do not become part of the employment contract unless expressly included in it.” (quoting *Walker v. Westinghouse Electric Corp.*, 77 N.C. App. 253, 335 S.E.2d 79 (1985))).
12. See *Standard Parts Co. v. Peck* (1924) 264 U.S. 52, 44 S.Ct. 239 (holding that employee Peck was hired under a contract to “devote his time to the development of a process and machinery for the production of the front spring now used on the product of the Ford Motor Company” was specifically hired to invent this machinery, and the inventor thus held title to the patent in trust and is obligated to assign it to the employer). Cf. *United States v. Dubilier Condenser Corp.* (1933) 289 U.S. 178, 17 USPQ 154 (“One employed to make an invention, who succeeds, during his term of service, in accomplishing that task, is bound to assign to his employer any patent obtained. The reason is that he has only produced that which he was employed to invent. His invention is the precise subject of the contract of employment. A term of the agreement necessarily is that what he is paid to produce belongs to his paymaster. . . . On the other hand, if the employment be general, albeit it cover a field of labor and effort in the performance of which he obtained a patent, the contract is not so broadly construed as to require an assignment of the patent.”).
13. For North Carolina cases relating to the hired-to-invent concept, see *Speck v. N.C. Dairy Foundation Inc.*, 311 N.C. 679, 319 S.E.2d 139 (1984); *Liggett Group Inc. v. Sunas*, 437 S.E.2d 674, 30 USPQ2d (BNA) 1678 (N.C. App. 1993) (“The fact of employment, standing alone, does not endow an employer with exclusive ownership rights to an invention, even though the invention may occur during working hours. . . . [A]bsent contrary agreement, the employer owns an invention if: (1) the employ-

- ee is 'hired to invent, accomplish a prescribed result, or aid in the development of products' or (2) the employee is set to experimenting with the view of making an invention and accepts payment for such work." (citations omitted)).
14. See *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 27 USPQ2d 1129 (Fed. Cir. 1993).
 15. In this situation, the faculty member is most likely already obligated to assign inventions to his or her own university. An agreement should be struck between the university's prior to the hosting to clarify each university's ownership rights.
 16. Also beware of possible claims of a breach of fiduciary duty. In *Chou v. University of Chicago*, 254 F.3d 1347 (Fed. Cir. 2001), the Federal Circuit held that Chou could support a claim under Illinois law that her professor supervisor, also her department chairman, breached his fiduciary duty by omitting Chou, a graduate student and later post-doctoral researcher in his laboratory, from the list of inventors on his patent applications.
 17. See 35 U.S.C. § 261.
 18. See *FilmTec Corp. v. Allied-Signal Inc.*, CAFC 939 F.2d 1568; 19 USPQ2d 1508 (interpreting 35 U.S.C. 261, under which assignment of interest in patent is void as against any subsequent purchaser unless recorded in USPTO within three months from its date or prior to the date of such subsequent purchase, only applies to a bona fide purchaser for value).
 19. 35 U.S.C. §§ 200-212; 37 C.F.R. § 401.
 20. 35 U.S.C. § 202(c)(7).
 21. Though there may be unwanted *consequences* if a patent is assigned, e.g., if the patent is the subject of a terminal disclaimer.

Identifying and Managing Joint Inventions

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Introduction

Joint inventorship is defined by patent law and occurs when the outcome of a collaborative project results in two or more people contributing intellectually to an invention. Depending upon the number and affiliations of the joint inventors, many interesting situations can arise, and a number of these issues will be addressed in this chapter. When referring to a joint invention in this chapter, the definition is an invention with one or more inventors from multiple institutions or companies.

Included in this chapter is a discussion of some of the issues involved in the identification and management of joint inventions, as well as potential hurdles that technology managers may face during these processes. Joint inventors are identified through a variety of ways, including an institution's invention disclosure report, publications, or at a patent drafting meeting with patent counsel.

Similar to any invention disclosed to a technology transfer office, once the joint invention is identified, an evaluation and decision is required to proceed with protection of the invention. In addition to the criteria used when evaluating inventions developed at a single institution, technology transfer offices need to consider additional factors, such as expense and revenue sharing, when deciding whether or not to pursue patenting of a joint invention.

In the process of determining whether to patent a jointly developed technology, the other participating inventors and institutions should be notified. If a decision is made to file a patent application, the institutions should consider entering into agreements with each other to establish the role each party will play in the patenting and licensing of the inven-

tion. While each joint invention is unique and may require special provisions, processes discussed here are presented as best practices for managing joint inventions.

Identifying a Joint Invention

When faced with a joint invention, follow your institution's inventorship guidelines, as you would when the inventors are only from your institution. To determine inventorship, focus on the individuals involved in the intellectual development of the idea. If someone merely provided a theory, data, or material but did not provide a firm or definite idea, he or she may not be an inventor. Correctly identifying inventors is crucial to the validity and enforceability of a patent. In most instances, a patent attorney should review the contributions of the proposed inventors and determine which contributors are inventors.

Identifying inventorship can be a multistage process using information from a variety of sources. Often, a technology transfer office's first source of information is the invention disclosure report submitted by the inventors. In addition to a description of the invention, these reports should also include a list of the inventors and their institutional affiliations.

Publications are also another source of information regarding inventorship of a technology. Although rules for authorship differ from those for inventorship, the list of the publication authors is an excellent way to start identifying those who contributed in some way to developing the technology. The invention disclosure report and publications then can be used as the basis for the inventorship discussion during the initial disclosure meeting.

This discussion should include questions regarding individual contributions to the conception of the invention and if they collaborated with anyone not listed as inventors, including people outside of the university. A similar discussion also should occur between the inventors and the attorney preparing the patent application. Patent law only requires contribution to the conception of one claim in order to establish an individual as an inventor, and so it cannot be determined prior to drafting the claims. Given this fact, attention should be directed back to a patent application if the patent claims are amended or deleted to ensure the correct inventors are, in fact, attributed to the application.

Once joint inventorship has been determined, it is important for the technology manager to instruct the joint inventors to disclose their invention to their designated technology transfer office, if the joint inventors have not already done so.

Evaluating a Joint Invention

As with any invention that is disclosed to a technology transfer office, many factors are considered when deciding whether or not to pursue patenting for a particular joint invention. Such factors include the likelihood of obtaining a patent, the quality and type of patent claims expected, whether the patent could be licensed and enforced, potential income and the timing of the income, and the existence of any administrative issues that may complicate handling the invention. However, in addition to evaluating joint inventions for their technical merit and commercial value, there are other factors to consider.

Often joint inventions result from collaborations between researchers at two universities. However, when the joint invention involves three or more entities that will share revenue, the potential revenue for each institution may become so small that it may not be worth pursuing a patent. Additionally, gathering all of the appropriate documentation that is necessary to file a patent from each joint inventor can be challenging. When a joint inventor is employed by a company, opportunities for licensing the technology to a competing company often are constrained. Conversely, developing a joint invention with a company may result in a license to the company for exclusive rights to the invention.

If the joint invention was developed under a research/collaboration agreement or under a funding contract, the intellectual property language of the agreement may also play a role in your decision to accept the joint invention. Many collaboration agreements discuss the intellectual property rights of the parties involved and detail how joint inventions should be handled. Additionally, as with research agreements, funding contracts may set limitations on the ability to file a patent application or provide intellectual property rights to the funder and should be reviewed prior to filing a patent application.

Managing a Joint Invention

Notifying the Other Party

When a joint invention is identified, it is in everyone's best interest to establish an open dialog early in the process regarding the invention and the framework for the parties to handle the invention. If possible, technology managers should work with the joint inventor to ensure the other institution (or company) is aware of the joint invention. This allows for accurate identification of the funding sources, important for subsequent reporting, as well as triggering a discussion of the basic issues of patenting and licensing. Many universities choose to enter into agreements with each other, such as an Inter-Institutional Agreement (IIA), to designate who will take the lead in the patenting and licensing processes. If the inventor is from a company, it is possible to enter into similar agreements or license agreements in which the company may license all of the rights to the invention.

Agreements between Parties: The Inter-Institutional Agreement (IIA)

An inter-institutional agreement is a mechanism for owners of a joint invention to establish the responsibilities of each party during the lifetime of the invention. Negotiating IIAs is sometimes difficult and time-consuming, and as such, these agreements often are not given priority in a technology transfer office. However, these agreements are important to the management of joint inventions. Without IIAs, there is no documented understanding between the parties about managing the patenting and licensing of the invention.

IIAs provide a number of benefits. They may provide a means of obtaining from the joint inventor all the proper documentation required to file and prosecute a patent application. The IIA should establish which institution handles the patenting and licensing of a joint invention, avoiding interference within the patent office if both groups are trying to pursue protection, as well as avoiding competition with each other when trying to license the invention.

IIAs usually allow one of the parties to exclusively license the joint invention and enable the licensing of the technology in foreign countries, as certain foreign jurisdictions

require that all owners of an invention approve the licensing of the patent. These agreements often also establish sharing of both expenses and revenue derived from the patenting and licensing of the joint invention.

When to Enter into the IIA

With respect to the intellectual property protection of a joint invention, it is best to enter into an IIA as soon as possible. This ensures that all appropriate documentation can be obtained from all of the inventors for the filing of the patent. With an IIA in place at the beginning of the process, the foundation and terms for the sharing of patent expenses is established. Alternatively, institutions could agree to wait to enter into an IIA until a company is interested in licensing the technology. One reason for waiting is the possibility that the claims are amended during prosecution of the patent application, possibly eliminating a joint inventor and the need for an IIA.

However, caution should be exercised when waiting to enter into an IIA due to several potential and significant drawbacks. Without an IIA, sharing of the patent expenses, which are incurred immediately, typically does not occur. Waiting can also delay the ability of an institution to enter into a license agreement as another party also has rights to the invention. A number of hurdles must be overcome during the licensing process, and the negotiation and execution of an additional agreement prior to licensing can slow down the licensing discussions. In general, entering into an IIA early in the process is best for all parties.

Essentials of an IIA

Many different terms are addressed in an IIA. Depending on the situation, the IIA can be straightforward or very complex. However, most agreements will include terms that establish a means for filing and prosecuting the patent, administering and licensing the patent, and sharing expenses and income derived from the patenting and licensing of the invention.

When entering into an IIA, the parties need to establish the rights of each party in the joint invention (e.g., will both parties own the invention or will one party assign his or her

rights to the other party). Ownership of the IP will determine the relationship between the parties and the terms of the agreement. Assignment of rights to the other party is not frequently seen in IIAs, particularly if federal or other funding agreements limit the ability of the institution to assign its rights.

However, assignment of rights may be appropriate if one of the parties does not wish to pursue the invention, does not want any involvement in the patenting and licensing process, or does not want to share in any of the expenses. In most cases, if a university does not want to be involved, its inventors can assign their rights to the other university and be treated the same as the other inventors.

Taking the Lead

In an IIA, typically the parties will designate one party to take the lead and be responsible for the patenting and licensing of the invention. This designation can be based on a number of factors, including each party's ownership of background IP, the number of inventors, existing relationships with potential licensees, case load in the technology transfer office, and experience in the technology field. Usually the party in the lead for patenting is also in the lead for licensing.

When taking the patenting lead of the joint invention, the lead party is then primarily responsible for preparing, filing, prosecuting, and maintaining the patent. Depending on the desired relationship between joint owners, the lead party may have sole discretion in making decisions regarding the patenting or the other party may have the opportunity to provide comments. If a commenting period is negotiated, then the lead party also may be obligated to send the other party copies of all formal correspondences with the patent office regarding the filing, prosecution, and maintenance of the patent. In addition to patent applications filed in the United States, an IIA also should address how foreign filings will be handled.

Often the responsibilities established for each party regarding the patenting of a joint invention are reflected in the responsibilities of the parties in the marketing and licensing of the patent. The party designated as the licensing lead is primarily responsible for

marketing the technology, as well as negotiating, executing, and administering licensing agreements. As with the patenting process, the decisions regarding the licensing of a joint invention can be at the sole discretion of the licensing lead or can have various degrees of involvement and approval from the other party.

In negotiating IIAs, some institutions prefer to receive copies of the executed agreements, while others want to be involved in all licensing discussions and negotiations. A certain level of involvement may be warranted; however asking for too much involvement puts an extra burden on the lead party when negotiating and finalizing licensing agreements. It is important to develop trust early in the process with the joint institution and recognize that the lead party must represent both parties' best interests when entering into license agreements for the joint invention.

Unlike the patenting process, there is some room for flexibility in allowing both parties to pursue licenses for the joint inventions. Typically IIAs give one party exclusive licensing rights. However, both parties may be given nonexclusive licensing rights or exclusive rights for different license fields. This flexibility may be desired if both institutions have other technologies that may be licensed along with the joint invention, making it easier for a licensee to acquire all desired technology from one source.

In addition to addressing how patenting and licensing will be handled, many IIAs also address how the parties will be involved in the enforcement of the joint invention. Typically, the lead party for patenting and licensing also will take lead in legal actions involving the joint invention. However, the law requires some involvement of the other party, and the costs and revenue usually are shared according to the patent expenses and licensing revenue allocations.

Sharing the Money

A primary goal of a university when patenting an invention is to license the technology for commercialization for the public benefit and receive license fees and royalties from the licensee as a result of that commercialization. Those funds are used to reward the inventors and fund additional research at the university. Therefore, it is important in an

IIA to establish how the revenue derived from the licensing of a joint invention will be shared. However, before revenue is earned, expenses are incurred.

It is important to determine how expenses will be split and when the expenses will be paid. The parties may agree to share in the expenses based on the number of institutions involved, the number of inventors at each institution, or the inventors' contribution to the invention. Cost sharing typically is determined by the number of institutions or the number of inventors. Basing the share on the contribution of the inventors questions the value that each inventor provided and may lead to disagreement among the inventors and/or the institutions, especially as the patent claims may change through prosecution.

After a decision has been made on the sharing of the expenses, it is important to consider when each institution pays its share of expenses. Typically, IIAs require that each party pay its share as the expenses are incurred. However, another option is for the party filing the patent to pay all of the patent expenses and then reimburse themselves prior to sharing revenue with the other party. This option is less popular as all of the parties are not sharing the risk involved in patenting the joint invention, and if the technology is never licensed, only one party will have incurred the financial burden.

As with expenses, the proceeds from the licensing of the technology can be split based on number of institutions, the number of inventors at each institution, or the inventors' contribution to the invention. An inventor's contribution can be based on either his or her intellectual contribution to the invention or on the research funding that each inventor directed toward the invention. It is critical that all parties come to a clear understanding on this term as it is one of the driving forces behind entering into such an agreement. If the parties cannot agree on the sharing of costs and revenue, the agreement most likely will not be finalized. Typically, the revenue sharing mirrors the patent cost sharing.

Another financial term that may be the subject of some negotiation is the concept of an administrative fee. This fee is used to partially reimburse the technology transfer office that has taken both the patenting and licensing lead for the time it has put into patenting, marketing, licensing, and administering the agreements. This fee can be a fixed fee or a

percentage of the gross income received, with or without a cap. Percentages typically range from 5 percent to 25 percent, and the caps typically range from \$10,000 to \$50,000. Each institution likely will negotiate an administrative fee that it feels reflects its costs and needs.

Special Issues to be Considered

Every joint invention seems to have its own interesting twist, but here are a few situations that deserve special attention.

Incorrect Inventorship

As previously discussed, determining the correct inventors can be challenging and can change significantly as the patent application moves through the patenting process. However, it is important to the validity of a patent to always list the correct inventors on the patent. Mechanisms exist to correct inventorship if it is believed that the inventorship of a patent is incorrect.

When a patent application is still pending and the inventorship error occurred without deceptive intent, inventorship may be amended by filing a petition with the patent office (35 U.S.C. §116). The amendment must include consent from the newly added inventor (or the removed inventor if such the case). If the patent has already issued, inventorship can be corrected via a certificate of correction or by the reissue process (35 U.S.C. §256). Since all assignees to the patent or application must agree to change inventorship, agreement must be reached among all the parties. Inventorship cannot simply be changed through an amendment or reissue process without consent from all the parties involved.

If agreement cannot be reached with the assignee of the patent regarding the inventorship, other methods, such as resolution through the courts or patent offices, can be used to correct inventorship. However, avoiding the necessity for this is desirable. An issued patent with incorrect inventors listed is an invalid patent, so it is important to be accurate in assigning inventorship of the invention.

Licensing without an IIA

As an assignee of a joint invention, an institution has the ability to license its rights in a United States patent to a third party without the permission of the other joint owners and without providing consideration to the other joint assignees. Without an IIA, an institution can license the patent rights nonexclusively or license its rights to the patent exclusively. However, as previously mentioned, some foreign jurisdictions require that all owners approve the licensing of the patent, which can prove difficult without an IIA.

Multiparty Joint Inventions

IAs can be difficult agreements to negotiate and execute when there are just two parties, let alone when three or more parties are involved. When dealing with multiple parties, it is very important to discuss early in the process the goals that each party hopes to achieve with the technology and the role it would like to play in achieving those goals. These discussions create the framework for any agreement that the parties enter into with each other for the management of the technology.

The ease of entering into such an agreement is a consideration that many technology managers think about when deciding whether or not to pursue a joint invention with multiple parties. A technology manager also should consider the potential value of a technology, as the financial benefits of patenting a technology can be diminished when multiple parties are involved.

When entering into a multiparty IIA, it is important for nonlead parties to recognize that their requests of the lead party for comment or updates on the patenting and licensing activity can be counterproductive. Requests for frequent updates reduce the amount of time and focus the lead party can allocate to essential patenting and licensing activities. For this reason, it is a recommended practice to minimize the obligations of the lead party in multiparty IIAs.

Sponsored Research Contracts and Joint Inventions

Many institutions have sponsored research contracts with industry, and these contracts usually provide the companies with some rights to inventions developed under the

contract. These rights usually extend to both inventions developed solely by the institution and joint inventions that are developed by both the institution and the company. The agreements usually establish how joint inventions will be handled, such as responsibility for filing the applications and the sharing of expenses.

However, these agreements typically do not address a joint invention developed by the institution and a research collaborator at a different institution, who is not part of the specific sponsored research contract. A company may simply consider this type of joint invention to be an institution invention and expect the same rights to these joint inventions as it would for institution inventions.

This situation requires the technology manager to work with the other institution to ensure the granting institution is able to give those rights. This may become an issue if the other institution has developed other plans for the technology or has a sponsored research contract of its own. Thus, when evaluating any new invention, it is very important to identify early in the process whether the inventors are supported and obligated by any research contracts or funding agreements.

Collaboration Agreements and Master IIAs

Once a collaboration has formed and been successful in developing inventions, it is likely that the collaborators will continue to work together in the future. In this situation, it may be to the benefit of both institutions to enter into an agreement to establish the process for handling any future intellectual property that results from the collaboration. These can include research collaboration agreements or a master IIA. In addition to IP terms, collaboration agreements help define other terms of the collaboration such as deliverables and publications, which may be important if funding is shared amongst the collaborators.

It is imperative to include language in the research collaboration agreement that assures all joint inventors must be informed of joint inventions before any patent actions are taken. This practice helps to ensure all inventor institutions are aware of the existence of a joint invention.

When institutions frequently share inventions, it may be beneficial to establish a master IIA between the parties to handle all joint inventions between their institutions. With a Master IIA, neither party will need to wait for a new IIA to be negotiated prior to moving forward with the patenting and licensing of the joint invention. Alternatively, institutions can develop a template IIA for joint inventions. When new IP arises, the parties can use the predetermined terms or modify them to better reflect the technology at hand.

Summary

As collaborations continue to flourish and large multicenter research projects spread across the country, joint inventions will continue to be part of a technology manager's daily life. In an effort to ease the joint invention process, technology managers should foster an open dialog with each other very early in the patenting process to establish the framework among the institutions for handling the invention. Technology managers should discuss the goals they want to achieve through the patenting and licensing of the invention and the roles that they want to play to help achieve those goals.

Once the institutions have agreed upon the responsibilities of each party and how they will share the expenses and the revenue, the parties should enter into an inter-institutional agreement, which serves as the basis for all future decisions regarding the joint invention. By creating an open dialog soon after a joint invention has been identified, technology managers can more efficiently determine how the technology will be managed and the more promptly they can license and commercialize the technology, which is the ultimate goal of patenting an invention.

Managing Joint Authorship and Joint Ownership of Copyrighted Works

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Introduction

An important task of university technology transfer offices is managing certain copyrights that may be owned by a university. Joint authorship and joint ownership of a work creates issues not present when a work has a single author and owner. A copyrighted work may have many contributors, but not all contributors are authors of the work. Determining who the authors are requires a fact-specific analysis of the extent of each contribution and the intent of the contributors. Joint ownership of a work often arises out of joint authorship, but may result from other circumstances as well. In addition, joint ownership creates unique issues in the licensing and transferring of ownership in copyrights. The ability of a technology transfer office to effectively manage copyrights hinges on effectively addressing all of these issues.

Determining Joint Authorship

The first step in addressing issues associated with joint authorship and joint ownership is to determine who the authors of the work are. The Copyright Act of 1976 defines a joint work as “a work prepared by two or more authors with the intention that their contributions be merged into inseparable or interdependent parts of a unitary whole.”¹ Thus, there are two basic requirements for a contributor to be a joint author within the requirements of the statute. First, his contribution must be one of authorship. Second, the authors must intend to merge their contributions into a unitary whole.

Is the Contribution one of Authorship?

The Supreme Court has defined the author of a work as “the man who really represents, creates, or gives effect to the idea, fancy, or imagination,” in other words, the mastermind of the work.² There is no requirement that the contributions of joint authors are equal, but each creative contribution must be more than de minimis.³ Thus, a contributor must add more than merely a word or a line to be a joint author.⁴ Yet a valuable contribution is insufficient; the author must also be someone who had artistic control over the creation of the work.⁵ For example, almost every person listed in a motion picture’s credits gave an important contribution to that movie; however, only the director, producer, screenwriter, etc., would have enough creative control to be considered an author.⁶

Most courts also require that a joint author’s contribution be independently copyrightable.⁷ Thus, someone who contributes substantial creative ideas to a work cannot be a joint author unless he or she contributes some copyrightable expression. However, a recent case, *Gaiman v. McFarland*,⁸ has called this doctrine into question. The court noted that it is possible that each contribution to a joint work may not be independently copyrightable, even though the final product would be copyrightable.⁹ “[I]t would be paradoxical if though the result of their joint labors had more than enough originality and creativity to be copyrightable, no one could claim copyright. That would be peeling the onion until it disappeared.”¹⁰ Although the holding in *Gaiman* was limited to comic books and motion pictures, the impact it will have on the requirement of an independently copyrightable contribution is unclear. In contrast, authorship of academic papers is determined by conventions of the faculty’s discipline. For example, often graduate students who run experiments but do act as authors and do not have any control over the experiments will still be listed as an author on a scholarly publication.¹¹

Do the Authors Intend to Merge their Contributions?

As noted above, the U.S. Copyright Act provides that joint authors must intend to merge their contributions “into inseparable or interdependent parts of a unitary whole.”¹² It is irrelevant that a contributor considers himself to be a joint author; rather, both contributors must intend for each other to be joint authors.¹³ In determining joint intent, it is important to consider who had artistic control over the work and whether there are

objective manifestations of intent.^{14, 15} The absence of decision-making authority implies that a contributor was not intended to be an author.¹⁶ A written contract, spelling out whether the contributors are considered to be joint authors, is the best objective manifestation of intent.¹⁷ If there is no written contract, an objective manifestation of intent may be demonstrated through how the contributors bill themselves or how the contributors contract with third parties.¹⁸

Ultimately, a determination of joint authorship requires a very fact-specific analysis and will turn on the specifics of a particular case. The factors described above should not be rigidly applied,¹⁹ particularly since courts are willing to depart from them when justice so requires.²⁰

Determining Joint Ownership

Even more important than determining authorship is determining who actually owns the copyright to a work. Although authorship and ownership often intersect, they are not one in the same.

Who Owns a Copyright?

Ownership of a work initially vests in its author or authors.²¹ However, if the work is a work made for hire, the employer or person for whom the work was prepared is considered to be the author, unless the parties have otherwise agreed in a written instrument.²² Thus, the authors of a work for hire, as the term *author* is commonly used, would not be the authors as the term is defined in the U.S. Copyright Act. A work for hire can fall into one of two categories: (1) “a work prepared by an employee within the scope of his...employment” or (2) “a work specially ordered or commissioned.”²³

Work Prepared by an Employee

The traditional common law of agency is used to determine if a person is an employee acting within the scope of his employment.²⁴ Whether a hired party is an employee requires the consideration of several factors including:

the hiring party’s right to control the manner and means by which the product is accomplished....the skill required; the source of the instrumentalities and tools; the

location of the work; the duration of the relationship between the parties; whether the hiring party has the right to assign additional projects to the hired party; the extent of the hired party's discretion over when and how long to work; the method of payment; the hired party's role in hiring and paying assistants; whether the work is part of the regular business of the hiring party; whether the hiring party is in business; the provision of employee benefits; and the tax treatment of the hired party.²⁵

If these factors weigh against employment, then the relationship is that of an independent contractor. As will be explained later, a work prepared by an independent contractor may still be a work made for hire and not owned by the author if it is a specially commissioned work.

If there is an employment relationship, an employee-prepared work is only a work made for hire if it is created within the scope of employment. To determine if a work was created within the scope of employment, courts will consider if “[i]t is of the kind of work he is employed to perform,” if “[i]t occurs substantially within authorized work hours and space,” and if “[i]t is actuated, at least in part, by a purpose to serve the employer.”²⁶ A work created by an employee outside of his or her scope of employment does not become the property of his or her employer.²⁷ As long as the employee does not create the work in accordance with his or her duties, it is irrelevant that it arose out of his or her employment activities or was created during working hours.²⁸

Employers and employees are free to contract around these statutory requirements. An employee and employer may contractually agree that the employee owns those works created within the scope of his employment. Often it is the case that universities will have such a provision for its employees. For example, the “North Carolina State University Copyright Use and Ownership Policy” provides that faculty will own nondirect-ed works created without the exceptional use of university resources.²⁹ Universities should create clear policies concerning copyright ownership and not rely on statutory provisions governing ownership. A clear and unambiguous university copyright policy provides all parties with greater certainty and can prevent expensive and time-consuming litigation that might otherwise occur.

Specially Commissioned Work

Unlike a work prepared by an employee, only certain categories of works are eligible to be a specially commissioned works.³⁰ Those categories includes a work for use “as a contribution to collective work, as a part of a motion picture or other audiovisual work, as a translation, as a supplementary work, as a compilation, as an instructional text, as a test, as answer material for a test, or as an atlas.”³¹ Parties must also agree in a written instrument that the work is to be considered a work made for hire.³²

Technology transfer professionals must carefully consider the work-made-for-hire doctrine. An employer may be the author and owner of a work, rather than the work’s actual creator. Additionally, a work created by two or more persons may not be joint work if those creators have the same employer and the work is a work made for hire. Also, in a university, it is not unusual for the university, under the work-for-hire doctrine, to own a copyright jointly with another member of the university community whose work, by university policy, belongs to the author.

When Does Joint Ownership Occur?

Joint ownership and joint authorship are not synonymous. Joint ownership occurs when a copyright is owned in undivided share by more than one person.³³ Joint ownership may occur in many circumstances in addition to joint authorship. *Nimmer on Copyrights* lists six circumstances in which joint ownership may occur: (1) if the work is a product of joint authorship; (2) if the author or copyright proprietor transfers such copyright to more than one person; (3) if the author or copyright proprietor transfers an undivided interest in such copyright to one or more persons, reserving for himself an undivided interest; (4) if upon death of the author or copyright proprietor, such copyright passes by will or intestacy to more than one person; (5) if the renewal rights under the Copyright Act or the terminated rights under the termination of transfers provisions, vest in a class consisting of more than one person; (6) if the work is subject to state community property laws.³⁴

Protecting Jointly Owned Works

Copyright ownership provides certain exclusive statutory rights.³⁵ Copyright owners must be vigilant in ensuring that these rights are protected. Prior to the Copyright Act of 1976, federal copyright protection required the observance of formalities such as registration and notice.³⁶ The Copyright Act of 1976 no longer requires the observance of these formalities.³⁷ Nevertheless, owners should register their works and provide copyright notice because following these formalities provides significant benefits to copyright owners.

Registration

Registration of a copyright requires the copyright owner to deliver to the U.S. Copyright Office an application of registration along with the application fee.³⁸ Registration also generally requires the owner to deposit with the U.S. Copyright Office two copies of the published work.³⁹ It is important to note that owners of published works are usually required to deposit two copies of the work even if work remains unregistered, and failing to do so may result in a fine.⁴⁰

Registration of a copyright provides significant advantages to its owner. Copyright owners should be careful to register in a timely manner after publication; otherwise some of the following advantages may not accrue. Registration is required before filing an infringement action.⁴¹ However, the owner of a work that does not qualify as a United States work may file an infringement action regardless of whether or not the work is registered.⁴²

Registration is also not required before filing an infringement suit if an audiovisual work is first fixed and simultaneously transmitted or before filing an action based upon a violation of moral rights provided by § 406A.⁴³ Registration is a prerequisite to an award of statutory damages or attorneys' fees.⁴⁴ Registration must occur prior to infringement or within three months of publication in order to ensure eligibility to collect statutory damages and attorneys' fees.⁴⁵ Registration within five years of publication is prima facie evidence of the validity of the copyright.⁴⁶ Additionally, registration is a condition to constructive notice of a recorded document⁴⁷ and is required before seeking relief from the United States Custom Service or the International Trade Commission.⁴⁸ However, with respect to the registration of copyrighted software, it is sometimes better not to register copyrighted code and to treat it as proprietary information since registration will

make the copyrighted code public.

Notice

There are four principle requirements for proper notice of a copyright for a visually perceptible work that comprise the following: (1) the word *copyright* or its equivalent (e.g., the symbol (c)), (2) the year of the work's first publication, (3) the name of the copyright owner, and (4) fixation of the notice in a location so as to give reasonable notice.⁴⁹ The notice requirements for a phonorecord of a sound recording are analogous, but differ slightly. For example, the C in the symbol (c) should be replaced with a P.⁵⁰ Notice does not need to be given when a work is not published.⁵¹

Notice provides a copyright owner with one significant benefit; proper notice defeats an innocent infringement defense used to mitigate damages by an infringer.⁵² For this reason alone, copyright owners should take care to provide proper notice.

Licensing and Transferring Jointly Owned Works

Licensing or transferring a copyright can result in profits for its owner or owners, including universities. Technology transfer professionals must be capable of addressing issues associated with licensing and transferring copyrights, including those derived from joint ownership of a copyright.

Unlike a sole owner of a work, joint owners must consider the interests of co-owners. The law prevents a joint owner from acting unilaterally in such a way that would harm the interests of other owners. This limitation is readily apparent in licensing and transferring ownership of copyrights.

Ownership of Jointly Owned Works

In those circumstances where joint authorship and ownership occur, joint authors of a work may agree by contract to the percentage of the work each author is to own.⁵³ In the absence of a contract, all authors own the work in equal shares regardless of the extent of their individual contributions.⁵⁴ When joint ownership does not result from joint

authorship, the ownership share of each owner is usually determined by contract or other document such as a will.

By default, the relationship between joint owners is that of tenancy in common and not joint tenancy.⁵⁵ Thus, upon the death of an owner, his or her portion passes to his or her heirs and not to surviving joint owners.⁵⁶ The owners of the copyright may however agree by contract that their relationship shall be one of joint tenancy.⁵⁷

Licensing Jointly Owned Works

A joint owner of a copyright does not need to obtain permission from the other owners to make use of the work.⁵⁸ Similarly, consent of other owners is generally not required for a joint owner to grant a nonexclusive license to a third party.⁵⁹ The corollary of this rule is, of course, that a joint owner cannot grant an exclusive license to a third party without the consent of all other owners.

A joint owner is not free to grant a nonexclusive license if such license would cause destruction to the work.⁶⁰ *Nimmer on Copyrights* suggests that destruction would ordinarily only occur in those circumstances where a work can only be used in one medium and if competitive versions of the same work do not ordinarily appear in that medium.⁶¹ This should not cause significant concern to licensors since this an unlikely situation.⁶² A more common limitation on licensors is when the joint owners agree that the consent of all joint owners is required prior to granting any license. Such an agreement is valid and applies to joint owners and third-party licensees.⁶³

Transferring Ownership Interest in a Copyright

An owner of a copyright has the power to transfer his interest to a third party.⁶⁴ A joint owner may not however transfer the interest of another owner, unless the other joint owner consents to the transfer.⁶⁵ A transfer of an interest in a copyright must follow statutory requirements for that transfer to be valid. A transfer is only valid if there is a written instrument or memorandum of transfer signed by the transferor.⁶⁶ In addition to following the transfer formalities, transferees should be sure to record a document of transfer in the U.S. Copyright Office since failing to record could result in problems if the transferor later attempts to convey the same copyright to another party.⁶⁷ In such a sce-

nario, proper recordation serves to ensure that a subsequent transferee will not prevail in an ownership claim over a prior transferee.⁶⁸

Duty to Account

A joint owner has the duty to account to other joint owners for profits reaped from using or licensing the work.⁶⁹ Each joint owner is owed a per capita share of the profits.⁷⁰ In the case of a license, the licensee has no duty to account to other joint owners.⁷¹ A licensee is only bound to his contractual obligation to the licensor.⁷² The situation is reversed when there is a transfer.⁷³ The transferee assumes the transferor's duty to account to other joint owners for the use of the work. After a transfer, the transferor has no duty to account to other joint owners for profits reaped from the transfer.⁷⁴

Conclusion

Determining joint authorship and joint ownership of a copyrighted work is often a complex task that requires an extensive factual analysis. Yet, the benefits that may accrue from copyright ownership make this task of critical importance to university technology transfer professionals. A university that is a joint owner of a copyright must be sure to adequately protect its interests in the copyright. Universities must also be able to address those issues associated with licensing and transferring joint copyright ownership. The challenges associated with managing joint copyright ownership may in part be addressed by adopting robust university copyright policies and through carefully drafted contractual provisions. Effective contracting may serve to reduce uncertainties and sidestep unfavorable default rules present in copyright law.

Notes

1. 17 U.S.C. § 101 (2006).
2. *Aalmuhammed v. Lee*, 202 F.3d 1227, 1233 (9th Cir. 2000) (quoting *Burrow-Giles Lithographic Co. v. Sarony*, 11 U.S. 53, 61 (1884)).
3. 1 Melville B. Nimmer and David Nimmer, *Nimmer on Copyrights* § 6.07[A][1] (perm. ed., rev. vol. 2007).
4. *Id.*
5. *Aalmuhammed*, 202 F.3d at 1233.

6. *Id.*
7. 1 Nimmer, *supra* note 3, § 6.07[A][3][b].
8. 360 F.3d 644 (7th Cir. 2004).
9. *Id.* at 659.
10. *Id.* at 658-59.
11. 1 Nimmer, *supra* note 3, § 6.07[A][3][c]
12. 17 U.S.C. § 101 (2006).
13. *Aalmuhammed*, 202 F.3d at 1234.
14. *Id.* The court in *Aalmuhammed* also considered a third factor: whether “the audience appeal of the work turns on both contributions and ‘the share of each in its success cannot be appraised.’” *Id.* (quoting *Edward B. Marks Music Corp. v. Jerry Vogel Music Co.*, 140 F.2d 266, 267 (2d Cir. 1944)).
15. Objective manifestations of intent are needed in order to prevent one contributor from defrauding another. *Id.*
16. *See id.* at 1235.
17. *Id.* at 1234.
18. *Id.*
19. *See id.* at 1235.
20. *See, e.g., Gaiman*, 360 F.3d at 658-59.
21. 17 U.S.C. § 201(a) (2006).
22. *Id.* § 201(b).
23. *Id.* § 101.
24. *Cnty. for Creative Non-Violence v. Reid*, 490 U.S. 730, 740-41 (1989).
25. *Id.* at 751-52.
26. 1 Nimmer, *supra* note 3, § 5.03[B][1][b][i].
27. *Id.*
28. *Id.*
29. Copyright Regulation, N.C. State Univ. Reg. § 01.25.03(5.3.1) (2006). The regulation defines directed works as those works “created as a specific requirement of employment or pursuant to an assigned institutional duty.” *Id.*
30. 17 U.S.C. § 101 (2006).
31. *Id.*

32. *Id.*
33. 1 *Nimmer*, *supra* note 3, § 6.01.
34. *Id.*
35. See 17 U.S.C. § 106.
36. 2 *Nimmer*, *supra* note 3, § 7.01[A].
37. *Id.*
38. 17 U.S.C. § 408(a).
39. *Id.* § 408(b). Two copies are required for works first published in the United States. Only one copy is required for unpublished works, works first published outside of the United States and a contribution to a collective work. *Id.*
40. *Id.* § 407.
41. *Id.* § 411(a).
42. *Id.*; *see also id.* § 101 (defining “United States work”); *Nimmer* 7.16[B][1][a][ii] (detailing circumstances where a work is not a “United States work”).
43. 17 U.S.C. § 411.
44. *Id.* § 412.
45. *Id.*
46. *Id.* § 410(c).
47. *Id.* § 205(c).
48. 2 *Nimmer*, *supra* note 3, § 7.16[G].
49. 17 U.S.C. § 401.
50. *Id.* § 402.
51. *Id.*
52. *Id.* §§ 401(d), 402(d).
53. 1 *Nimmer*, *supra* note 3, § 6.08.
54. *Id.*
55. *Id.* § 6.09.
56. *Id.*
57. *Id.*
58. *Id.* § 6.10[A].
59. *Id.*
60. *Id.* § 6.10[B].

61. *Id.*
62. *Id.*
63. *Id.* § 6.10[C].
64. *Id.* § 6.11.
65. *Id.*
66. 17 U.S.C. § 204(a) (2006).
67. 2 *Nimmer*, *supra* note 3, § 10.07.
68. *Id.*; see also 17 U.S.C. § 205.
69. 1 *Nimmer*, *supra* note 3, § 6.12.
70. *Id.*
71. *Id.* § 6.12[B].
72. *Id.*
73. *Id.* § 6.12[C].
74. *Id.*

Invention Management in a Major Japanese University and its Implications for Innovation

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Introduction

This chapter describes the system of technology management in the University of Tokyo and the dominance of joint/sponsored research as the main mechanism of technology transfer that gives large, established companies privileged access to university discoveries and inhibits startup formation. The University of Tokyo is Japan's most important university, accounting for approximately 12 percent of all Japanese university research and development (R&D).¹ Its faculty and administrators have played important roles in shaping changes in the Japanese system university-industry collaboration, and it serves as model for other universities. Nevertheless, practices do vary and some of the descriptions in this chapter do not apply to other universities. I try to indicate when this is the case, as well as aspects that are common to most universities, such as the legal framework summarized next.

Past and Present Legal Framework for Technology Transfer

Prior to 2004, ownership of inventions arising in Japanese national universities² depended upon the source of funding that gave rise to the inventions. Inventions arising under government research grants as well as all contractual sponsored research were supposed to be owned by the nation—in effect by the Ministry of Education, Culture, Sports, Science and Technology (MEXT, or its predecessor, Monbusho).³ This was true even in the case of private corporate sponsors, although these could usually negotiate the right to co-own inventions with the government. Government ownership meant that inventions either were free for anyone to use or would be licensed nonexclusively for modest royalties. Because Japanese patent law (Article 73) requires the consent of all co-owners of a patent for even a nonexclusive license, co-ownership by a sponsor meant the sponsor had a de facto perpetual, royalty-free, nontransferable exclusive license to the invention.

On the other hand, inventors could retain ownership of inventions arising under corporate donations⁴ or the standard research allowance allocated to each faculty member.⁵ Considering the proportions of the various sources of funding, inventions ought to have been roughly equally distributed between government and inventor ownership. In fact, except for some contractual sponsored research inventions co-owned by the sponsoring corporations, almost all commercially relevant university inventions were attributed to donations.⁶ As quid pro quo for receiving donations, the donor companies expected faculty to pass their inventions and related intellectual property (IP) rights to them and also recommend those companies to their capable students as places to work.

Thus, prior to 1998, Japan had a system of de facto faculty ownership of university inventions, shaped in large part by direct links between faculty and companies. Donations were among the most important of these links.

In addition, as government employees, faculty members in national universities were barred from compensated consulting for outside organizations (although much consulting occurred under donations). Also, opportunities to use research funds to provide stipends to graduate students or to hire postdoctoral researchers, technicians, or secretaries, were limited, although less so in the case of corporate donations.⁷ Using research funds to supplement salaries of permanent faculty was (and remains) prohibited. In other words, unlike the United States, Japan still does not have a soft money system of funding tenured faculty, although steps in this direction are under discussion.

The following four laws implemented between 1998 and 2004 changed the legal framework governing IP management and university-industry cooperation, so that it is now very close to the so-called U.S. Bayh-Dole Act system:

- The 1998 Law to Promote the Transfer of University Technologies (the TLO Law) established a system for the government to approve and subsidize university technology licensing offices (TLOs). Starting with five approved in 1998, the number of approved TLOs had increased to about 40 by 2006. Even more important than approval and subsidies, this law legitimized the transparent, negotiated, contractual transfers of university discoveries to industry (especially the inclusion of due dili-

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gence and royalty obligations in contracts) and the channeling of royalties back to the inventors, discovering laboratories, and universities as a whole. Although the system of IP ownership was left unchanged, in practice, careful inquiries as to the sources of invention funding were avoided, and faculty in universities with competent TLOs began to let those TLOs manage a considerable number of inventions even though they may have arisen at least in part from government grants or contracts.

- The 1999 Law of Special Measures to Revive Industry (the Japan Bayh-Dole Act) has the same effect as U.S. Bayh-Dole Act, except that it did not apply to national universities until they obtained legal status as semiautonomous administrative entities in 2004.⁸
- The 2000 Law to Strengthen Industrial Technology established procedures permitting university researchers to consult for, establish, and even manage companies. It also streamlined the procedures for company-sponsored commissioned and joint research. Thus it opened the door for university researchers to found companies. At the same time, it eliminated many bureaucratic obstacles that had previously dissuaded established companies from using contractual sponsored research, rather than donations, to fund university research. In particular, it opened the door to the use of sponsored research funds to pay personnel expenses, although not to the extent of covering salaries of permanent administrative and teaching staff.
- The University Incorporation Law gave national universities independent legal status when it went into effect in April 2004. Previously, they were merely branches of MEXT. By gaining status as independent legal entities, Article 35 of Japan's Patent Law, which enables employers to require assignment to them of employee inventions, became applicable, as did the Japan Bayh-Dole Act. MEXT has urged the incorporated national universities to assert ownership over commercially valuable inventions.

Key Steps and Policies in the University of Tokyo's Invention Management Process

Invention Reporting and Determining Whether an Invention Is Work-Related

Under Article 35 of Japan's patent law, universities can require their employees to assign work-related inventions to the university. Thus, determining which inventions are work-related is an important issue. University of Tokyo guidelines set forth a broad definition, saying that any invention that relied substantially on university facilities or whose conception was related to an employee's research in the university is work-related.

All inventions should be reported using a set form to departmental-level invention committees, whose main responsibility is to make a preliminary determination whether an invention is work-related. The standard form can be supplemented with diagrams, articles, etc. In addition to information about the invention and the identity and affiliation of the inventors, it asks:

- whether the invention relied upon university funds or facilities,
- whether it arose under joint research (and the identity of any joint research partner),
- whether the invention is not work-related ("Yes" is possible only if the answers to the two preceding is "no." Also the inventors must explain why the invention is not work related.), and
- even if the inventors claim their invention is not work-related, whether they nevertheless want to assign it to the university.

It also asks the inventors to provide their perspectives on:

- how their invention solves unresolved problems in its technical field,
- practical uses and likely important markets,
- ability to produce as (or incorporate in) a commercial product,
- antecedent technologies/discoveries,
- background IP (e.g., patent applications on prior related discoveries),
- plans to disclose the invention in publications or conferences,
- whether patent applications ought to be filed overseas,

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- development plans, and
- whether they have a desired development/commercialization partner.

One notable feature is that the lead university inventor designates the percentage contributions of each individual inventor. In the case of inventions arising under joint research contracts with private companies, corporate researchers are almost always listed as co-inventors. These percentage allocations are usually decided by discussions between the lead university inventor and the company collaborators. They are rarely, if ever, questioned at the university/TLO level, and I have heard of no cases of the outside attorneys who file patent applications scrutinizing them.

Co-inventorship automatically gives the sponsor co-ownership rights, whereas it would otherwise have to negotiate with the university for a license. The default provisions of the university's standard joint research contract provide for the university to have the sole ownership of any inventions made only by its personnel. As noted above, a patent co-owner has unlimited use rights and the right to veto any transfer by other co-owners. In practice, if the sponsor wants exclusive control over a co-owned joint research invention, it will usually pay patent application and maintenance costs, but little more.⁹

The ease with which university inventors can designate company employees as co-inventors has been a key factor in the resurrection of the pre-1998 donation system, the main difference now being the requirement for a formal contract and reporting to legitimize the transfer. As in the past, companies sponsor research (but such support is still small in proportion to total university R&D funding and also in relation to the proportion of U.S. university research funded by industry¹⁰), they employ students and they receive nontransferable exclusive rights at low cost with no development obligations. Most university researchers seem comfortable with this. Joint research and joint patent applications have become the dominant mechanism of technology transfer, at least in the University of Tokyo and probably most other major universities.

Deciding Whether to Require Assignment and to Apply for Patents

The departmental-level invention committees in the University of Tokyo should decide within two weeks of receipt of an invention report whether the invention is probably work-related and forward the report and their assessment to departmental-level administrators. These then forward the report to central university administrators and then to the TLO. In practice, many inventors first send their reports directly to the TLO so as to receive early feedback on commercialization prospects.

The Intellectual Property Management Office in the central university administration has final authority whether to require assignment from the inventor and to apply for patents, copyrights, or trademarks. In practice, in the University of Tokyo, the TLO makes these decisions, although the IP Management Office (also known as the IP Headquarters) must ratify these decisions. This dual authority is due to the University of Tokyo's TLO being an independent for-profit corporation that nevertheless has a special relationship with the university and special obligations arising from this relationship.¹¹

As a matter of practice, the university usually does not require assignment of inventions by company researchers engaged in joint research or by students. In the case of the remaining invention reports, the TLO assesses patentability (mainly by searching Japanese and to some extent foreign patent applications) and market demand for the invention (by discussions with the inventors, a growing network of companies and review of trade and other publications). This work is the responsibility of approximately twelve licensing associates, most of whom are relatively young and have university science or engineering training and industry experience. Inventors are usually required to assign to the university rights to inventions deemed patentable and for which there will likely be market demand. Thereupon the same licensing associate who was responsible for making the decision whether to require assignment assumes responsibility for licensing.

In principle, the TLO and IP Headquarters should decide within two weeks whether the university will require assignment. Thus, within a month of submission of an invention report, the inventor ought to know whether the university will require assignment (and will apply for patents) or let the inventor retain title. If the university does not decide

within a month, in principle, the inventor should automatically retain title unless the university provides reasons for its delay. This guideline has been administered flexibly. Occasionally the time limit is exceeded, but, to my knowledge, inventors rarely complain or insist that they retain title because of a delay.

Patent Application, Marketing, Licensing, and Startup Formation

In part because the University of Tokyo's TLO has cash reserves from the sale of stock in a startup that had a successful initial public offering in 2003, the university can afford to patent inventions for which it does not have a licensee waiting in the wings. Few other TLOs have this financial cushion. Patent applications are handled by outside attorneys. In 2006, the university was applicant (or co-applicant) on 432 Japanese patent applications.¹² Overall, it files patent applications on roughly half the inventions reported to it.

Royalty income was about \$1.7 million in 2006, slightly higher than the previous year. The TLO license associates use a variety of databases, personal contacts, as well as cold calls to search for potential licensees. They also advertise some inventions on the Internet, but this method probably accounts for a small proportion of licenses. I have been impressed with the frequency with which they enter into negotiations with large and small companies including companies overseas. Close communication with the inventors also is an important part of the licensing associates' work. Although some faculty members are still skeptical about university ownership invention management by the TLO, those faculty members who have actually worked with the TLO usually seem satisfied. In other words, the staff seems to be doing a competent job. However, many other TLOs lack such competence. Staff of the University of Tokyo's TLO frequently take part in training sessions for staff of other TLOs. The fate of Japan's new system of technology management depends largely upon such efforts.

In 2006, the University of Tokyo concluded nearly 277 technology transfer contracts, not including material transfer agreements and consulting contracts. This indicates it transfers to industry about two-thirds of the inventions on which it files patent applications.

However, the breakdown of these contracts shows how joint research and joint patent applications have become the dominant mechanism of technology transfer. Two hundred

of the 277 contracts were contracts with a joint research sponsor to apply jointly for patents. The actual number of inventions covered by these contracts is greater than 200, because one contract occasionally covers more than one invention. On the other hand, the 77 license contracts cover nonpatented inventions and multiple nonexclusive licenses of the same invention, as well as exclusive licenses. Thus, the number of inventions licensed independently of joint research is less than 77, suggesting that only about one-quarter (or even less) of transferred inventions are licensed at the discretion of the TLO, i.e., the TLO actually sought out a licensee able and committed to developing the discoveries. Three-quarters were transferred in a pre-ordained manner with weak obligations on the part of the transferees to develop the discoveries. This trend of increasing dominance of joint research has been evident since 2004.

My own analysis of a sample of invention reports confirms this phenomenon and also shows its differential impact on startups and established corporations by technology field. Only about 20 percent of life-science inventions are attributed to joint research. Thus, the TLO is free to license 80 percent of the life-science discoveries to the companies most able and willing to develop them. In fact, these are licensed to a wide variety of companies including startups. Of the 20 percent that are attributed to joint research, over three-quarters of the sponsors are startups or other small companies. In other words, in the life sciences, established companies do not receive the lion's share of university discoveries, and startups have access to a large proportion of university discoveries.

However, in non-life-science fields (engineering, chemistry/materials science, and software) 40 percent of reported inventions are attributed to joint research, and among those on which patent applications are filed, well over half are joint research inventions. More than 80 percent of the sponsors of the inventions attributed to joint research are large, established companies. So in non-life-science fields, which account for two-thirds of the University of Tokyo inventions, most of the inventions are transferred automatically to large, established joint research partners.

These findings show that, under current conditions, transfer of a substantial proportion of university technologies via joint research, whatever its other merits, is not conducive

to the formation of vibrant new companies. In light of Japan's experience under the pre-2004 donation system, it also shows that academic inventors retaining ownership does not necessarily promote entrepreneurship and the formation of new companies. Japan had, and still has, a system where inventors usually determine the recipients of their discoveries (because of the way they and their sponsors can manipulate the reporting system) and, thus, effective control over their discoveries. But this freedom usually results in the direct transfer of discoveries to research sponsors which, except in the life sciences, are almost always large, established companies.

Examination of startups themselves confirms this phenomenon. Official METI data indicate that 54 University of Tokyo startups were in existence as of April 2004, with founding dates range from 1980 to early 2004. However, these include subsidiaries of established companies and other companies whose only tie with the university is the existence of a joint research contract or board membership by a university researcher or recent graduate. Defining startups as companies based upon university discoveries would require reducing the overall figure by about 40 percent. Looking only at startups actually based on university discoveries, year-by-year rates of formation began to rise from near zero prior to 1997 to a peak of seven formed in both 2000 and 2001 and then to decline in subsequent years. No startups based upon licenses from the university were found in 2005 or 2006. The rise coincides exactly with the period between the enactment of the 1998 TLO law and the 2000 Law to Strengthen Industrial Technology.

A careful assessment of the technologies, sales, and employment trends of all these startups indicates that almost all those with growth potential are in the life sciences. About one-third of all University of Tokyo startups are in the life sciences. There are only a few startups in engineering, materials science, chemistry, and software that seem to have unique or high-demand technologies, and the basic elements of a business development strategy in place. It is clear from invention reports and government research grants awarded to the university that first-class research is occurring in non-life-science fields. But with just a few exceptions, only large, established companies are developing these discoveries. Outside of the life sciences, university entrepreneurship is weak.

Concluding Points

Judging from official pronouncements and a host of government programs to support startups and other new high-technology companies, promotion of such companies is a high priority. The University of Tokyo has even organized a private venture capital consortium to target startups based upon university discoveries. This consortium has the right to offer to be lead investor to any university researcher contemplating forming a company, although inventors are free to seek funding elsewhere. It is not clear that this particular consortium offers as much guidance and other support to startups as do a handful of other venture capital companies that concertedly try to help new companies grow. But its privileged status may discourage competition from more capable funds.

There are other examples of official policies working at cross purposes to the goal of promoting viable new high-technology startups—in particular, the government's continued fostering of consortia between leading universities and large established companies to pursue research in cutting-edge fields of science and engineering. The ubiquity of such consortium research, along with accounts of various startups managers, strongly indicate that consortium research, coupled with the system of invention management described above, has limited the scope of new companies to grow. Although I am most familiar with the situation in the University of Tokyo, available information indicates that the same situation prevails in other leading Japanese universities.

There are other factors that contribute to the weakness of new high-technology companies in Japan besides the system of university-industry cooperation. These include the continued prevalence of lifetime employment in high-technology industries, a strong social preference for employment in large companies, and an autarkic approach to innovation in large companies. But the system of university-industry cooperation is a major factor that continues to inhibit high-technology entrepreneurship in Japan.

The system of technology transfer in the University of Tokyo and other major universities works well for large, established companies. But to the extent Japan needs vigorous new companies to be pioneers in new fields of technology, its system of technology transfer is a drag on innovation and long-term scientific and economic progress.

The same is probably true in other countries whose technology transfer systems are biased in favor of large, established companies—particularly those where joint/sponsored research is the dominant mechanism of technology transfer. I hope others will pursue research to support or refute this claim—and to clarify the extent and implications of joint research in other universities, as well as the relative merits of technology transfer via joint research vs. startup formation.

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Notes

1. Unless otherwise indicated, supporting materials for this chapter can be found in the R. W. Kneller sources listed in the bibliography, as well as other sources cited therein.
2. National universities account for approximately 75 percent of all R&D university expenditures. With a few exceptions, the most important academic R&D centers are national universities. In addition, even the most important private and local government universities tend to follow the example of national universities with respect to technology transfer policies. Thus, although this section focuses on national universities, it is also largely applicable to private and local government universities.
3. Or in a few cases, by another sponsoring ministry.
4. In theory, donations are charitable gifts. At least prior to 2000, however, they were the principal mechanism for companies to fund university R&D. Even today, they are probably still the largest source of corporate support for universities, although joint or commissioned research may have surpassed donations as the principal form of corporate support for specific R&D projects. In 2005 donations (mostly from corporations) to the University of Tokyo were 9.9 billion yen (approximately \$90 million), compared with 4.5 billion (approximately \$40 million) for joint research (roughly 80 percent of this was from private companies, the remainder from government-affiliated organizations) and 22.4 billion yen (approximately \$200 million) for commissioned researcher (less than 20 percent of which was from private companies). (University of Tokyo Data Book 2007) However, some donations only peripherally support R&D. In other words some of the 9.9 billion yen in donations supports endowed faculty positions, specific building projects, etc., but a significant proportion is earmarked for specific professors' laboratories.
5. The standard research allowance is usually a few thousand dollars annually after mandatory deductions for infrastructure and other fixed laboratory expenses.
6. Less commonly to the standard research allowance.
7. This was another attractive feature of donations.

8. The Japanese Bayh-Dole Act authorizes, but does not require, government-funding agencies to let contractors and grantees own inventions. However, at the urging of the Ministry of Economy, Trade, and Industry (METI), most funding agencies now let universities claim ownership, the principal exception being inventions arising under ERATO projects funded by the Japan Science and Technology Agency (JST).
9. The standard joint research contract of the University of Tokyo, as well as those of some other prominent public research institutes, contain provisions that attempt to limit the effect of Article 73 of Japan's Patent Law. For example, article 21.3 of the University of Tokyo's standard contract stipulates that, if the sponsor has not taken an exclusive license to the university's ownership share, the university can request permission from the sponsor to license its share to a third party, and the sponsor *should not refuse this request without justification*. Some sponsors demand up front that even this clause be stricken from the agreement. When these clauses are retained and sponsors exclusively license the university's ownership rights (thus obtaining unified exclusive rights) their royalty obligations are usually no more than total patent application and maintenance costs. Even if they forego an exclusive license to the university's share, it is rare for the university to license its co-ownership interest to a third party. By 2007, some other leading national universities had shifted to letting university inventors retain their co-ownership rights in inventions arising under joint research contracts thus stepping out entirely from the management of co-invented joint research inventions. Just as under the old donation system, these inventors can manage their co-ownership rights as they wish. Most will let the sponsors have unified exclusive ownership in return for research support and providing training and employment opportunities for students.
10. In 2006, joint research sponsored by private companies accounted for less than 7 percent of all project-specific research funding in the University of Tokyo (i.e., government grants and contracts, corporate-sponsored research and donations, *but excluding* salaries for permanent staff, infrastructure, and most overhead costs (University of Tokyo 2006 Data Book, pp. 39-40). In comparison with the U.S., according to Organization for Economic Cooperation and Development statistics, industry funded only 2.5 percent of Japanese university R&D in 2000, compared to more than 7 percent in the United States (National Science Board, *Science and Engineering Indicators* 2004).

11. The reason the TLO is an independent corporation trace to its formation in 1998 when universities were still just branches of MEXT. At that time, to be able to manage royalties and recruit competent staff at competitive salaries, it made sense to be an independent corporation rather than part of the university. The same applies to many of the TLOs of other leading national universities that were formed in 1998, 1999, and 2000. Cooperation between the University of Tokyo's TLO and the IP Headquarters has been fairly smooth, with the TLO responsible for operational decisions and the IP Headquarters making policy decisions. However, in other universities, this dual authority had resulted in friction or, in what seems to be an increasingly common trend, marginalization of the TLOs. Total domestic patent applications by Japanese TLOs fell two years in succession from a peak of 1,679 in 2003 to 1,054 in 2005. But applications by IP Headquarters more than made up for the decline, increasing from zero to 1,522 over the same two-year period (data from the 2006 Technology Transfer Survey of the University Technology Transfer Association, Japan (in Japanese), p. 111).
12. It also filed foreign applications on about 170 inventions.
13. This list is not exhaustive and I am indebted to other researchers and many other sources of information, which are cited and discussed in the listed bibliography.

The Ownership of Intellectual Property Rights and the Collaboration between Universities and Industry in Japan

Hideho Tanaka, PhD, and Chikako Saotome, PhD

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During the early days of the Meiji Restoration, universities were established in Japan for the purpose of training scientists and engineers for Japan's developing industry. The creation of the Japanese university system resulted in collaborations between the corporate and academic sectors. A natural result of this activity was the establishment of close relationships between industry and academia.

The career of Nagayoshi Nagai, PhD, in the Meiji era is an example of a successful relationship resulting from the movement within Japan to establish strong ties between academia and industry. Nagai, after completing his studies in Japan, traveled to Germany for further studies in the field of chemistry. Upon returning to Japan, Nagai was requested by the Japanese government to assume the position of professor in the Department of Pharmacology at the University of Tokyo. In addition, Nagai concurrently held the position of director of engineering in a Japanese pharmaceutical corporation.

Before the 21st century, official Japanese government statistics did not totally reflect the extent and complexity of industrial-academic collaborations. This is partly because these statistics tracked executed research agreements and may have missed many university and corporate partnerships that were not memorialized on formal research contracts. In 1978, the Japanese Ministry of Education announced that university-based inventions arising under government research grants would belong to the nation.¹

On the other hand, patent applications covering inventions arising under corporate donations could be applied for by the corporate sponsor and name the university inventor(s) as the inventor(s) of record on the application. As a result of this policy, Japanese companies and university professors established tight, informal connections, with the companies enjoying commercial benefits from these relationships.

By the end of the 20th century, the Japanese government instituted major changes in intellectual property policies affecting the national university system. These policy changes led to the enactment of two laws: The 1999 Law of Special Measures to Revive Industry and the University Incorporation Law. The latter law was enacted in 2004. These two laws enabled universities to file, own, and license patents arising from collaborative research.

Also, the initiative Innovation 25 was instituted by the Council for Science and Technology Policy in 2007.² The long-term goal of Innovation 25 is to foster innovation and growth in various fields such as medicine, engineering, and information technology in Japan by the year 2025. The renovation of social systems, globalization of science and technology, and fostering of human resources are also part of the long-term goal of Innovation 25. Collaboration between industry and academia across multiple science and technological disciplines is considered a key factor in this initiative.

From the time these legislative changes were instituted, the number of industrial-academic collaborations in Japan have steadily increased. For example, in 1995, there were about 1,700 collaborations between the various industries and the national universities. This number had surged to 9,400 cases by 2004. This represents a fivefold increase in the number of collaborations over a ten-year period. As a result, the revenues of universities from these types of collaborations have increased from 6.5 billion yen (approximately \$60 million) in 1999 to 21.9 billion yen (approximately \$200 million) in 2004. The revenue data show a continued tendency of further increase.

Increased interest in activities by university-industry partnerships have raised a number of issues with regard to intellectual property rights and ownership as derived from industrial-academic collaborative research. The major issues are discussed below.

Joint Patent Ownership under Japanese Patent Law

While some collaborative research may result in joint invention, some collaborative research may also result in sole invention. Determination of inventorship in Japan is similar to how inventorship is determined in the U.S. There are, however, some distinctions between Japanese and U.S. patent law pertaining to inventorship.

Joint patent rights (or joint inventorship) in Japan are controlled by Article 73 of Japanese patent law. Unless otherwise agreed upon by contract, jointly owned patent rights may be exercised by a patent owner without the consent of the other joint owners (Article 73, Paragraph 2).³ Namely, each owner may make, use, and sell patented product without the consent of a joint owner.

On the other hand, under Japanese patent law, it is necessary to obtain the consent of the other joint owners with regard to assignment, establishment of a right to pledge one's share of the patent rights, and to license any third party (Article 73, Paragraph 1 and 3).^{4,5} Therefore, there are two points that should be noted with regard to university licensing practices in Japan.

First, when there is a low likelihood of licensing a jointly owned patent to a third party, the university patent owner should seek compensation from the joint owner to cover the costs associated with filing the application and payments of annuities.

Second, unless agreed beforehand, the university may not license a jointly owned patent to a third party without the consent of the other joint owners. This is in contrast to U.S. patent law, which permits a joint owner of a U.S. patent to license a jointly held invention or patent to a third party without the consent of the other joint owners. It is important to note this difference if a research collaboration results in a joint patent or invention that is in part owned by a Japanese inventor.

In addition, when a joint invention is created, many Japanese universities expect their industrial collaborators to pay them a form of royalty payment called *nonimplementation compensation*.⁶ In exchange for this payment, the university joint patent owner

agrees not to exercise his or her patent rights. However, many corporations (such as electronic and engineering firms) protest paying such a royalty to universities citing as their main concern royalty-stacking obligations in the event that multiple patents are required to produce the resultant product. Nonimplementation compensation has been a controversial issue and the subject of much discussion between industry and academia in Japan.

Recently, many Japanese universities have attempted to implement a more flexible approach to nonimplementation compensation to promote collaborative research between industry and academia. Several different types of arrangements have been attempted.

One approach is to request that the corporate partner pay a royalty for the exclusive exercise of the jointly owned patent rights. In particular, this strategy is effective for pharmaceutical companies because, in many cases, they desire an exclusive license. In another approach, the corporation may not want exclusive patent rights and will allow the university to license the jointly owned patent rights to a third party without authorization of the joint corporate owner. Japanese universities may also assign their rights in the joint invention to the industrial collaborator if a mutually acceptable price can be agreed upon by the parties. Lastly, even if a corporation pays a nonimplementation compensation, Japanese universities may attempt to retain the right to license the patent to a third party if the corporation fails to make appropriate efforts for production and marketing the joint invention.

Guidelines for Collaborative Research Agreements

Guidelines have been issued for constructing collaborative research agreements in Japan. The Japanese Fair Trade Commission has issued antitrust guidelines with the expectation that joint collaborative research will result in fair and increased competition. These guidelines state that it is appropriate, in principle, for the parties to agree upon the ownership of the fruits of their collaboration and also to prevent the licensing of the joint invention to a third party. On the other hand, it would not be appropriate for the parties to agree to restrict research and development based upon the research results or to obli-

gate an inventor to assign an invention or agree to an exclusive license to improvements prior to the creation of the invention.

In March 2002, the Ministry of Education, Culture, Sports, Sciences, and Technology (MEXT) issued a model agreement for industry-academia collaborative research.⁷ The model agreement states that ownership of an invention resulting from an industrial-academic research collaboration will be determined by the laws of inventorship. The model agreement includes terms stating that, in the event of sole inventorship, consent to file a patent application must be given by the sole inventing party.

In the case of joint inventions, the model agreement states that a patent application must be filed jointly by the joint owners. Furthermore, the agreement states that a joint patent application agreement must be executed by the parties. The ministry advises that it is preferable that the parties negotiate the terms of intellectual property ownership and patent management prior to the execution of the research agreement. In addition, in the case of joint inventions, the agreement should confirm that the industrial party is responsible for the filing, prosecution, and maintenance of any patent application.

University Policies on Intellectual Property Ownership

In 2005, MEXT selected six universities: University of Tokyo, Tokyo University of Agriculture and Technology, Tokyo Institute of Technology, Kyoto University, Osaka University, and Nara Institute of Science and Technology, to participate in a project initiated by the Super-Industry-Government-Academia Headquarters in Japan. These universities were asked to develop a model program to promote the use of research and development resources for the acquisition of industrial research funds.

The six universities published their policies, rules, and collaborative research agreements on their Web sites. Included below are brief summaries of the approaches each of the participating universities have taken to implement this program.

The University of Tokyo has created the “Guideline Concerning the Handling the Joint Invention by Collaboration Research with Private Corporation.” The University of Tokyo

guideline states that the ownership of the intellectual property rights obtained from collaborative research should be determined using the laws of inventorship. The document provides guidance on how negotiations should be conducted with industrial collaborators. Kyoto University's and Tokyo Institute of Technology's policies, as described in their guidelines, state that the intellectual property rights resulting from collaborative research will be jointly owned and based upon the relative contributions of the inventors.

Nara Institute of Science and Technology states in its guideline that intellectual property rights will be jointly owned in principle and that an invention may be independently owned when the invention was completed by one party.

The ownership of patent rights is also described in model agreements published by each university. In principle, all of the agreements provide that ownership of an invention is to be determined by the affiliation of the inventor. That is, an invention made by a university researcher shall be owned by the university. If the invention was made by a researcher employed by a corporation, the invention shall be owned by the corporation. Ownership of a joint invention made by both university and corporation researchers is to be determined by mutual discussion between parties and according to the relative contributions of the inventors. All of the six universities' model agreements state that joint inventions will be covered under a joint patent application agreement.

Five of the six universities' model agreements require that a confirmation (Nara's agreement states that consent must be provided) should be obtained from the noninventing party before the inventing party files a patent application. The University of Tokyo agreement states that only a notice to the noninventing party is required.

Many Japanese universities have instituted invention committees whose responsibility is to make a determination as to whether or not an invention is to be assigned to the university. If the committee decides that the university will not take assignment to an invention, then the university shall allow the inventor to manage his or her invention freely. The model agreement of the University of Tokyo states that, if the university decides not to require assignment, it will provide notice to the collaborative partner. If the partner

desires to file a patent application to protect the invention, the partner may negotiate the conditions for assignment of the intellectual property rights directly with the university inventor.

In summary, all six universities determine ownership of patent rights based upon the laws of inventorship. This means that the ownership of patent rights is not predetermined. Instead, the ownership of the patent rights shall be determined after an invention is created. We believe that these policies are reasonable and should not result in any major problems in determining ownership of patent rights resulting from collaborative research between universities and corporations.

Challenges for the Future

As the system to promote industrial-academic collaborations improves through the leadership of the Japanese government, the number of research collaborations between university and corporations will substantially increase. This trend is likely to continue into the future. Hereafter, research collaborations between industry and academia are likely to become more strategic. The scheme is likely to change from individual, small-scale collaboration to comprehensive large-scale collaboration and from short-term collaboration to longer-term collaboration.

The changes in the ownership policy of intellectual property rights may be minor, however, Japanese universities are likely to be asked to be more flexible with their management of intellectual property rights in their negotiations for strategic alliances. There have been some large-scale strategic alliances between Japanese corporations and American universities. Such alliances are likely to provide ideas and important insights for future collaborations between corporations and Japanese universities. We hope that the issue of ownership of intellectual property rights will be handled properly between corporations and universities and expect industrial-academic collaborations to result in the creation of true innovation.

Endnotes

1. See http://www.mext.go.jp/b_menu/hakusho/nc/t19780325001/t19780325001.html (In Japanese).
2. See http://www.kantei.go.jp/foreign/innovation/index_e.html.
3. Where a patent right is jointly owned, unless otherwise agreed upon by contract, each of the joint owners of the patent right may work the patented invention without the consent of the other joint owners.
4. Where a patent right is jointly owned, no joint owner may assign or establish a right of pledge on the said joint owner's own share without the consent of all the other joint owners.
5. Where a patent right is jointly owned, no joint owner may grant an exclusive license or nonexclusive license with regard to the patent right to any third party without the consent of all the other joint owners.
6. *Nonimplementation compensation* means royalty to university, which does not implement patent rights (exclude execution in research activity) generally for joint invention. However, some think it is inappropriate to call nonimplementation compensation for royalty to university about joint invention.
7. See http://www.mext.go.jp/a_menu/shinkou/sangaku/sangakuc/sangakuc4_8.htm (In Japanese).

Understanding and Applying the CREATE Act in Collaborations

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The Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act)¹ amends the United States patent laws to provide that subject matter developed by another person will be treated as owned by or subject to an obligation of assignment to an inventor for purposes of determining the obviousness of an invention made by that inventor provided that the requirements of the act are satisfied. The act applies to inventions made by or on behalf of parties to a written joint research agreement where the inventions are made within the scope and term of the agreement.

This amendment was motivated by concerns raised by a recent Federal Circuit Court ruling in a case called *OddzOn Products Inc. v. Just Toys Inc.*,² which publicized the fact that nonpublic information shared between collaborators during a joint project may be used as prior art to inventions that emerge from the project under certain circumstances. The intent of the amendment was to provide participants in research collaborations with additional protections during the sharing of private information between collaborators, and the main thrust of the act is to exclude some prior art (that possessed by participating collaborators) from obviousness considerations if the invention arose from a joint research agreement.

This chapter provides some practical guidelines for technology transfer professionals seeking to manage the application of the CREATE Act in common types of collaborative activities taking place within universities. Since many common agreements involving third-party rights, licenses, access to university labs, and/or use of university resources will satisfy the terms of the act, and the act can be relied upon unilaterally once the joint research agreement is in place to obtain patents over incremental improvements, it is important to understand the act and identify strategies for how to manage it.

In those situations when the act applies, it can result in significant advantages and disadvantages. While the guidelines provide a framework for thinking about the issues raised by the act, and by collaborative activity with third parties more generally, they may not be applicable to any particular scenario, and legal counsel should be sought when determining how best to protect the university during the collaboration agreement, patent filing, and prosecution process to utilize the benefits and mitigate the risks of the act.

When Does the Act Apply?

When a university employee enters into a formal or informal collaboration with a person or entity who is not a university employee and is not under any obligation to assign inventions to the university (a third party), the information that the university employee and the third party share with each other can limit the ability of both the university and the third party to obtain patent protection for any resulting inventions. The information provided by the third party will, in the absence of a joint research agreement satisfying the requirements of the act, be considered prior art to any invention made by the university employee solely or jointly with the third party, and the information provided by the university employee will similarly be considered prior art to the invention made by the third party solely or jointly with the university employee. If the sole goal of the collaboration is to contribute the results to the public domain, the act can generally be disregarded, but it cannot be ignored where the university and/or the third party seek to obtain patent protection for the fruits of the collaboration.

The act excludes subject matter provided by one of the parties to a joint research agreement (including public and nonpublic disclosures) from being considered as prior art for purposes of determining the obviousness under 35 USC 103 of an invention developed within the scope of that joint research agreement. Use of the act's safe harbor enables the university and the third party (company, individual, or collaborating institution) to unilaterally exclude certain research results from being considered obvious and, therefore, unpatentable under U.S. patent law. The act has an impact on the patentability of inventions that are incremental improvements (i.e., improvements over existing technology that would not be separately patentable if the existing technology were treated as prior art) that arise from the collaboration.

The act only applies to patents (including any reissue patent) granted on or after December 10, 2004. The act and implementing rules³ specify three requirements to overcome certain obviousness rejections under 35 USC 103(a)⁴ over subject matter developed by another and certain obviousness-type double-patenting rejections over patents and patent applications owned by another. These requirements are:

- the claimed invention must have been made by or on behalf of parties to a written joint research agreement that was in effect on or before the date the claimed invention was made, and
- the claimed invention must have been made as a result of activities undertaken within the scope of the joint research agreement, and
- the application for patent for the claimed invention must disclose or be amended to disclose the names of the parties to the joint research agreement.

The act applies where the subject matter that might be considered prior art for purposes of patenting inventions is owned by one of the parties to a joint research agreement and the invention is made within the scope and term of this agreement. The act can be used to overcome a rejection under 35 USC 103 based upon subject matter of either party to the joint research agreement, which only qualifies as prior art under 35 USC 102(e), (f), or (g). It applies if the subject matter qualifies as prior art only under one or more of Sections 102(e), (f), or (g).⁵

Prior Art not Addressed by the Act

Sections 102(a), (b), and (d) cover certain kinds of publicly available information. Sections 102(c) is a loss-of-rights provision. The act does not apply to the types of prior art covered by Sections 102(a)-(d), and if these sections apply to the subject matter, then the subject matter cannot be excluded under the act when making a prior art determination.

Prior Art Addressed by the Act

Section 102(e), (f), and (g) apply to subject matter developed by another. Prior art under Sections 102(e), (f), and (g) can be used to support a rejection of a patent application based on obviousness of the invention under Section 103.⁶ This includes both

public and secret disclosures of information. An inventive entity's own ideas and inventions and patent application(s)/patents are not included as prior art under these sections when determining if the same inventive entity's subsequent invention is patentable.

What Is a Joint Research Agreement under the CREATE Act?

The act includes a broad definition of what constitutes a joint research agreement for purposes of the act. To satisfy the requirements of the act, there must be an agreement:

- between two or more parties;
- in writing;
- for performance of experimental, developmental, or research work;
- in the *field* of the invention; and
- signed prior to the invention.

As long as the parties enter into a written agreement that involves research, development, or experimental activity, the act will be available to either party to the agreement for inventions that arise within the scope and term of this agreement unless the agreement expressly provides otherwise. The agreement may be amended to add new parties or to amend the field of the collaborative activity, but the amendment must be in place before the inventions arising within the amended scope to benefit from the act.

Types of agreements that may fall within the sweep of the act could include collaborations, sponsored research, grant applications, licenses, material transfer agreements, equipment loan and lease agreements, visitors or visiting faculty agreements, and public use of university facility and equipment. Similarly, there may be a variety of joint research participants, including nonprofit/interinstitutional parties, commercial entities, government, foreign entities, and individuals.

Potential Benefits of the CREATE Act

The act allows the parties to the joint research agreement to obtain patents that might otherwise be precluded by prior art, thus allowing them to build a broader and stronger patent portfolio. It also reduces the risk of inequitable conduct arising from failure to disclose communications between collaborators in the patent prosecution process.

Expand Patent Portfolio

The primary benefit of the act is that it facilitates the patenting of incremental improvements to core inventions, allowing collaborators to expand their patent portfolios around core inventions that are further developed pursuant to collaboration.

Consider, for example, a university that wants to encourage the development of a new product based on its platform technology using the university's preexisting patents and know-how. The university collaborates with a third party to develop the new product, the two collaborators jointly invent (and jointly own) the resulting product, and the university seeks to patent the product. Provided that the university and the collaborator have entered into a written joint research agreement prior to the inventive activity, and provided further that the new product falls within the scope of the agreement, the university will be able to exclude its preexisting know-how and patents (and the collaborator's preexisting know-how and patents) from being considered as prior art for the purpose of patenting the product. Prior to the act, the university's and the collaborator's preexisting know-how and patents would be considered as prior art and patent protection could well have been unavailable for the resulting product.

New Deal Point for Negotiation

The act could provide significant benefits to collaborators who derive considerable commercial benefit from protecting incremental improvements to their products or processes. By turning the availability of the benefits of the act into a deal point, to be negotiated and bargained for, universities may be able to obtain better deal terms (e.g., higher royalties) from their collaborators, particularly commercial collaborators.

Managing Inequitable Conduct Risk

Under 37 CFR Section 1.56 (Rule 56), there is a duty to disclose to the U. S. Patent and Trademark Office all information known to be material to patentability with respect to each pending claim in a patent application. Proprietary information shared by collaborators on a confidential basis is subject to Rule 56 disclosure requirements. The act reduces the risk of inequitable conduct during patent prosecution by removing the need of collab-

orators to a joint research agreement to disclose the secret prior art of other collaborators (and their own prior secret art for joint inventions) when prosecuting patent applications for inventions arising within the term and scope of the joint research agreement.

Potential Risks Arising from the CREATE Act

The two key areas of concern arising from the act are (1) the ability of any party to a joint research agreement to rely upon the act unilaterally to obtain patent protection over incremental improvements to inventions, patents, or know-how owned by other parties to the agreement and (2) potential accounting and tax implications from expanding the universe of joint research activities involving commercial entities.

To illustrate through example, consider one of the most likely scenarios. The university enters into a joint research agreement with a company and, pursuant to this agreement, the university grants to the company a license to use the research report that is a deliverable under the joint research agreement (report) and a preexisting university-owned patent application (university application) that later issues (university patent). The agreement does not explicitly address ownership of inventions that are developed during the course of the joint research (which means that the default rules of inventorship and ownership under U.S. patent law will apply). During the term of this research agreement, the company files its own patent application (company application), which covers an obvious improvement to the university application and the information included in the report. The company application is rejected by the U.S. Patent and Trademark Office as obvious over the university application and/or the report. The company relies on the act, and the rejection is withdrawn, because the university application and report are no longer prior art for company application. The company is granted the patent for the company application (company patent).

Problems for the University under the Act

Continuing the example, the following issues may arise for the university.

Company May now Control a Blocking Patent

The company now owns the company patent, which covers obvious implementations of the university's technology as described in its report and university application. If there is a divorce of the university and the company without agreement over control of the company patent, the company will own blocking rights to what are obvious improvements to the university's intellectual property. The company might be able to block the university from further developing and/or licensing the university application or any patentable inventions included in the report because the company owns and solely controls the blocking company patent, which means that the company may be able to limit third-party development activity.

Company May Benefit from University Intellectual Property while Avoiding Royalties

The university has provided the company with a report that may include inventions that the university did not file patent applications on. The company can file patent applications on incremental additions to that information and may obtain a company patent. This company patent may offer substantial exclusive rights to the company. Absent a specific agreement with the university, the company would not be required to pay a royalty to the university and, more importantly, can block the university and its researchers from continued use of their developments covered by the company patent. The company gets a monopoly benefit from the university's report (and the inventions included in it) but does not have to share that benefit with the university.

The Dangers of Terminal Disclaimers

In the event that claims in the patent application filed by the company are obvious in light of claims in the university application, and a patent is granted to the university for the university application before the company receives the company patent, a terminal disclaimer will be required to take advantage of the act. The company does not need to

notify the university to file the terminal disclaimer and obtain the company patent. It is important to note that, although the act, and the implementing rules provided by the U.S. Patent and Trademark Office, do not require consent of the senior patent owner, consent may well be sought as a practical matter (although perhaps not until enforcement becomes an issue) since the company will not be able to separately enforce its patent.

The implementing rules are unclear about how the senior patent owner will be effected by this restriction on separate enforcement, since they do not provide for notification or consent of the senior patent owner. If, however, a patent is granted on the company's patent application before the university receives a patent for its university application, and claims in the university application are obvious in light of the company patent, then the university will be required to file a terminal disclaimer to obtain the university patent, and the university will need to agree not to enforce the resulting university patent separately from the company patent. Even though the company patent may have been an incremental improvement to the technology described in the university patent, the university will have given the company effective control over the enforcement of the university patent.

Categorizing Activities as Collaborations

It is important to consider the implications of using the words *joint research agreement* or *collaboration* when characterizing arrangements between universities and third parties because how agreements are labeled and categorized can have implications for how the corresponding activities are treated for accounting and tax purposes. The way in which these arrangements are characterized as well as how they are structured can have implications on how they are treated for tax and accounting purposes. It is also important to consider which agreements may fall within the act's definition of a joint research agreement, regardless of how they are named.

Specific Drafting Tips

Here are some specific drafting tips.

Make Sure the Agreement Satisfies the Requirements of the Act

To utilize the benefits of the act, the university must ensure that the following requirements are satisfied.

(a) The parties to the collaboration must enter into a written joint research agreement. Tip: Specify that the agreement is entered into for the purposes of conducting joint research, development, or experimental work. Make it clear that the parties will be doing collaborative work (although note that this could raise tax issues) and that they want to utilize the benefits of the act. Existing joint agreements can be amended to satisfy the requirements of the act—if amended, it may be the date of the amendment that is included as the date of the joint research agreement for purposes of the act.

(b) The claimed invention must be the result of activities undertaken within the scope of the joint research agreement. Tip: Define the scope of the joint research carefully to correspond to all aspects of the research statement of work, and amend the agreement to reflect changes in the scope of the joint research activities when such activities change. Make sure that changes to the scope of the agreement are only done by mutual written consent. There is tension between how narrow the university might want a collaboration to be and how broad the language needs to be to capture inventions.

(c) The specification of the patent application for the claimed invention must disclose, or be amended to disclose, the names of the parties to the joint research agreement. Tip: There will be some administrative steps involved in obtaining the benefits of the act, and the parties should consider how and when they want to deal with these issues.

(d) Where the claimed invention is patentably indistinct from a prior filed patent, the owner of the claimed invention must expect to waive the right to separately

enforce the subsequently filed (patentably indistinct) patent application and resulting patent to obtain the benefits from the act. The disclaimer must be executed by the owner of the subsequent application/patent. The implementing rules for the act are unclear about how the senior patent owner is impacted by the disclaimer, since notification and consent of the senior patent owner is not required by the act. What is clear is the restriction imposed on the subsequent patent owner/applicant, who cannot separately enforce this owner/applicant's patent. Tip: A clear agreement setting forth the circumstances under which the patent rights will be licensed and enforced, and who will control these decisions and receive the benefits, should be entered into where both parties have or are likely to file patent applications relating to the subject matter of the collaboration.

Neutralize Unilateral Nature of CREATE Act

The parties subject to the act are treated as a single entity solely for purposes of allowing one party to obtain a patent over certain prior art, but the parties may well have divergent rights and interests over the use of the prior art and resulting patent(s). Because the act can be relied upon unilaterally, those divergent interests can be exploited by the party making the otherwise obvious contribution, to the disadvantage of the innovator. The problems that can arise from these divergent interests (as illustrated in the prior sections) can be managed by contract.

(a) Contract for veto over right to rely on CREATE Act. Here's an example of a contract provision: "Neither party may invoke the CREATE Act with respect to any invention that is developed pursuant to this agreement without the prior written consent of the other party, such consent to include specific reference to the invention for which the benefits of the CREATE Act are claimed."

(b) Include a penalty if there is a breach of the agreement not to unilaterally rely on the act. An example of a contract provision: "In the event that a party (the "Relying Party") avails itself of the benefits of the CREATE Act in connection with an invention developed pursuant to this Agreement without the prior written approval of the other party ("Other Party"), the Other Party will own all right, title, and interest in any patent resulting from this impermissible reliance on the CREATE Act, and the Relying Party hereby agrees to assign all of its right, title, and interest in such patent to the Other Party."

Labeling Agreements: The Danger of Mischaracterizing and Miscategorizing the Arrangement

Some proposed language is included below to illustrate how to ensure clarity in the treatment of joint research agreements.

(a) Limit the meaning of “joint research agreement” by linking it to “for purposes of CREATE Act.” For example a contract provision might say: “This university research agreement is a “Joint Research Agreement” solely for purposes of the CREATE Act.”

(b) Include strong nonagency language. For example: “University and Company are independent contractors. Neither party has the authority to bind the other. Any reference to “Joint Research Agreement” is intended solely for purposes of the CREATE Act and should not be construed to create an employer/employee relationship, joint venture, partnership, or other such joint relationship between the parties.”

(c) Limit the scope of the research to reduce the activities that are covered by the joint research agreement. But, care needs to be taken to balance circumscribing the joint research to narrow the scope of the collaboration with expanding the scope of the joint research to capture the benefits of the act.

Manage Timing of Joint Research Agreement

To obtain the benefits of the act, the university must have a written agreement signed by the parties before claimed invention is made. Moreover, invention must be made *as a result of* activities undertaken within the scope of the joint research agreement, meaning that the statement of work for such agreements needs to be periodically updated as the scope of research changes. Where agreements are amended to add parties or to expand the field of the invention, the date of the amendment will apply for inventions that are subsequently developed if they would not otherwise have fallen within the scope of the initial joint agreement.

A university may manage the timing by taking steps that include: (a) informing potential collaborators at different institutions of advantage in documenting, in writing, their proposed working arrangement before research begins and (b) considering when standard

form agreements may satisfy terms of the act (where such agreements may end up leading to joint research) and modify as appropriate.

Address the Implementation of the Act during Patent Prosecution

Where the act is likely to have an impact (e.g., where incremental improvements are likely to emerge), the joint research agreement should address the implementation of the act during patent prosecution. The agreement should cover:

- whether to invoke the act at filing,
- whether to require consent to invoke the act,
- use of confidential information,
- notice requirements for actions taken that utilize the act, and
- handling of joint enforcement if a terminal disclaimer is required.

Addressing the CREATE Act

So, what are the implications of the CREATE Act? Here are some issues to consider.

Revisit Existing Agreements and Collaborative Activities

Universities should be aware that many of their existing collaborative agreements may already satisfy the requirements of the act. The parties do not need to opt in to the provisions of the act to be covered by the provisions of the act. This means that existing research agreements, including sponsored research agreements; interinstitutional collaboration agreements; and some kinds of grants, material transfer agreements, and perhaps even confidentiality agreements, could de facto be joint research agreements subject to the terms of the act. Where the disadvantages of the act are most likely to arise (discussed further below), prior agreements should be revisited to assess whether any of the above discussed risks apply.

On the other hand, some collaborations may not be formalized in appropriate written agreements, and, in this case, the benefits of the act will not be available unless action is taken to formalize the arrangements with a written agreement that satisfies the requirements of the act. Where the benefits of the act are most likely to arise (as discussed

further below), effort should be made to put joint research agreements in place to cover the new inventions taking place after the date of the agreement.

Identify Scenarios Where the Act Is Least and Most Likely to Have Impact

The act is least likely to have a material impact on the university in the following situations:

- Where there is no joint research, development, or experimental work.
- Research that is unrelated to the prior contributions of the collaborators (i.e., collaborations where all of the resulting inventions and/or research results are nonobvious over any existing subject matter and patents, meaning that there would be no successful Section 103 rejections based on the prior art of participants in the joint research).
- Collaborations where there is common ownership of the prior art and the new inventions (e.g., a first patent application and a second patent application both co-owned by the same institutions).
- Collaborations in which there is unlikely to be any inventive activity or where the resulting information and inventions are made publicly available (i.e., there would be no patent applications and patents filed on inventions arising from the collaboration).
- Where equivalent prior art qualifies under the categories of prior art provided in Section 102(a) or (b) or the invention falls under the categories set forth in Section 102(c) or (d). Section 102(a) includes inventions that are known or used by others in the United States, or are patented or described in a printed publication in the United States or abroad, before the invention in question. Section 102(b) includes inventions patented or described in a printed publication in the United States or abroad or in public use or on sale in the United States more than one year prior to the date of the patent application in question in the United States. Section 102(c) covers the case in which the invention in question has been abandoned. Section 102(d) covers situations in which the invention in question was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country, more than 12 months prior to the date of the U.S. patent application.
- Where there is no qualifying joint research agreement, even if there is joint research. This is not uncommon as between collaborators at different institutions.

Where is the act most likely to have an impact? The key benefit of the act arises where a patent application later filed is an incremental improvement over either prior unpatented information or a prior filed patent application or patent that is not owned by the later patent filer. This is most likely to take place in the following arrangements:

- Sponsored research with commercial entities.
- Interinstitutional collaborations that are formed to develop and expand upon a technology (such as a platform technology) that includes contributions from both sides to further develop the preexisting technology.
- License to use university intellectual property or university resources (including licenses in and licenses out, particularly where improvements or grant-backs of intellectual property are involved).
- Material transfer that includes collaboration and exchange of documentation and materials that have proprietary value.
- Confidentiality agreements that involve the exchange and use of proprietary information by both parties for the purpose of collaborative research activity.

This list is not exhaustive, but should provide some guidelines for how to think about and screen agreements and collaborations in light of the act.

Guidelines for Specific Arrangements

Sponsored Research

The concerns about the act are perhaps most likely to emerge in sponsored research arrangements with commercial entities. Companies can obtain results and know-how from university faculty and pursue an aggressive patenting strategy based on this transfer of know-how by invoking the act, and the transferred information will not be considered as prior art to the company's incremental improvements. The timing of patent filings and patent grant will become important where terminal disclaimers come into play. Things to think about when reviewing sponsored research arrangements in light of the act include:

- Careful definition of the field of sponsored research—taking into account considerations of when to make the field broader to increase the scope for benefiting from the act, when to make sure that it stays limited to avoid the risks of the act.

- Periodic updating of the statement of work for sponsored research agreements to ensure that it accurately describes the scope of the research and to ensure that no new third parties (e.g., other institutions) have been involved in the sponsored research.
- Keep in mind the relationship between sponsored research and license agreements—what happens when the sponsored research continues and the license terminates, for example?
- Implications where the company now has rights to future developed intellectual property that third parties do not have (via ability to obtain title to intellectual property using the act).

Interinstitution Collaborations

One of the key challenges of interinstitution collaborations will be to get the joint research agreement in place before the inventive activity takes place and keep the agreement continually updated to manage the changing scope of the work and potentially changing parties to the agreement. If collaborations take place without an agreement, the technology transfer professional will need to determine what activities took place before the written agreement was signed and whether the activities and resulting inventions fall within the scope of the joint research agreement. A question (for further discussion) arises as to whether it is practical to expect collaborators to get a written agreement in place before beginning to collaborate, and if not, whether it is useful or dangerous to use a simple standard form that is not tailored to individual circumstances to document collaborative activity in early stages.

Licensing and Material Transfer

Universities should carefully consider the implications of the act for incremental improvements being developed either by the university, a third party using university resources, or jointly by both. If the university is providing proprietary materials and know-how and has not established its own patent protection around such materials, it should expressly address the ownership of any inventions that are developed as a direct result of such materials by written contract. If the license provides for use of university know-how and improvements, the parties should consider and contract for the use and benefits of the

act. If the license provides for a grant-back of improvements to the university (perhaps for internal research use or more broadly), then the act may offer some opportunities for university patenting that it would not otherwise have.

Implementation of CREATE Act during Patent Prosecution

Legal counsel should be sought when determining how to manage the implications of the act in particular situations and when determining what steps are required in the patent filing and prosecution process. A brief overview of some of the steps involved is provided below, but this description is by no means comprehensive.

Rejection of Patent Application on Qualifying Prior Art Grounds

When a patent application is rejected on CREATE Act-qualifying prior art grounds (a rejection under 35 USC 103(a)), the patent applicant must provide a statement to the effect that: (i) the prior art and the claimed invention were made by or on the behalf of parties to a joint research agreement, and (ii) the joint research agreement was in effect on or before the date the claimed invention was made, and (iii) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement. The patent applicant must amend the patent application specification to name all of the parties to the joint research agreement.

Obviousness-Type Double-Patenting Rejections

Invoking the CREATE Act may give rise to an obviousness-type double-patenting rejection when Section 102(e) prior art is involved. A terminal disclaimer will be required to overcome this obvious-type double-patenting rejection.

Disclosure Requirements under Rule 56

Under Rule 56, there is a duty to disclose to the U.S. Patent and Trademark Office all information known to be material to patentability with respect to each pending claim in a patent application. This duty may apply, whether or not there is a joint agreement.

Notes

1. Public Law 108-453.
2. 122 F.3d 1396 (Fed. Circ. 1997).
3. 70 Fed. Reg. 54259 (14Sep2005); 70 Fed. Reg. 1818 (11Jan 2005).
4. 35 USC 102 (Section 102 of the U.S. Patent Act) sets forth the rules for what is prior art. 35 USC 103 (Section 103 of the U.S. Patent Act) provides that an invention is not patentable if it is obvious in light of the prior art described in Section 102. The act only applies to certain kinds of prior art.
5. 35 USC 103(c), as amended by the act, [emphasis added] now reads as follows:

Section 103(c) (1) Subject matter developed by *another* person, which qualifies as *prior art only under one or more of subsections (e), (f), and (g)* of Section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. (2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be *deemed to have been owned by the same person or subject to an obligation of assignment to the same person* if (A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; (B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and (C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.(3) For purposes of paragraph (2), the term “joint research agreement” means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

6. A person shall be entitled to a patent unless ...
 - (e) the invention was described in (1) an application for patent, published under Section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in Section 351 (a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21 (2) of such treaty in the English language; or
 - (f) he did not himself invent the subject matter sought to be patented, or
 - (g)(1) during the course of an interference conducted under Section 135 or Section 291, another inventor involved therein establishes, to the extent permitted in Section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or
 - (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Definitions of Intellectual Property

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The term *intellectual property* encompasses a variety of different forms of intangible property rights that serve to protect unique, original, and/or valuable creations of the human intellect. Intellectual property can encompass, but is not limited to, ideas; inventions; literary works; chemical, business, or computer processes; company and product names and logos; and other creations.

Regardless of the form of intellectual property right under consideration, intellectual property value is derived from an ability of the owner or licensee to preclude others from practicing or using a given idea, invention, process, name, etc. In other words, the value of intellectual property results from the property holder having the right to prevent others from doing something of a commercially relevant nature. This right can be enforced in appropriate courts or tribunals. As such, intellectual property can generate income for its owner, either via providing an exclusive area in which the intellectual property holder can commercialize products or services, or, as is common in the university technology transfer arena, via licensing. Intellectual property can also be a valuable marketing tool for a company.

There are multiple types of intellectual property, and a technology transfer professional should be aware of the basic aspects of each. The major forms of intellectual property include: patents, which protect inventions; copyrights, which protect literary works, art, music, videos, computer programs, and other works of authorship that are fixed in a tangible medium; trademarks, which can protect university and company product names and logos; trade secrets; and domain names. Of these, patents, trademarks, and copyrights are typically the most important in the university context. Each of these forms of intellectual property is discussed in greater detail below.

Patents

Patents are legal monopolies granted by a government that provide to the inventor, or the inventor's assignee, the right to stop others from making, using, or selling the patented invention. Machines, chemical molecules, genetically modified organisms, methods of manufacture, methods of testing, methods of treating disease, drugs, chemical processes, computer programs, and, in some jurisdictions, business methods are patentable, with the precise boundaries of what constitutes patentable subject matter varying by jurisdiction.

In the United States, the requirements of patentability are governed by the Patent Statute (35 USC § 1 *et seq.*). Patents are examined and issued by the United States Patent and Trademark Office (USPTO). Other legal provisions and agencies govern patenting in other jurisdictions around the world. However, there are relatively common elements to each of these systems. This section will focus primarily upon U.S. patents.

The monopoly provided by a patent is granted in exchange for full disclosure of the invention to the public. A patent lasts for a term of twenty years from the patent application's filing date. Publication of the patent document places all information concerning an invention at the disposal of anyone who wishes to review the patent. The public can use this information in any manner it wishes, so long as it does not infringe the claims of the patent or some other intellectual property right. There are two major sets of requirements that must be met to obtain a patent.

The first requirement of patentability is that the invention must be novel and nonobvious. Patents are properly granted only for inventions that were previously unknown in the prior art. *Prior art* is the body of publications, patents, Web articles, actions, etc., that can be cited against a patent application or patent to show or suggest that the invention is not patentable. What can and cannot be considered prior art against a given patent or patent application is determined with respect to the *priority date*, which is determined by the filing date of the application or the filing date of a previously filed patent application to which the application is entitled to claim the benefit. In the United States, 35 USC § 102 also defines what constitutes prior art.¹ Note that various other jurisdictions have different precise parameters on what does and does not count as prior art against a given patent application.

For example, U.S. law provides a one-year grace period after the publication of a scientific article. If an application has a priority date during this one-year period, the article is not prior art against the application. However, as discussed below, many foreign jurisdictions do not have such a grace period.

It is not possible to patent an invention that is not new in view of the prior art, even if the invention is believed to be new by the person inventing it. In the U.S., the provisions of 35 USC § 102 require that, to be patentable, the invention must be *novel*, meaning that every claimed detail of an invention cannot have been disclosed or publicly practiced by another prior to the date of the invention or more than one year before the filing of the patent application.

In addition, even if an invention is novel, it cannot be patented if one of ordinary skill in the field of the invention, or a field related to the invention, would have found the invention to be obvious, as set forth in 35 USC § 103.² While precise definitions may vary, most jurisdictions have analogs of the U.S. novel and nonobvious requirements for patentability.

The second set of requirements defines the appropriate contents of a patent application. Essentially, the application is supposed to be a written description of the invention that sufficiently describes how to make and use the invention to one having skill in the field with which the invention is concerned. In the U.S., the requirements of an appropriate patent application are set forth in 35 USC §§ 111 and, especially, 112. Each patent application should include a specification and claims. The specification describes the invention in text form and will typically contain a background of the invention; a summary of the invention; a detailed written description of the invention, which includes an enabling disclosure of how to make and use the invention; and, if necessary, drawings. The claims are a series of one-sentence statements that define the property right granted by the issued patent.

After a patent has been prepared and filed, it will eventually enter *prosecution*—the process of arguing back and forth in an attempt to convince the patent office that the invention is new and not obvious and that the patent specification adequately supports a

set of claims. Typically, this examination process is conducted via paper correspondence between the patent attorney (or patent agent) and the relevant patent office. Note that, in some jurisdictions, including the U.S., there is a duty of disclosure wherein patent applicants must disclose to the patent office all material information of which they are aware that might be relevant to the prosecution and allowability of their claims. Typically, during prosecution of a patent application, the specification will remain essentially the same, while the claims may be amended several times.

Patent rights are geographically limited. Therefore, a U.S. patent can only be enforced against a party who is making, using, or selling the patented invention within the territorial limits of the United States. Especially in the increasingly global markets, U.S. patent rights may not be sufficient to protect an invention to its fullest, commercially viable, scope. Therefore, the technology transfer professional should be aware of the possibility for obtaining patents in jurisdictions other than the United States. There are a variety of treaties and conventions that make it easier to pursue patent protection around the world, the most significant being the Paris Convention for claiming priority when filing in other countries and the Patent Cooperation Treaty (PCT) for filing an international patent application. However, each jurisdiction has its own rules, and one should be aware of the need to consult a patent attorney (or patent agent) in sorting out the best manner in which to proceed with international protection for an invention.

Note that, whereas the U.S. has a one-year grace period from date of public disclosure (i.e., publication) to allow one to file a patent application and avoid having the publication be prior art, no such grace period exists in many foreign jurisdictions. Therefore, it is often beneficial to file a U.S. patent application prior to the publication of any information on the invention, because that information could become prior art against the application in foreign jurisdictions. Also note that many foreign jurisdictions are *first-to-file* jurisdictions in which the first person to file a patent application for a given invention is entitled to the patent for that invention. This is in contrast to the *first-to-invent* system, which is currently used in the United States.³

Trade Secrets

Trade secrets consist of information that can be used in a business and that give that business an opportunity to obtain an advantage over competitors who do not know or use the information. Such information can include recipes, drawings, computer software formulas, compound calculations, processes, deduction know-how, quality-control procedures, maintenance know-how, financial information, customer lists, price information, negative know-how, client information, customer preferences, buyer contacts, market strategies, blueprints, etc.

Typically, trade secret protection is not common in the university intellectual property context. The general goal of universities in publishing their technologies makes trade secret protection for a university-generated technology difficult to do.

Intellectual property protection provided by trade secret law derives from the fact that the person inventing or developing the trade secret keeps all information concerning the trade secret from the outside world. In contrast to patents, there is no need to prepare or file any application to protect the trade secret. In fact, publication of such an application would destroy the trade secret.

Likewise, in contrast to patents, trade secrets last indefinitely, not a set term of years. So long as the trade secret is kept secret, it confers intellectual property protection. However, if another party, through legitimate means, for example, independent deduction, or reverse engineering, obtains via publicly available sources the information that was once a trade secret, there is no possibility for preventing that party from using the trade secret information. As such, it is necessary for a party protecting information using trade secret laws to employ rigorous security procedures, including employing independent contractor confidentiality agreements, fiscal and security restrictions on access, the use of confidential ledgers or warnings on documents, password protection of computer files and databases, and/or conducting exit interviews.

The trade secret holder may be able to obtain recourse from misappropriation of his or her trade secret provided that he or she can establish that: a trade secret existed, the

trade secret was either acquired by the party accused of misappropriation through a breach of a confidential relationship or discovered by improper means, and the party accused of misappropriation used or disclosed the trade secret without authorization from the trade secret holder. Typically, trade secret litigation is controlled by state law in the U.S.⁴ Although the Economic Espionage Act of 1996 makes the theft or misappropriation of a trade secret a federal crime.

Trademarks

In the U.S., the requirements for registering and maintaining a federally registered trademark are governed by the Lanham Act (15 USC § 1051 *et seq.*). Trademarks are examined and issued by the USPTO. A trademark is a name, symbol, figure, letter, color, sound, or logo used in trade, legally reserved to the exclusive right of the owner, which identifies the source of the product or service and distinguishes the product or service from other sources. In the university context, trademarks include the university name, logo, mascot, etc. Further, many universities develop trademark protection in their names, the terms they use, or services they provide.

The general term *trademark* generically covers a variety of closely related forms of intellectual property protection including trademarks, service marks, and trade dress. More specifically, *trademark* is defined as being a name, symbol, figure, etc., that identifies the source of goods. By contrast, a *service mark* identifies the source of services, whereas *trade dress* protects the look and feel of a product or packaging, for example, the color arrangement or scheme. A specific source of goods acquires federal trademark rights by usage of the trademark in commerce. There are schemes for obtaining state trademark protection, which are geographically limited to the state in which such protection is obtained. In addition to federal and state trademark registration procedures available in the U.S., most other countries also have trademark protection available.⁵

Trademark protection can extend for an indefinite period of time. However, in the U.S., and most other jurisdictions, there are periodic renewal requirements of such rights.

Copyrights

A copyright is the exclusive protection granted by U.S. law to an author that prevents unauthorized copying, use, or preparation of a derivative work of the author's original, tangible, published, or unpublished work. In the United States, the requirements for acquiring a copyright are governed by the Copyright Act (17 USC § 101 *et seq.*).

Copyrights are available for original works of authorship that have been fixed in a tangible medium. An original work of authorship must be minimally creative and independently created (*i.e.*, be original). These can include literary works, musical works, dramatic presentations, sculpture, architectural works and designs, choreography, pictures, graphics, movies, videos, sound recordings, music, software, etc.

Copyright law protects against unauthorized copying, reproduction, distribution, public performance, or display of the copyrighted work. The author of a work obtains copyright protection at the time the work is fixed in a tangible medium of expression. In the United States, there is an additional federal registration procedure that allows registration of the copyright with the Library of Congress. Federal registration provides various advantages in the event of copyright infringement. In addition, federal registration is required before filing a copyright infringement lawsuit, as well as obtaining statutory damages and attorney fees if there is infringement.

Copyright infringement occurs when an unauthorized party makes a substantial copy or derivative work of a copyrighted work. Remedies against a copyright infringement may include actual damages, the infringer's profits, injunction and/or seizure, and destruction of the copyrighted work. In the event of a copyright registered before infringement occurs, one can obtain statutory damages and attorney fees.

There are some limited circumstances where the Copyright Act statutorily allows copying to occur, the most well-known of which is called fair use and is governed by 17 USC § 107, which includes four nonexclusive factors for determining whether or not the use is fair.⁶ Even though it is not infringement of a copyrighted work to copy it "for purposes such as criticism, comment, news reporting, teaching (including multiple copies for class-

room use), scholarship, or research,” it is important to realize that it can be difficult to determine whether a particular activity qualifies as fair use because the determination is based upon a balancing test. Copyright of the work internationally may also be obtained using the provisions of the Berne Convention for the Protection of Literary and Artistic Works.

Endnotes

1. 35 USC § 102, conditions for patentability; novelty and loss of right to patent.
A person shall be entitled to a patent unless:
 - (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
 - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
 - (c) he has abandoned the invention, or
 - (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or
 - (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or
 - (f) he did not himself invent the subject matter sought to be patented, or
 - (g)(1) during the course of an interference conducted under section 135 or section

291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

2. 35 USC § 103, conditions for patentability, non-obvious subject matter.
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
 - (b)
 - (1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if
 - (A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and
 - (B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.
 - (2) A patent issued on a process under paragraph (1)
 - (A) shall also contain the claims to the composition of matter used in or made by that process, or

- (B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.
- (3) For purposes of paragraph (1), the term “biotechnological process” means
- (A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to
- (i) express an exogenous nucleotide sequence,
- (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or
- (iii) express a specific physiological characteristic not naturally associated with said organism;
- (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and
- (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).
- (c)
- (1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.
- (2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if
- (A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;
- (B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
- (C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

- (3) For purposes of paragraph (2), the term “joint research agreement” means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.
3. Note that the question of whether or not the U.S. should adopt a first-to-file regime has been debated by the U.S. Congress, and the U.S. may well adopt such a system at some point in the future.
 4. 18 USC § 1831-1839.
 5. International trademark protection can be simplified by using the Madrid system for the international registration of marks. The Madrid system was established in 1891 and functions under the Madrid Agreement (1891) and the Madrid Protocol (1989). It is administered by the International Bureau of WIPO located in Geneva, Switzerland, and offers a trademark owner the possibility to have his or her trademark protected in several countries by simply filing one application directly with his or her own national or regional trademark office.
 6. 17 USC § 107, limitations on exclusive rights: fair use Notwithstanding the provisions of sections 106 and 106A [17 USC §§ 106, 106A], the fair use of a copyrighted work, including such use by reproduction in copies or phonorecords or by any other means specified by that section, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright. In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include
 - (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
 - (2) the nature of the copyrighted work;
 - (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
 - (4) the effect of the use upon the potential market for or value of the copyrighted work.

Five Winning Strategies for Crafting Claims in U.S. Patent Applications

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The foundation for the modern patent system in the United States is established in the U.S. Constitution, which provides that “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹ Inventors are to be given exclusive rights, but only for limited times, thereby guaranteeing that the public will ultimately benefit from innovations that are granted exclusivity. Thus, a fundamental goal of the patent system is to give the public meaningful disclosure of inventions in exchange for the government grant of exclusive rights.

Since one of the first patent acts passed by Congress in 1793, the obligation to disclose in detail the features of the invention has been a critical part of ensuring that inventors meet their end of the bargain to obtain patent protection.² Although the practice had been informally required by the U.S. Patent and Trademark Office and the U.S. Supreme Court, Congress amended the Patent Act in 1952 to formally mandate that inventors detail with specificity the scope of the invention using discrete claims particularizing their inventions. In particular, 35 U.S.C. §112, ¶2, was added to require that:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Since this provision was added to the Patent Act, patent claims have been a central fixture in the development of a significant body of case law affecting the scope and enforcement of patent rights. At times archaic and often indecipherable to the layperson, claims are the source of significant scholarly debate and expensive federal litigation, where claims

are frequently the subject of specialized hearings where courts attempt to construe the scope of the right to exclude afforded by the patent.

The language of the Patent Act and the subsequent case law thus requires that claims be considered in light of the remaining portions of the specification.³ As a result, claims are inextricably bound to description of the invention. Effective claim drafting can, therefore, never be divorced from the disclosure of the invention, and the context provided by the specification can have a dramatic effect on the validity and scope of the exclusive rights.

Five Strategies

Following are five strategies that may be employed when crafting patent claims and their supporting disclosures to improve the value, patentability, and enforceability of the patent grant.

Capture downstream profits using broad claims supported by concrete examples.

In most cases, research discoveries at higher educational institutions have abundant possibilities, but the institutions have limited resources to fully exploit the possibilities. In the hands of well-funded commercial entities, however, basic research may lead to lucrative products. Thus, a fundamental goal of patent-claim drafting in a higher educational setting is to capture the lucrative markets, i.e., the commercial products, rather than or in addition to, the less profitable markets, such as the research tools, assays, and the like that are more readily developed from the basic research. Claims such as these that try to extend from the basic research to capture profitable downstream commercial products are commonly referred to as *reach-through claims*.

The Federal Circuit appeared to sound the death knell for reach-through claims in its decision invalidating the claims of the patent directed to the underlying mechanism of COX-II inhibitors that led to drugs such as Celebrex.⁴ Instead of an assay or tool for uncovering drugs that would have the requisite effect on the COX II mechanism, the claims of the patent were directed broadly toward any substance that had the desired effect on the COX II mechanism. Unfortunately, the patent description did not describe

any actual substances that would have the claimed effect, and the Federal Circuit upheld the trial court's decision that the claims were invalid under 35 U.S.C. §112, ¶1, for lack of a written description. The failure to provide this written description was viewed as a failure to meet the basic requirement of the patent system to properly disclose the invention so that the public may ultimately benefit, despite the grant of exclusive rights to the inventor.

At first glance, the problem with reach-through claims does not appear to be a drafting issue. However, quality claim drafting begins with the fundamental understanding that the claims define the invention, and the invention that is defined in the claims is the one that must be disclosed to the public to fulfill the obligation to properly disclose the invention that is at the very heart of the patent system. As the claimed invention cannot be divorced from the description of the invention, neither can the strategies used to craft broad claims that capture downstream profits.

Although the Federal Circuit held particular reach-through claims invalid, the court took the opportunity to describe several ways in which claims of such breadth could have been valid. In particular, the court provided a roadmap for developing a sufficient written description when a patentee, such as a university, lacks the means to specifically identify the commercial products that embody basic research. For example, the written description requirement could have been fulfilled by describing just a single compound that would have the desired effects. In the event that such a compound cannot be identified, it is also possible to support broad claims by describing the characteristics of a compound that would have the desired effect. Finally, broad claims may be supported by describing the process of making a compound that would have claimed properties. These examples are not limited to pharmaceuticals and may be applied to virtually any commercial chemical or biological products that stem from basic research.

Using this roadmap, universities may rely on resourceful patent drafting to close the void opened by the invalidity of inadequately supported reach-through claims. If a sufficient supporting disclosure for broad claims is simply not available, care must be taken to craft patent claims that encompass the precursors to the commercial product. In the case of a pharmaceutical discovery, basic discoveries can certainly support claims to assays for

finding one or more successful drugs. While the profits derived from licensing a patent for an assay for finding a drug are not as great as the profits obtained from license a patent for the drug itself, the commercial value of a drug discovered by the use of the assay is a valid consideration in negotiating the license. Similarly, the commercial value of a drug discovered by the infringing use of an assay arguably qualifies as an important factor to be considered by courts when determining the amount of infringement damages. An infringed claim is always more valuable than an invalid one.

Broaden claim protection through creative dependent claiming.

An unfortunate number of patents contain dependent claims comparable to “The widget of claim 1, where element A is made of metal.” A dependent claim directed toward an obvious or otherwise unremarkable variation of an invention is not just a waste of filing fees, but a significant lost opportunity. Dependent claims, when used effectively, can strengthen the validity and scope of the claimed invention by avoiding the need for claim amendments and serving as a foil to broaden the claims from which they depend.

In light of the decision of the Supreme Court in *Festo Corp. v. Shoketsu Kinzoku Kogyokabushiki Co.*, claim amendments made during prosecution of an application before the U.S. Patent and Trademark Office will often limit the scope of the claims or, perhaps worse, provide endless fodder for clever patent litigators to drive a wedge into anything other than a clear case of literal infringement.⁵ As a result, an important claim-drafting strategy is to avoid having to make such amendments in the first place, and the effective use of dependent claims is the best tool in the claim drafter’s kit for avoiding amendments.

An effective set of dependent claims gradually narrows the scope of the invention past the point where any reasonable interpretation of the claims would give rise to a substantive patentability rejection. Contrary to the process employed during patent litigation, patent examiners are bound to give claims their broadest reasonable interpretation.⁶

Anecdotally, this usually results in a much broader understanding than the claim drafter ever envisioned, and quite often, results in a much broader understanding than is legally appropriate. Thus, a patent claim drafter must anticipate that his or her claims will likely

be stretched beyond initial expectations and then use a meaningful dependent claim to target both the expected point of novelty as well as a somewhat unreasonable point of novelty.

Dependent claims that include meaningful structure or steps to gradually narrow the scope of the invention provide a secondary bonus once issued, as one of the canons of claim construction is that an independent claim and its dependent claim must have different scope.⁷ This principal, referred to as claim differentiation, means that a dependent claim is presumed to be narrower than the claim from which it depends. As a result, a dependent claim that includes a limitation to a particular claim term effectively broadens the scope of the term in the claim from which it depends. For example, consider the following independent and dependent claim:

1. A knife, comprising:
 - a handle,
 - a blade, and
 - a spring contacting both the handle and the blade.
2. The knife of claim 1, wherein the spring is a leaf spring.

In the example above, the term *spring* must encompass more than the specific limitation to a *leaf spring* that follows in the dependent claim because of the doctrine of claim differentiation. By virtue of its dependency, claim 2 above instructs that the spring of claim 1 is broader than just a leaf spring, and, thus, claim 1 could be asserted against other springs, such as coil springs. Thus, use of a dependent claim that provides a limit to a prior element provides a sound basis under claim differentiation for the argument that the independent claim must cover more than just the dependent claims.

Defend against *KSR* when drafting claims.

In 2007, the Supreme Court rejected a rigid application of the longstanding “teaching, suggestion, motivation” test for determining whether a claimed invention is obvious under 35 U.S.C. §103 that had been endorsed by the Federal Circuit.⁸ In cases where a claimed invention was composed of elements already in the prior art, the Supreme Court

in *KSR* endorses a number of rationales in addition to the “teaching, suggestion, motivation” that could be used to establish obviousness. According to the U.S. Patent and Trademark Office, these rationales include:

- Combining prior art elements according to known methods to yield predictable results;
- Simple substitution of one known element for another to obtain predictable results;
- Use of known technique to improve similar devices, methods, or products in the same way;
- Applying a known technique to a known device, method, or product, ready for improvement to yield predictable results;
- “Obvious to try” by choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.⁹

These changes to the U.S. Patent and Trademark Office guidelines on applying obviousness rejections thus encourage obviousness rejections where all claim elements can be found in the prior art, promote rejections based on prior art from technological fields beyond that of the claimed subject matter, and provide rationales for obviousness rejections that will be hard to overcome by sheer argument alone. Strategic claim-drafting techniques are, therefore, necessary to help avoid the application of obviousness rejections in the first instance and to reduce the odds that a patent will face a final rejection.

The first way in which a claim drafter may protect against a *KSR* rejection is to capture an element or limitation that is not disclosed in the prior art, thereby foreclosing the application of any of the broad rationales endorsed by the Supreme Court. Although this will undoubtedly be more difficult to accomplish in some technological fields than in others, an extraordinary effort should be made to including an element or limitation that will be difficult to identify with exactness in the prior art. It will likely be easier to overcome an

obviousness rejection by arguing that the prior art fails to disclose exactly what is recited in the claim than to rebut the reasoning applied by the examiner.

The second way in which a claim drafter may protect claims from attack under *KSR* is to avoid the use of functional language that is otherwise unnecessary in view of the structure already recited in the claims. Prior to *KSR*, the primary problem with mere functional language was that it failed to distinguish the structure of an invention from similar structure in the prior art. Indeed, the Federal Circuit rarely gives significance to such language when comparing it against the prior art, and the U.S. Patent and Trademark Office procedures place the burden on the applicant to show that an invention recited in mere functional language would, in fact, function differently from similar structure in the prior art.¹⁰ For example, a claim to a popcorn shaker that recited the function of only allowing several popped kernels to pass at the same time was held invalid in view of an oil can dispenser that was presumed to have the same ability because of its correspondingly similar structure.¹¹

In light of *KSR*, functional claiming should also be avoided because it may unwittingly provide a roadmap for an examiner to apply an obviousness rejection whenever the claimed invention is a combination of elements that may be found in the prior art. Each time that the intended use of an element is affirmatively recited in a claim, it provides an examiner with a sound basis for taking that element in the prior art and combining it with other known elements. A savvy patent examiner will simply uncover the requisite elements in various references and then assert that one of ordinary skill in the art would have included each element in the combination to provide the function that is recited in the claim. Thus, in the shadow of *KSR*, what is not recited in a claim may be almost as important as what is recited in the claim.

Draft claims that target the appropriate infringers.

Suing your customers or potential customers for patent infringement is rarely, if ever, a sound business practice. Creative claim-drafting strategies can help focus liability for patent infringement on entities that are more readily taken to task for infringement—and that have the resources to provide compensation for the infringement.

In the example of an invention for a pharmaceutical compound, such as a drug, there are several ways to claim the invention. Claims may be directed toward the chemical formula for the drug itself, the method of making the drug, the method of using the drug to treat a patient, and perhaps even the method of using the drug to discover others drug or drug byproducts that have similar efficacy. Nearly all of these claims have distinctly different infringers that must be taken into consideration when crafting the claims. For example, claims directed to the drug itself would be infringed by anyone that made, used, sold, offered to sell, or imported the substance. Claims to the method of making the drug, however, would only be enforceable against the manufacturer. Similarly, claims to using the drug to treat a patient would have to be asserted against the doctor prescribing the drug and could only, in certain circumstances, be asserted indirectly against the supplier of the drug.

Selecting the appropriate claim sets to include or enforce may involve political, economic, and particular considerations. For example, many educational institutions may not want to risk the negative publicity associated with suing doctors for prescribing drugs, and thus, would have to forgo patent royalties or damages if the claims were directed solely to the use of a drug. In the case of a new use for an existing compound, method claims may be the only way to obtain patent protection. In other circumstances, identification of the potential infringers may be difficult. In a recent case involving the processing of debit transactions, the steps of a single claimed method were implemented by four separate parties. As the parties were not acting in concert or with knowledge of the steps performed by the other parties, none of the parties were found liable for the infringement that indisputably resulted.¹²

Apply lessons learned from recent case law.

The courts are constantly addressing and deciding issues of significant consequence to patent-claim drafters. While the Supreme Court decision in *KSR International Co. v. Teleflex Inc.* received all of the attention and discussion, several cases decided by the Federal Circuit in the last year provide guidance on claim-drafting and patent-prosecution strategies that may be employed to increase the odds of obtaining claim allowances and enhance the offensive strength of issued patent claims.

As explained above, functional claim drafting (i.e., claiming only the function performed as opposed to the structure invented to perform the function) may lead to undesirable anticipation and obviousness rejections. In a case involving gel drilling fluids, the Federal Circuit also held functional claim limitations invalid for indefiniteness under 35 U.S.C. §112, ¶2, because the specification did not clearly explain the scope of the recited function.¹³ If functional limitations must be used, the court provided a number of ways in which ambiguities arising from functional claiming could be remedied. For example, the patent drafter could include quantitative metrics in the specification to more definitively describe the functional aspects of the invention. Alternatively, a functional limitation could be supported by including concrete examples in the specification that describe what the functional limitation covers and what it does not.

Although every claim drafter should seek the broadest protection available in view of the prior art, care must be taken to ensure that the description in the specification can support the breadth of the claimed invention. In a case involving side impact sensors for airbags, the Federal Circuit held that claims that were broad enough to cover mechanical and electrical side impact sensors were invalid for lack of enablement under 35 U.S.C. §112, ¶1, because the specification only described the mechanical sensors in any detail.¹⁴

Since the Federal Circuit definitively held that so-called business methods were to be treated as any other process when determining patentability in *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, the U.S. Patent and Trademark Office has been inundated with business method patents addressing a surprising number of fields.¹⁵ In a case involving a mandatory arbitration resolution method, the Federal Circuit took the opportunity to clarify the scope of subject matter for such inventions and held that a method is only proper subject matter for a patent if it falls within the meaning of “process” in the Patent Act.¹⁶ The court explained that systems that depend entirely on mental processes or abstract ideas are unpatentable because they are not “useful” unless they are combined with a machine. Thus, a method that is not implemented in a computer is not proper subject matter, while the same method will satisfy §101 of the Patent Act if it is implemented on a computer. While this result may seem incongruous, the U.S. Patent and Trademark Office will undoubtedly reject claims directed toward business

methods that are not affirmatively tied to a computing system as not comprising sufficient statutory subject matter.

Conclusions

As if the repeated attempts by Congress to amend the Patent Act are not enough to keep patent claim drafters alert, the courts are constantly addressing and deciding issues that affect the way that claims are interpreted and applied. Although many decisions do not represent a significant change in the way that claims will be addressed by the U.S. Patent and Trademark Office or enforced by the courts, recent case law from the Supreme Court and the Federal Circuit has made some meaningful changes to way that patents and patent claims will be considered. Regardless of these changes, a patent-claim drafter who is cognizant of the fundamental principles of the U.S. patent system will be better prepared to craft claims that will survive the rigors of examination and litigation.

Notes

1. Art. 1, §8.
2. Patent Act of 1793, §3.
3. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).
4. *University of Rochester v. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004).
5. 535 U.S. 722 (2002).
6. *Manual of Patent Examining Procedure*, §2111.
7. 35 U.S.C. §112, ¶4 (“a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed”).
8. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 127 S. Ct. 1727 (2007).
9. *Manual of Patent Examining Procedure*, §2143.
10. *In re Schreiber*, 128 F.3d 1473 (Fed. Cir. 1997).
11. *In re Schreiber*, 128 F.3d 1473 (Fed. Cir. 1997).
12. *BMC Resources Inc. v. Paymentech L.P.*, 498 F.3d 1373 (Fed. Cir. 2007).
13. *Halliburton Energy Services Inc. v. M-I LLC*, No. 2007-1149 (Fed. Cir., January 25, 2008).

14. *Automotive Technologies Int'l Inc. v. BMW of North America Inc.*, 501 F.3d 1274 (Fed. Cir. 2007).
15. 149 F.3d 1368 (Fed. Cir. 1999).
16. *In re Comisky*, 499 F.3d 1365 (1997).

Attorney's View on How to Select and Work with Patent Counsel

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Introduction

Technology transfer offices at a university or other academic institution have only one product to sell—technology. The value attributed to such technology is impacted heavily by the quality and scope of the intellectual property protection, specifically patent coverage. If a patent is drafted poorly or does not provide adequate coverage for the technology and reasonable extensions thereof, licensing opportunities may either be lost or greatly devalued. Unlike manufactured goods, patents are not made by machines—they are prepared by people, i.e., patent attorneys or patent agents. As a result, patents will vary in style and quality as a function of who prepares them. Due to the possibility of such variability, it is important to select carefully a patent attorney whose patent work will enhance the institution's prospects for obtaining profitable licensing arrangements. Guidelines on making this selection are suggested in this chapter.

Once suitable patent counsel is selected, it is important to develop a good working relationship between the patent counsel, the technology transfer manager, and any other individuals involved in these processes. One aspect of this developing relationship involves ensuring that patent counsel can prepare and prosecute patent applications in a manner that achieves good results in a cost-effective fashion. Beyond that, however, it is important to recognize that patent attorneys can provide general counseling, resolve inventorship issues, provide licensing and agreement support, and resolve disputes. Suggestions on how technology transfer offices can work effectively with patent counsel in all these areas are also provided in this chapter.

By selecting qualified patent counsel and developing a smooth working relationship with him or her, technology transfer offices can develop a resource that will ease their

workload and facilitate their ability to handle difficult situations. Inevitably, when patents are well-prepared and prosecuted, they become more valuable and licensing income may be enhanced. Making an appropriate selection of patent counsel and developing a good working relationship with him or her is one of the essential elements to operating a viable technology transfer operation.

Selecting Patent Counsel

The Patent Attorney

Attorneys and agents must be registered with the U.S. Patent and Trademark Office (USPTO) to practice before that governmental agency. Obtaining such registration is not like registering to vote. Patent attorneys and agents have passed an extensive examination given by the USPTO. To qualify to take this exam, attorneys and agents must have a degree in science or engineering or a sizable amount of course work in those areas.

Those with law degrees and admission to a state bar are registered as patent attorneys, while individuals who are not lawyers are registered as patent agents. In a law firm (as opposed to in a university setting) the practice of a patent agent is usually limited to preparing and prosecuting patent applications before the USPTO. Patent attorneys also handle these responsibilities and, additionally, may litigate patent disputes, prepare and negotiate license agreements, and provide legal advice.

Names of patent attorneys can be obtained from a variety of sources. Like most professionals, patent attorneys are best located by seeking references and by word of mouth. Listings in the Association of University Technology Managers (AUTM) directory and the USPTO's register of patent attorneys are potential sources; however, they provide no basis for distinguishing between the listed individuals. The local bar association or intellectual property law association may be somewhat better resources, because these organizations would have some knowledge about individuals' reputations in the community and, presumably, would recommend someone with a solid reputation.

As members of AUTM, technology transfer managers have an excellent source of counsel who have experience with academic institutions and have provided quality assistance to

peers in other technology transfer offices. A few calls to the technology transfer offices of other institutions should result in names of recommended individuals.

Another source of patent counsel recommendations is through local companies. Companies with their own in-house patent attorneys are still likely to use attorneys in private practice for some projects. As a result, in-house patent attorneys can be a very good resource. In companies with no in-house patent attorney capability, the individual in charge of research, development, or engineering or the company's general counsel are likely to be working with outside patent counsel and should have some recommendations.

Evaluating Patent Attorneys

Once the names of some patent attorneys have been obtained, the technology transfer manager is ready to begin the evaluation of those recommended. The following items are offered as criteria to be considered when determining which attorney will best meet the needs of the institution:

- size of the attorney's firm
- scope of the attorney's legal experience
- attorney's experience with academic institutions
- attorney's technological background
- firm's location

Size of the Firm

One consideration is the size of the firm with which the attorney is affiliated. Large firms will have a critical mass of patent attorneys and the resources to handle whatever problems the institution might encounter. These resources include large libraries, access to databases, staff to maintain and utilize these resources, etc. The staff of patent attorneys at a large law firm is likely to include individuals with biotechnology, chemical, mechanical engineering, and electrical engineering backgrounds, so that the firm can handle work in virtually any technology.

In addition, these attorneys will collectively have experience in patent prosecution, litigation, intellectual property counseling, interferences, and licensing. As a result, a large law

firm is generally able to handle most any legal problem that confronts a technology transfer manager.

On the other hand, smaller firms might have the advantage of lower cost while having individuals with the skills needed to service the institution. Although firm size is a consideration, its significance should not be overstated. The technology transfer manager will be working with individual attorneys, and, therefore, the attorney's capabilities should receive the bulk of the manager's attention during this evaluation process.

Scope of Legal Experience

A manager should know the patent counsel's scope of legal experience. Because a significant portion of the work required by technology transfer offices involves preparation and prosecution of patent applications, the attorney selected should have a solid patent prosecution background. Careful scrutiny of an individual's capabilities in prosecuting patent applications is appropriate. Ask how long the attorney has been doing such work, how many applications he or she has prepared and prosecuted, etc. Make sure the attorney does a significant amount of original patent application drafting as opposed to prosecuting cases that originated overseas.

Ask to review patents and patent applications that the attorney prepared and the files of issued patents he or she prosecuted (these are publicly available after the patent issues or when the patent application publishes). The technology transfer manager should also examine whether the attorney being considered has experience in other areas, such as litigation, interferences, licensing, and counseling. There will inevitably be times when a technology transfer office will need such skills.

Experience with Academic Institutions

It is also beneficial for the patent attorney selected to have experience representing academic institutions. Attorneys with such a background are comfortable working with technology transfer offices as clients and in dealing with faculty. Unfortunately, such experience includes the ability to prepare patent applications under the seemingly constant pressure of filing a case prior to publication.

Another facet of expertise in handling patent matters for academic institutions is the ability to work with faculty who have little knowledge about intellectual property and have a variety of undertakings competing for their time and attention.

Lastly, the attorney needs to be acquainted with procedures commonly used by technology transfer offices to delay or minimize costs. For example, patent counsel should be familiar with the Patent Cooperation Treaty procedure for foreign filing to delay payment of national filing fees in the selected foreign countries. Further, patent counsel without experience working with universities may not know Bayh-Dole regulations, such as the fact that a reference to government rights should be inserted in the specification. Rapport and mutual respect between patent counsel and faculty inventors are also crucial to cost-effective strong patent protection.

Technological Background

Another selection criterion is the extent that patent counsel's personal or the firm's technological background matches the needs of an academic institution. Larger institutions may have work in a myriad of technologies from electrical engineering to biotechnology. As a result, such institutions must retain different attorneys with these backgrounds (or a firm with such attorneys).

On the other hand, a smaller institution, such as a medical center, may only need an attorney with a biotechnology or medical background. In selecting patent counsel, technology transfer offices should evaluate their needs technologically and find someone with a matching background and assure that counsel has sufficient depth within the needed technology areas.

The Firm's Location

How close are patent counsel's offices to the institution? Generally, it is preferable to utilize a local attorney if he or she is otherwise satisfactory. If there is no local attorney with the necessary legal and technical expertise, however, proximity must give way to quality. If a manager needs to go outside the local vicinity to find a patent attorney with suitable credentials, the manager should try to structure the relationship so that the attorney has

maximal opportunities to be at the institution. For example, if possible, the technology transfer manager should give the attorney more than one project to work on at a time so that he or she can come to campus, talk to the inventors, and handle the matters in a cost-effective fashion.

Personal meetings between technology transfer office personnel and patent counsel are also important in fostering a good working relationship and making it easier for the technology transfer manager and office staff to receive advice. When personal meetings are not possible or cost effective, a patent attorney outside the local area should be able to work effectively with the technology manager and the institution's faculty by telephone, e-mail, fax, overnight courier, and other means, such as scheduled annual meetings.

Selecting one Firm vs. Many

Another criterion to consider in retaining patent counsel is how many individuals or firms the technology transfer manager should select. This depends on the volume of work generated at the institution. The technology transfer manager must, of course, select enough individuals or firms to handle the institution's work volume. On the other hand, it is preferable to use as few firms as possible to ease administrative requirements on the technology transfer office and to increase the visibility of the office within the firm. It is also easier to establish a good working relationship and to ensure that the institution's procedures are followed when only a few firms are utilized.

Nevertheless, it may not be a good idea to use only one firm, because that firm may not be able to handle certain projects for any of a variety of reasons. For example, the legal profession has rigorous conflict-of-interest standards that prevent attorneys from representing one client in an action against another client. In patent matters, conflict-of-interest issues are complicated by the need to avoid representing clients with technologically similar inventions. It is difficult to anticipate conflict-of-interest issues; they may never arise or may arise years after patent counsel is first retained.

Another potential problem is that the counsel or the firm selected may not, at some distant time in the future, have the capacity to handle a particular project. This may occur

because the attorney or his or her firm are otherwise engaged or lack the required technical expertise. Rather than dealing with a conflict-of-interest or a lack-of-capacity situation on a crisis basis, it may be better to select and work with a backup firm that can handle such projects.

Conditions of Representation

Once the technology transfer manager has selected patent counsel, the conditions of representation should be established. In many jurisdictions, lawyers are required to establish such a relationship in writing through an engagement letter.

One purpose of the engagement letter is to establish contact people on both sides to handle administrative matters, particularly billing issues. The technology transfer office should select the person from its staff who is most likely to interact with patent counsel as counsel's contact person. The retained attorney or law firm will designate the attorney who will prepare and send out bills. It may also be appropriate to use one attorney as the point of contact between the institution and the law firm. That person can act as ombudsman within the law firm to ensure that the institution's special needs or requirements are met. It is still a good idea, however, to know which attorney will be taking primary responsibility for particular projects and to ensure that that individual is qualified.

The engagement letter should also establish billing procedures. Because most law firms work on an hourly rate basis, the engagement letter will likely specify attorneys, agents, and other personnel and the billing rates for those likely to be handling the institution's work. There is also occasional use of alternative billing procedures, such as fixed fees or fee-and-equity combinations. Further, some technology transfer offices choose to pay their counsel a monthly retainer fee to cover routine counseling and advice. This makes technology transfer office personnel and faculty less reluctant to contact counsel with small but important questions. The terms of any special fee arrangement should be stated in the engagement letter.

The engagement letter will also specify billing cycles. Generally, bills are rendered by most law firms every month and other costs, such as USPTO charges, legal research resources, travel, and copies are addressed at that time.

Another feature of the engagement letter will be a specification of the bill content. An acceptable bill will include, on a daily basis, an indication of which attorney worked on a particular project, the amount of time spent daily on that project, and what that work involved. This will make clear the services for which the technology transfer office is being charged. Block bills containing a narrative of all work done on a particular project without specifying which attorney did that work, how much time that attorney spent on a particular task, and when that task was done should not be accepted.

Regardless of whether there is an engagement letter, the technology transfer office should state what it expects from counsel in general and on every project. For example, as a general matter, the technology transfer office—not the faculty—is counsel's client. This is a seemingly simple concept, because the technology transfer office is receiving and paying the attorney's bills. Nevertheless, things can become confusing in academic settings where patent counsel is working heavily with faculty members who operate somewhat autonomously. It is easy for such faculty members to regard patent counsel as their attorney and to begin asking the attorney to perform tasks without approval by the technology transfer office. The technology transfer office should emphasize to both counsel and faculty that patent counsel represents the technology transfer office—not the individual faculty member—and that any patent work the faculty member wants carried out should be channeled through the technology transfer office.

Working with Outside Patent Counsel

Allocation of Work

Having selected patent counsel, the technology transfer office should begin establishing a working relationship with that attorney. Determining how work is to be allocated between patent counsel and the technology transfer office is an important starting point in establishing such a relationship. Generally, the less work that is sent to the attorney, the lower the technology transfer office's legal fees. On the other hand, the more work the technology transfer office retains for itself, the less time its staff will have for other matters and the expertise of the attorney will be lost. It is, therefore, important for the technology transfer office to assess how its resources are to be utilized and then to distribute its workload accordingly.

Evaluating the Invention Disclosure

Quite often, a technology transfer office will receive an invention disclosure from a faculty member while the underlying research is ongoing. An evaluation must then be made to determine whether the matter is ripe for filing a patent application. The technology transfer office should consider:

- whether there has been or will be a public disclosure regarding the invention;
- what the stage of development is, what is planned, and how it is being funded;
- whether that publication will enable those skilled in the art to practice the invention; and
- whether meaningful protection can be obtained at this stage of the invention's development.

Generally, the technology transfer office should make an initial effort to decide whether (and when) a patent application should be applied for on a particular technology. However, where resolution of this issue becomes legally and technically complex, patent counsel should be consulted.

Another important consideration with respect to a newly submitted invention is whether that *invention warrants an investment* in patent protection. This decision should be made by the technology transfer office that has experience in marketing and valuing technology.

Prefiling Patentability Evaluation

Once the technology transfer office makes a preliminary decision to proceed with obtaining patent protection, it is advisable to make a *prefiling patentability evaluation*. An initial evaluation of this type can be conducted by the technology transfer office if it has access to computer search databases or is willing to work directly with an outside search firm. Generally, computer searching is appropriate for biotechnology and chemical inventions.

On the other hand, devices are best searched by manually reviewing the USPTO's collection of patents in the relevant area. The technology transfer office, of course, must have the staff to conduct and/or evaluate such searches.

One possibility to increase staff assistance in a technology transfer office is to use engineering or law students at the institution on a part-time basis for such work. When utilizing such part-timers, however, it is recommended that their role be restricted to gathering information for evaluation by patent counsel or a staff person who has experience in evaluating patentability. Staff persons making initial patentability evaluations need to acquire a working knowledge of patentability standards and what is prior art (i.e., subject matter capable of preventing issuance of a patent). An ideal way to gain such an understanding is to attend AUTM programs on the subject. Other organizations also have basic courses about patents and patentability. Ultimately, however, knowledge is best obtained over time by working with (and learning from) patent counsel.

A technology transfer office that does not have the staff to make an initial patentability evaluation should send disclosures out to patent counsel who can then arrange for a patentability search and make an evaluation. This, of course, is the more expensive route, because patent counsel is taking responsibility for obtaining a patent search, evaluating that search, and providing a recommendation. Many technology transfer offices, however, utilize this approach because their staffing resources are committed to marketing and technology transfer.

It is important to discuss the scope of claims the attorney thinks are likely to issue so that you can determine whether those claims will be commercially relevant, i.e., licensable.

Preparation and Prosecution of a Patent Application

Once a patentability search has been obtained and a decision is made to proceed with preparation and prosecution of a patent application, patent counsel will bear the bulk of work responsibility. Nevertheless, the technology transfer office should act to facilitate the process (i.e., to minimize costs and ensure that there is valuable intellectual property to license). This can be achieved in a number of ways.

Inventor Participation

The technology transfer office should make introductions between patent counsel and the inventor(s) personally or by mail. The technology transfer office should insist that

the number of meetings between counsel and the inventor(s) be held to a minimum. In most cases, one meeting to discuss the invention and one meeting to discuss a draft application is sufficient. Brief telephone conferences can be used to fill in gaps left by such meetings.

It is important to impress upon the inventor(s) the need to cooperate with counsel's requests for information. The inventor should furnish any draft journal article, grant application, prior publications, and/or patent application related to the invention to facilitate preparation of written examples for the patent application. If the article does not provide sufficient information for examples, the inventor will be requested to provide additional experimental writeups. This often requires a fair bit of work, but the inventors are much better able to do this than patent counsel. Moreover, having the inventors undertake this task (as opposed to patent counsel) will reduce cost.

For biotechnology and chemical inventions, patent applications will frequently be faced with a rejection under 35 USC § 112 (first paragraph), because the application's disclosure does not support the broad scope of protection being sought. To overcome this problem, the scope of protection may have to be narrowed to an often unacceptable extent. Applications based on little more than draft publications are particularly susceptible to such problems, because publications generally report only what work was actually carried out by the researcher; it does not usually discuss alternatives or how the invention can be expanded. To obtain a broad scope of protection, the inventor(s) will be requested to assist patent counsel by providing information about how the invention can be utilized. The technology transfer office should impress upon the inventor(s) the importance of their cooperation in this regard so that commercially valuable patent rights are obtained in a timely manner.

Duty of Disclosure

It is important for the technology transfer office to understand the duty of disclosure to the USPTO. Under this duty, patent applicants must disclose all information that a reasonable examiner would consider material in deciding whether a patent should issue. Inventors must not submit inaccurate data or neglect to submit bad data and must dis-

close all patents, publications, and other disclosures (i.e. prior art) that would be relevant to patentability.

In the drafting process, it is often helpful to have copies of prior publications and/or patent applications relating to development leading up to the invention. Counsel can pay to obtain copies of these publications, but it is more cost effective for the technology transfer office to provide them. This includes the inventor's own efforts to disseminate information as well as those of others. Published abstracts and information disseminated at poster sessions must also be disclosed. This duty is not extinguished upon filing of the application. If the inventor discovers prior art after his or her application for patent has been filed, he or she has a continuing duty to submit such information to the USPTO.

Coordinating Patenting with Commercial Activity

It is also important for the technology transfer office to advise patent counsel what aspects of an invention it regards to be valuable. The attorney can then frame the patent claims in a way that will provide the desired protection and enhance licensing opportunities. It would be prudent for the technology transfer office to monitor what is being claimed initially and throughout prosecution to ensure claim-scope expectations are met.

Most U.S. patent filings by nonprofit entities are entitled to a 50 percent reduction in fees paid to the USPTO as a result of qualifying for small-entity status. However, if patent rights are exclusively optioned or licensed to a company with more than 500 employees, the university is not entitled to such a reduction in fees going forward. Failure to pay the proper fees jeopardizes the validity of any patent. Therefore, it is important for the technology transfer office to advise the patent attorney when an exclusive option or license is granted to a company so that the entity status can be evaluated and the correct fees are thereafter paid.

The nonexclusive license to the U.S. government arising from federally funded inventions pursuant to 35 USC 200, et al., does not affect the ability to qualify for small-entity status.

Office Actions

After the application has been filed, the USPTO will eventually issue an office action that must be responded to by patent counsel. Generally, counsel will need input from the inventors when preparing this response. The technology transfer manager can assist in this process by stressing to the inventors that a prompt response to the attorney's request for information or additional experimental data is imperative and will save money in unnecessary fees. If a response to the USPTO office action is filed without all the information requested by counsel, it is likely that the USPTO will mail another office action; thus requiring the technology transfer office to incur the expense of filing another response, which includes the information that should have been put into the prior response.

In responding to office actions, extensions of time can be obtained by payment of additional fees. However, doing so may reduce the term of the patent, if one eventually issues. As a result, there should be limited use of such extensions.

Foreign Filing

After an application is on file, counsel will eventually inquire as to whether the case needs to be filed overseas. Decisions on foreign filing require consideration of whether:

- the return on foreign filing justifies the expense;
- such filing is going to be considered valuable by domestic licensees; and
- the invention has sufficient value to attract a licensee in a particular foreign country.

There are, of course, other factors that must be considered in deciding whether to foreign file, but they are beyond the scope of this chapter. A technology transfer manager should provide the attorney with plenty of advanced notice about foreign filing plans. This will enable the necessary papers to be prepared without rushing at the last minute or paying a surcharge to foreign counsel. Estimates of the filing costs, including translation fees, are useful in evaluating options.

Further Research and New Data

After an application is filed, inventors often breathe a sigh of relief and assume that they are done with patent applications. They then continue their research without informing the technology transfer office or patent counsel of any developments. This is unfortunate, because such later work can be the basis for further (and, indeed, often more valuable) patent protection. The technology transfer manager should impress upon the inventors the need to keep the technology transfer office apprised of future development—positive and negative—as well as licensee activity in development and commercialization, so this can be conveyed to the patent counsel.

Maintenance Fees and Annuities

Once patent protection is obtained in the United States or overseas, it is necessary to decide who will be responsible for paying maintenance fees and annuities. The technology transfer office can undertake this task itself or work directly with an annuity service. On the other hand, it can rely upon patent counsel and counsel's docketing system to handle this task.

Working with Patent Counsel on other Matters

Working with patent counsel should not be thought of only in terms of preparing and prosecuting patent applications. There are a number of other areas where counsel can provide valuable assistance.

Dispute Resolution

Quite frequently, inventorship disputes arise in academic settings. These issues are best resolved before any patent application is filed.

Inventorship disputes may arise between faculty members and their graduate students. Sometimes, graduate students are merely a pair of hands who simply follow instructions from the faculty member. In other situations, the student conceived or helped conceive the invention. To make a proper inventorship determination, it is necessary to interview the parties and review their documents to ascertain each inventors' contribution. Patent

counsel should have a level of expertise in resolving inventorship disputes that will make all parties involved feel that their views have been properly considered.

Faculty often collaborate with scientists at other institutions or companies. Such collaboration is rarely undertaken with an eye toward patents. However, once a decision is made to go forward with a patent application, disputes can arise regarding who will be named as inventors. Again, patent counsel can be useful in investigating the situation and providing an opinion on how to resolve the matter. This is particularly important when dealing with a collaborating institution or company, because, in order to maintain what has been up to that point a good working relationship with the collaborating institution, the technology transfer manager may choose to use patent counsel as an advocate to resolve these conflicts. Moreover, early involvement of patent counsel in any such dispute will enable the attorney to position the dispute to the advantage of the client—the technology transfer office.

Preparation and Negotiation of Agreements

Patent counsel can also provide technology transfer offices with support in the preparation and negotiation of licenses and other intellectual property agreements. Some technology transfer offices have a great deal of experience in these efforts but a skilled patent or licensing attorney often can make a unique contribution based on experience in many deals for a variety of types of clients.

For instance, counsel can prepare agreements, review draft agreements from potential licensees or the technology transfer office, provide selected clauses for inclusion in any agreement, and negotiate with potential licensees. Involving patent or licensing counsel in such negotiations is particularly critical where discussions are centered around substantive patent issues, such as the scope of patent protection available and whether the potential licensee has rights in the subject technology due to a dispute over inventorship or over who was first to invent.

Patent counsel should be involved in such due-diligence investigations and negotiations to help persuade potential licensees that his or her client has a meritorious position. At

the very least, patent counsel should be kept apprised of the substance of any license negotiations so that any changes needed to enhance the quality of the application can be promptly made.

Interference Proceedings

Issues of priority of invention (i.e., who was first to invent) are resolved in the USPTO through proceedings known as interferences. Often, these issues become apparent during license negotiations as discussed above. Alternatively, the inventors may become aware of similar work by others when they attend conferences. No matter how this information becomes known, it is important that patent counsel be kept apprised. This enables the attorney to undertake a strategy that will put the technology transfer office in the most advantageous position possible in any interference proceeding. The attorney should be involved in such situations at a very early stage and should meet with the inventors to discuss strategy. In the event that an interference is declared, such a proceeding is like a minipatent litigation. This is a complex proceeding, and patent counsel will need to be involved. Indeed, the attorney or patent agent should be the institution's representative in any such proceeding.

Available to Answer Questions

Lastly (and most importantly), patent counsel can serve a technology transfer office by being available to answer simple questions on intellectual property matters. Most patent counsel are willing, without charge, to help a technology transfer manager in patent-awareness efforts by giving seminars to groups of institution faculty or participating in special events such as invention fairs relating to the technology transfer program. By providing such advice to that office and faculty, patent counsel can help ensure that protection for valuable technology is not lost but, instead, enhanced.

Conclusion

The product sold by technology transfer offices is their technology. The patents covering this technology are an important investment often critical to incentivize the investment required by a licensee to develop and commercialize the technology. To ensure that there

is a valuable product to sell, it is important to select the institution's patent counsel carefully. Once counsel is selected, a good working relationship with him or her should be actively pursued. This will ensure that quality patents are obtained in an enjoyable, efficient, and cost-effective manner.

Working with Outside Counsel: Selection, Engagement, Maintenance, and Termination

Ray Wheatley

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Introduction

Effective utilization of the specialized skills of outside counsel is essential to the success of a university technology transfer program. Besides providing services in the areas of patent, trademark, and copyright law, outside counsel can provide advice on licensing transactions, valuation, and new-company formation. Developing and maintaining an effective, long-term relationship with outside counsel is very important, especially when considering the amount of time necessary to commercialize the nascent-stage business opportunities created at most universities.

While there are many intellectual property firms available to choose from, their service strategies are designed to meet the needs of the most lucrative clients—industry. The needs of industry are distinct from those of universities. Industry focuses on maximizing business advantages and shareholder return. Implementing intellectual property strategies into the day-to-day operations of a company is viewed as a critical component of success at many companies. Companies employ resources in a concerted fashion to exploit new innovations in the marketplace.

Universities focus on the creation of new knowledge and the dissemination of research results, which can sometimes present challenges when attempting to maximize the value of their intellectual property. The importance of license revenue generation and new-venture development are certainly recognized, but usually not at the expense of the traditional core values of the university's mission.

Still, the services of outside counsel can be utilized in a variety of ways to maximize the effectiveness of a university technology transfer program. Most commonly, these services will be concentrated in the area of patent prosecution. While it is possible to commercialize unpatented technologies, few would question the benefits patent protection provides in most circumstances. While these are universally recognized, securing such rights is not without the associated cost of investing financial resources in early-stage, high-risk investments. In fact, for most university technology transfer offices, such legal expenses exceed all other expense categories. Given the limited financial resources available to support university technology transfer efforts, it is essential to employ these resources as effectively and efficiently as possible.

A relationship with outside counsel can be divided into four basic stages: selection, engagement, maintenance, and termination. This chapter will discuss some important factors a university should consider in each stage to create a reliable partnership with outside counsel. The chapter will also discuss what to do when things go sour and how to terminate a relationship.

Selection

Certainly, the selection of appropriate outside counsel is a very important first step in determining the potential for success of a university technology transfer program. Upon initial review, the expertise and abilities of potential service providers may appear indistinguishable, but, in fact, the services available and professional expertise may vary greatly from firm to firm. As there are a variety of potential service providers, from large law firms to individual practitioners, there are also a wide variety of practice areas and specialized services. The goal is to select the most capable service providers for the university's intellectual property needs. Identifying those firms most likely to fit the university's needs can be quite complex, even for seasoned professionals.

Each class of service providers has certain advantages and disadvantages. Large law firms, for example, typically offer a wide range of services. Many have experienced professionals available in a number of fields and, therefore, have the resources to respond to urgent filing needs or other unanticipated situations. When specific situations are

encountered requiring specialized services (such as litigation consultation, etc.), specialized resources may be readily available within the firm to assist as needed.

Of course, this advantage can be offset somewhat by the increased overhead costs for maintaining these specialized resources. With the larger support staffs and higher rents, large firms will feel pressure to control costs through other means. One popular strategy is to assign the drafting of cases to junior associates and scientific advisers (individuals with advanced technical degrees who also may be patent agents). Although these junior members of the firm will be working under the guidance of a more senior attorney, it is important to ensure adequate guidance is being provided and quality is not compromised. Like it or not, most universities will usually not be considered bread-and-butter clients at large law firms. Corporate clients with deeper pockets are usually viewed as being more desirable. These clients will typically engage in more litigation, which is the lifeblood of many large law firms. A large law firm with a corporate client base should not be considered a disadvantage. Working with outside counsel having such experience with corporate clients can be a valuable source of information and contacts for the university.

In contrast to larger firms, medium-sized law firms will usually provide services in a boutique environment with more specialized expertise. If these areas of specialization overlap with the university's needs, this can be a tremendous asset. Depending on the size of the firm, overhead rates may be more modest, thereby reducing expenses. At many medium-sized firms, senior professionals may be more readily available to university clients and less dependent upon junior associates and scientific advisers. Many medium-sized firms pride themselves on their ability to provide more personal service to their clients. They may actively seek university clients, which can result in the development of very beneficial long-term relationships. For this reason, universities often find medium-sized law firms very desirable.

On the other hand, medium-sized law firms may not be able to provide the specialized services available from larger law firms. Furthermore, the information technology resources necessary to support the university's information requirements may not be as robust or flexible as those available at larger law firms.

Initially, universities may view very small law firms and individual practitioners unfavorably. It is true that these service providers may have limited capabilities and may not have the more flexible resources usually available from larger firms to respond to emergency situations. As an example, many may be totally incapable of handling litigation or be unable to respond to last-minute filing requests due to limited staffing. Once the limitations of these firms are identified, they may still be able to play an extremely valuable role, especially when their specialized skills overlap in strong areas of need. With fewer people involved in the process, communication is usually simplified and direct, which may result in strong bonds forming between inventors and outside counsel. This can prove to be very beneficial when working with challenging inventors.

When evaluating potential service providers, it is easy to fall into the trap of simply listening to the presentations, comparing their relative capabilities, and selecting the firm or firms that appear to be best for the university. Rather than initially approaching the selection process in this way, it is better to first determine what services the university may require. Consider viewing service providers as tools, with the use of some tools having certain advantages over the use of others.

For example, while a rock or a hammer may be suitable alternatives when considering a need to drive a nail, one will typically yield a better outcome than the other. However, a particular type of hammer may not be suited to the task at hand. Have you ever tried to drive a railroad spike with a tack hammer?

Assess the university's needs as objectively as possible. The areas of need most universities should assess include:

- *Technical*: Identifying needs from a technical standpoint is always a good place to start. Looking at the content of past disclosures will provide important insights into your needs. Temper your evaluation of these needs based on past license performance. If you have had more success licensing technologies from some areas and little success in other areas, then this difference is important to recognize. Assessment of past disclosures will not always predict the future, however. Speak with institutional

planning and selected executives to identify new research areas being developed at the university. Also, certain sectors of the research effort within the university may have higher performance expectations than others. Use this information to anticipate what types of technologies may be disclosed in the future.

- *Search and opinions:* If the university technology transfer office is limited in its ability to assess the patentability of new technologies, then patentability search and opinions rendered by outside counsel will be very important. This information must be as accurate and complete as reasonably possible to allow the university decision maker to triage the opportunities presented and only invest in those technologies with the most potential.
- *Patent prosecution:* Not only is it important to know the types of technologies developed on campus, it is also important to characterize the types of patents the university has selected to prosecute in the past. Past patent filings provide an accurate indication of the types of technologies the institution has found to have the most promise. If the objectives of the university technology transfer program change, it may be necessary to re-assess the capabilities of the service providers currently being used. If this assessment leads to concerns regarding the ongoing prosecution of existing cases, identify deficiencies and evaluate alternative service providers. Let experience be your guide.
- *Licensing:* Given the increased resources dedicated to providing licensing capabilities within universities over the years, most basic licensing needs can be met internally. However, the university may need to seek the consultation and assistance of outside counsel in handling more advanced and complex licensing situations. For example, while the internal licensing staff may be able to handle most licensing issues arising from the creation of a startup company, the complexity of issues surrounding the equity portion of such transactions may require accessing the specific expertise of outside counsel.

- *Litigation:* Most institutions do not view the possibility of litigation favorably. Nevertheless, the potential of having to settle a dispute via litigation remains real. While many universities maintain internal legal counsel, this staff will usually have little to no expertise in intellectual property litigation, which is considered a boutique area of the law. If you anticipate a need to possibly initiate litigation or respond to a threat of litigation, this should be factored into your selection process.
- *Trademark and copyright:* When evaluating the intellectual property needs of a university technology transfer program, it is natural to focus on patenting. This should not come at the expense of an evaluation of the university's potential needs in the areas of copyright and trademark law. Not only can the faculty's needs be served, the licensing of such properties can generate significant revenue without a heavy investment of financial resources in outside counsel fees. Seeking assistance with the unique needs of filing for such protection is highly suggested, since it is so rarely pursued.

When the assessment of the university's needs is complete, it is important to identify which needs are the most important given the experience of the technology transfer program. As part of this process, it may be necessary to separate wants from needs. Concentrate on the top three or four requirements and document the specific characteristics of each. It will be important to be able to refer to these in the future when assessing the capabilities of potential service providers.

It is important to document the performance guidelines for potential service providers. Detailing these expectations in an outside counsel agreement executed by both parties is highly recommended. If there are certain practices the university either requires or prefers, document them for potential inclusion in the outside counsel agreement. If there are specific practices or procedures the institution wishes to avoid, document those as well. Rely on your experience when constructing your guidelines and do not compromise. Harmonizing the university's performance guidelines with the established procedures of service providers may lead to some challenges.

However, the university is the client, and outside counsel should be able to reasonably accommodate university requirements. Important points to consider include, but are not

limited to, the field of services to be provided, docketing requirements and reporting, billing rates and procedures, and procedures for communicating patent correspondence and authorizations.

After identifying the university's needs and basic performance guidelines, you can now begin to identify potential service providers. Contacting other university technology transfer professionals may be the best place to start, as they will lead you to firms accustomed to working with universities and university-based inventors. Besides suggesting individual firms, colleagues may be willing to comment on the performance of various firms. They can also share specific contact names and numbers. If possible, use these discussions to identify potential client managers at the desirable firms and which other universities may use these firms. These contacts can be used to confirm information from various sources, particularly when overly positive or negative comments are received. Additionally, inquire about the performance guidelines these universities have incorporated into their outside counsel agreements with specific service providers. Any unique guidelines identified through this process may be helpful in refining your institution's performance guidelines.

There are many other sources of information regarding potential service providers. For example, contacting companies (either existing licensees or potential licensees), can be particularly helpful. Several different types of searches on the Web site of the U.S. Patent and Trademark Office can also yield valuable information. By searching for particular attorneys, agents, or firms on this Web site, you can gauge the prosecution expertise of a law firm in particular technical areas. A search of this same Web site using technical terms resulting from the university's assessment of needs will also identify service providers. If specific areas of overlap are identified with university assignees, individuals at that university may be contacted to confirm whether the patent was licensed and how the service provider performed. Special attention may be paid to potential service providers in proximity. Besides the advantage of increasing the ease and frequency of face-to-face meetings with inventors, travel costs are minimized when local firms are engaged. At the conclusion of this process, create an initial list of potential service providers that may best fit the university's needs and comply with the performance

guidelines. Share the list with the legal services department of the university. In some cases, there may be conflicts precluding the use of certain service providers.

It is desirable to establish contact with the individual who may serve as the university's client manager. Most of the time, these first contacts are made via telephone, but it is best to meet face to face. This will provide an immediate assessment of the responsiveness of the service provider. Concentrate the discussion on the needs of the university, its performance guidelines, and the mission and goals of your university's technology transfer program. Seek to determine how flexibly the service provider can respond to your needs.

A suggested questionnaire is provided below:

- What are your firm's areas of technical expertise?
- Who would serve as the university's client manager?
- What is the size of your firm?
- Where are your offices?
- Which individuals at the firm will most likely work with the university and where are they located?
- What qualifications do they possess?
- To what extent are patent attorney extenders used, such as patent agents and scientific advisers?
- What is your firm's experience working with university clients?
- What problems have you experienced with university clients?
- Are there any particular practices certain university clients use that you like?
- What is your firm's philosophy on patentability search and opinions?
- Does your firm provide estimates for work before authorization?
- What are the typical charges for patents filed by the firm?
- What is the typical timeline for the filing of an application?
- What is the reporting capability of your docketing system?
- Are your clients charged for docket reports?
- Are there any special billing programs available? If so, describe.
- How are charges for overhead services handled?
- What information is included in your bills and what level of detail is used to describe the services rendered?

- Does your firm handle the payment of maintenance fees and foreign annuities?
- What kind of licensing support services are available?
- What kind of litigation experience does the firm have? How would your litigation experience potentially overlap with the needs of the university?
- What additional services are available from your firm of potential interest to the university?
- Does your firm provide newsletters or offer seminars or other educational sessions to keep their clients aware of changes in intellectual property laws, recent court decisions, and licensing practices?
- Why should my university select your firm?

While meeting with the potential client manager is essential, there are other principals you should also meet. In most law firms, client managers are selected from the more senior staff at the firm. As a result, they usually will have some of the highest billing rates. They typically recognize the financial limitations of their university clients and will, therefore, play more of a role in developing strategy and overseeing the quality of the final product. Once the claiming strategy has been finalized, most of the actual drafting will be completed by less senior staff, associates, patent agents, or scientific advisers. It is important that you also meet these individuals and assess their capabilities, since it is likely they will be the primary contacts for the inventors during the drafting process. Although their billing rates may be more modest, they are not necessarily less qualified. In many cases, these individuals have concentrated solely on the drafting and prosecution of patent applications for years, avoiding the administrative burdens of more senior partners.

During your meeting with the potential client manager, be sure to ask about how charges for overhead services are handled (expenses such as long-distance phone charges, copy fees, fax charges, etc.). These charges can add significant expenses. In the early years of university technology transfer, charges for overhead services were routinely billed as their own line items. Increasingly, firms are no longer billing their university clients for such overhead services, preferring simply to adjust the hourly rates of their professionals to recover these costs. It is not uncommon for service providers to seek fixed rates for accomplishing certain tasks, such as filing required documents, etc.

It is also highly advisable to meet the primary support staff of the firm. For example, if the university has a sizable foreign portfolio, meeting with those individuals responsible for day-to-day responsibilities in this area is recommended. This is a complex area of responsibility, so gauging the level of experience handling foreign matters is very important. It is also important to get to know the support staff reporting to the potential client manager. In many cases, contacting support staff directly will yield quicker results at much less cost than working with a patent attorney or patent agent. Beware any service providers that do not showcase the capabilities and accessibility of their support staff. This may be an indication of a lack of resources or skills or a tendency to be too controlling.

Use the responses to these questions, the results of your interview and the reviews of the firms provided by trusted peers to assess the fit of the service provider. It is unlikely a single service provider will meet all of the university's needs, so anticipate using multiple service providers. It is best to limit the initial evaluation to no more than three or four best fits initially. If any of the university's primary needs are not met, consider adding specialized firms for these needs. Of course, if none of the firms seem to fit the university's needs, performing a reality check on the university's basic performance guidelines may be in order.

Engagement

At some point in the review process, it will become relatively obvious which service providers will best meet the needs of the university. Many universities use an outside counsel agreement, or similar agreement, to document their relationship with service providers. Do not assume that outside counsels' experience with other universities and their performance expectations will translate into knowing what they should do in their relationship with your university. The outside counsel agreement should clearly include the service guidelines desired by your university. Any important distinctions, key capabilities, or assurances made by a service provider which may have led to the selection of one service provider over another should be detailed in the outside counsel agreement. If, upon negotiation of the outside counsel agreement, these distinctive elements disappear, or if there is any equivocation of assurances made, you should question your service provider selection.

Typically, determining the term of engagement is a balance between the need of the university to lock in rates to be able to predict and manage expenses and the service provider's need to adjust the rates (upwards, of course) to meet future requirements. Most service providers will agree to a two-year term without much resistance, but some may insist on annual contracts. Alternately, it may be advantageous under limited circumstances to engage outside counsel on a case-by-case basis. This strategy can be particularly effective when working on resource intensive special cases like litigation, patent interferences, and license consultations. Expenses associated with such boutique services can exceed those of normal cases, so negotiating an outside counsel contract to fit the specific nature of the relationship can make it easier to manage the relationship and monitor expenses.

Use the outside counsel agreement to describe the university's needs and its performance guidelines in detail and how they will be implemented. Some basic components may include required liability coverage, records retention, established institutional limits for reimbursement of expenses (travel, hotel, etc.), and guidelines for reporting potential conflicts.

Universities may also find it advantageous to include very specific terms, many of which are the result of past experience. For example, in addition to specifying who the university has empowered to authorize actions, it is recommended the agreement clearly state any actions taken by outside counsel that were not authorized by such individuals cannot be billed to the university. The university should also consider the advantages of describing an acceptable invoice format in detail and specifically show what information will be required. To aid in monitoring the financial status of individual files, the university may find it helpful to require the inclusion of other specific information, such as expenses incurred on the file for the current fiscal year and the total expenses incurred since inception of the file.

Of course, outside counsel will also seek to include provisions of its own. Many firms will request that all-important authorizations be made in writing (letter or e-mail) or that oral instructions be confirmed in writing within a specified time period. This is not an unrea-

sonable request given the increased exposure to risk associated with oral authorizations. Outside counsel may also require a certain level of timeliness in responding to outstanding actions or deadlines. Again, this is not unreasonable, especially from smaller firms or solo practitioners. Given the time-sensitive nature of patent prosecution, it can be difficult to re-task their resources to meet last minute deadlines.

Maintenance

The key to maintaining a good relationship with your service providers is just like maintaining any other relationship. In all cases, effective communication is necessary for success. Effective communication starts by understanding the specific needs of your service provider and following the communication requirements described in the outside counsel agreement. Besides certain authorizations associated with the prosecution of specific cases, it is also necessary to provide other written instructions to outside counsel, such as a request to copy patent-related correspondence to a co-owner or licensee or a request to transfer files from one service provider to another.

Most communications with outside counsel will be more informal, such as discussing options available in responding to a particular obviousness rejection. Often, these informal discussions will provide the basic framework of the relationship, with this framework strengthened by candid and frank discussions of various issues. Both parties will be better informed about the intent of the other party, leading to increased predictability and trust. All of this enhances the basic goal of working as partners to build a valuable patent portfolio.

Communications with outside counsel, whether formal or informal, should be clear and concise, but most importantly, they should be delivered in a timely manner. One of the most common concerns voiced by outside counsel about their university clients is the lack of the timeliness in receiving authorizations. Typically, outside counsel will promptly deliver patent-related communications and documents, providing their clients with sufficient time to decide what to do. Many will even request their clients provide instructions by specific dates in advance of deadlines to provide them with sufficient time to prepare and file a timely response. Despite this, universities will sometimes wait until the last

minute to provide authorizations. While outside counsel is a service provider hired to meet the needs of the university, this does not mean the university should abuse the relationship by not responding to requests for instructions promptly.

Another key to success is working as a facilitator between the outside counsel and your inventors. Simply exchanging contact information between outside counsel and your inventors and expecting them to work together effectively is not adequate. Outside counsel is often unaware of the inventor's personality. Absent this awareness, he or she may not be comfortable dealing with certain issues directly with the inventor or he or she may ask inappropriate questions. This may lead to incorrect assumptions about the inventor's familiarity with patent law, potentially leading to confusion.

Under extreme circumstances, outside counsel may seek to communicate with inventors directly without the involvement of the technology transfer office. Not only can this drive up costs, but also inventors may feel that repeated contacts from outside counsel are distracting or too intrusive on their time, resulting in a loss of cooperation. An inventor may feel more comfortable if a university representative is also involved and serving as a steward of the inventor's and university's interests. The inventor may be willing to ask more questions and less likely to hold back information. One of the most important reasons to participate in such communications is to educate both the inventors and outside counsel about the role of the technology transfer office.

To help minimize expenses, inventors should be encouraged to initially contact the technology transfer office with any questions they might have about patenting or licensing issues. Besides helping to control costs, providing helpful and informative responses to inventor's questions will help build trust between the inventors and the technology transfer office.

Finally, be sure to continuously monitor compliance with your outside counsel agreement. Beware of any drift away from its terms. Often, only a few individuals at larger law firms are aware of the terms of the outside counsel agreement and the performance expectations of the university. When you work with others in the firm, they may continue

to perform as usual for them, but not within the terms of the outside counsel agreement. To avoid this, as you begin to work with others in the firm, suggest that they contact your client manager to familiarize themselves with the terms of the outside counsel agreement. Alternately, you may supply them with a copy of the agreement yourself. Pay special attention to routine operations, such as billing procedures, invoice content, and document management, since small deviations can lead to big problems that can be difficult to resolve.

Despite investing your best efforts into maintaining a good relationship, things may not always go according to plan. Sometimes, one party's performance does not meet the other party's expectations. This is usually a sign of a lack of effective communication. By increasing your efforts to communicate more effectively, many of these problems can be easily solved. When problems are encountered, be sure to communicate potential concerns promptly and work constructively toward a solution.

Termination

Performance expectations, service requirements, and relationships change with time. Obviously, if the law firm decides to discontinue services essential to meeting the university's service requirements, then the relationship should be terminated with the agreement of both parties. Sometimes, the university may only utilize a single attorney or small group of attorneys in a law firm. If this individual or group decides to move to a different firm, you may wish to terminate your relationship with their original firm.

Alternately, a law firm may also independently decide to terminate its relationship with the university. If a law firm decides to discontinue providing services essential to the university's service requirements, or if it determines a conflict exists between its clients, the decision to terminate the relationship may be out of the university's hands. This type of termination rarely causes problems.

If the university becomes dissatisfied with the performance of outside counsel, it is only reasonable to seek to correct any deficiencies. Ultimately, it may become necessary to sever the university's relationship with outside counsel. Under such circumstances, it is

important to remain objective and dispassionately communicate the reasons why outside counsel's services will not longer be required. Most of the time, previous attempts to work through problem situations will make it unnecessary to communicate this decision in great detail. It is usually easiest to simply re-assign the cases to new outside counsel rather than terminating the outside counsel agreement altogether.

If it becomes necessary to terminate the relationship between outside counsel and the university, the primary concern is determining how active cases will be transferred upon termination without jeopardizing the cases. If the outside counsel firm has elected to terminate the relationship, it should provide a high degree of cooperation to make sure the university's files are transferred promptly to a new firm (or firms). In most cases, it has considered the possible termination of the relationship for some time and may already have its plans in place to make sure the files are transferred with minimal risk.

If the university decides to terminate its relationship with outside counsel, there are several important steps to be taken. First, determine what files are assigned to the law firm. Second, identify those cases having time-sensitive issues pending, such as an upcoming response deadline or maintenance fee due, so deadlines are not missed during the transition. Third, select a new law firm capable of handling the transfer of files and contact them to verify their willingness to accept the files. This discussion should include plans for handling any time-sensitive cases as well as contact information at the law firm responsible for forwarding the files. Last, when written notice of termination is supplied to outside counsel, the notice should include a complete list of files and a list of time-sensitive actions necessary. Ask outside counsel to verify this information. Contact information for the client manager at the new law firm should also be included to facilitate transfer of the files.

Conclusion

Considering the pendency of patent applications in the U.S. Patent and Trademark Office, evaluating the performance and overall effectiveness of outside counsel may take years. This highlights the importance of implementing an effective outside-counsel selection process, engaging outside counsel on the most favorable terms to the university, and pro-

moting relationships based on well-defined expectations, reliability, and effective communication. The relationship between the university and outside counsel is not static. Effective communication techniques must be used to build trust between the parties, which is very important when cooperating in an uncertain and changing environment with unpredictable outcomes.

Crafting Claims in the Life Sciences for an International Application

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“The world is flat,” says Thomas Friedman in his bestseller of the same name, and it’s getting flatter every day. Just a few years ago, no one would ever think of filing a patent application in China or India. Yet today, with manufacturing leaving the United States and foreign markets opening to advanced medical technology, the U.S. remains an important, yet shrinking, part of a global patent portfolio. When drafting applications, U.S. patent practitioners typically draft claims with the U.S. market in mind. While there is continuing discussion about harmonizing patent systems, recent developments in patent law have accentuated the differences between the systems. Although a “foreign” associate can revise the claims to comply with the particular requirements of each jurisdiction, these jurisdictions often have their own particular requirements regarding the disclosure necessary to support claims. This article provides guidance on adequate support and proper claim coverage in jurisdictions outside of the United States. First, the article reviews the requirements for the major jurisdictions, then provides some suggestions for use when drafting applications under the Patent Cooperation Treaty (PCT).

A major consideration for building a patent portfolio is whether or not to pursue protection in countries outside the United States. National and/or regional filing outside of the United States is expensive, often requiring costly translations and yearly annuity payments. Additionally, the value of filing in certain jurisdictions remains questionable. Nevertheless, companies continue filing applications outside of the United States. Indeed, nearly 90 percent of the world’s patents are issued through the U.S., European, and Japan patent offices. Although there are many similarities between drafting claims for a U.S. application and those for an international application, there are also significant differences. Understanding these differences can ultimately improve examination, and ensure both support for your claims and proper claim coverage, resulting in cost savings.

Because of the difficulty in summarizing all the legal differences that exist in each country, we will concentrate on filing for medical technology inventions in the most popular countries or regions: the European Patent Office (EPO), Japan, China, Canada, and Australia. First, we briefly summarize differences in claiming medical methods, including the patentability of treatment and diagnostic claims. Next, we will provide suggestions for preparing claims for an application under the PCT.

Overview

Method of Treatment vs. Use of

In the United States, you can claim a method of treating a human. In most of the rest of the world, such methods of treatment claims, particularly those focused on humans, are not allowed. The typical way that such a subject is claimed is by “use of” claims.

However, such claims do not comply with U.S. practice.

Multiply Dependent Claims

In the United States, you can have a claim depend upon more than one claim, but you cannot have a claim that depends upon more than one claim (a multiply-dependent claim) depend upon another multiply-dependent claim. In most of the rest of the world, multiply-dependent claims can depend upon multiply-dependent claims. As will be explained below, this is important for support purposes in Europe.

European Patent Convention

Under the European Patent Convention, European patents are granted for any invention that has industrial application, i.e., can be made or used in any kind of industry and is new and involves an inventive step.¹ Similar to the patentability of subject matter in the United States, there are exceptions to patentable subject matter in the EPO, such as scientific theories, mathematical methods, schemes, rules, and methods for mental acts. A major difference between the U.S. and EPC law is that the EPC excludes methods for treatment of and diagnostic methods practiced on the human or animal body. EPC Article 52(4) states that, “Methods for treatment ... and diagnostic methods practiced on the human or animal body ... shall not be regarded as inventions susceptible of industrial

application within the meaning of paragraph 1 [of EPC Article 52]. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”

Thus, for example, the following claims would not be allowed:

1. A method of treating disease X by administering compound Y (nonpatentable)
2. A method of measuring R (a marker for disease Q) by taking a sample from a subject and analyzing the concentration of substance R.

The second sentence in Article 52(4) EPC provides, however, that substances or compositions for use in any of these methods referred to in the first sentence are not excluded. Therefore, applicants can claim substances or compositions for use in a medical treatment. The EPC allows first medical-use claims for substances, such claims can be written as, for example: “the use of compound X or pharmaceutically acceptable salt thereof as a medicament.”

Further, second medical-use claims, i.e., claims directed to a specific medical use, have been granted if written in “Swiss style,” which generally has the following format: “the use of X (known drug) for the preparation of a medicament for the treatment of Y.”

The patentability of first medical-use claims has never been in question. There has been some question, however, regarding the patentability of second medical-use claims written in Swiss-style form for known compounds with a new medical use. Such second medical-use claims are not explicitly authorized in the EPC articles, and debate has existed as to whether or not such claims are valid if the composition claimed is not novel.

A revision to the current EPC, EPC 2000, went into force in December 2007. The revised law explicitly confirms and provides that second and subsequent medical uses of a known substance or composition are not excluded from patentability, provided that inventive step is involved.² Under the revised law the following forms of medical use claims are patentable:

1. Product X for use as a medicament (first medical use)
2. Product X for the treatment of disease Y (second medical use)

The traditional Swiss style, second medical-use claim, i.e., a method for manufacturing a medicament using product X, should also still be allowable. Thus, after December 2007, applicants will be able to choose which style better suits their needs.

Strategies for claiming medical technologies related to diagnostic methods remain unclear, because the European courts have been inconsistent in defining “diagnostic method.” Hence, it remains advisable to claim diagnostics through their compositions or otherwise follow the Swiss style.

Finally, regarding patentable subject matter, the EPO will not grant patents for inventions that are contrary to public order or morality.³ For example, processes for cloning human beings would be considered contrary to morality.

In the EPO, great emphasis has been placed on finding literal support for a claim. Two recent EPO cases illustrate this. In one case, a claim was not allowed because the exact support for that combination of elements could not be found. In the second case, because the applicant had used a style of having multiply-dependent claims depend upon multiply-dependent claims, it was held that a combination not explicitly discussed in the specification was supported by the claims.

Japan

In Japan “high-grade creation among creations of technical ideas using natural rules” or “the creation of a technological idea that exploits principles of nature” are patentable. The Japanese definition of patentable subject matter is essentially coextensive with that of the EPC and also excludes processes in the fields of medicine, diagnosis, therapy, and pharmacology in which the human body is an indispensable element. The Japanese Patent Office holds that method inventions in the field of therapeutic or diagnostic treatment of humans are not being part of “industry.”

The legal precedence relating to diagnostics is unclear at this time: In some instances, claims relating to a step in diagnosis short of a full diagnosis or final indication have been allowed in some cases, but not in others. As with the EPC, patent protection is open to

the materials that are used in the excluded methods or the products of those methods. Unpatentable inventions are those “likely to injure the public health.”⁴ Typically, the subject matter is claimed as “a composition for doing something.”

People’s Republic of China

In China, inventions possessing novelty, inventiveness, and practical applicability are patentable.⁵ As with the EPO and Japan, an important exception is that methods for diagnosis or medical treatment are not patentable. Swiss format claims to second medical uses are patentable. In China, there is a clear distinction, however, regarding allowable claims relating to diagnostic methods. Claims directed to live humans or animals, to the immediate purpose of obtaining a diagnosis, or to the entire process of diagnosis are not patentable. In contrast, claims directed to obtaining intermediate information or to testing tissue or biological samples *in vitro* are patentable.

Australia

Australian law with respect to methods of treatment, surgery, and diagnostics is similar to the U.S. law in terms of patentable subject matter. Section 6 of Australia’s Statute of Monopolies provides that a manner of manufacture is patentable as long as the invention is novel and has an inventive step. Human beings and their biological processes for their generation are not patentable.

Accordingly, methods of treatment and diagnostic methods directed to both humans and other animals are patentable subject matter in Australia. In addition, the requirements for support, enablement, and utility are less stringent than those found in the United States, and it is easier to obtain broader methods of treatment claims in Australia versus the United States.

Although methods of treatment and diagnostic methods are patentable subject matter in Australia and it is often easier to obtain such claims, Swiss-style claims, which differ in their scope, are also accepted. Therefore, it may be desirable to include both method-of-treatment claims as well as Swiss-style claims for maximum coverage. It bears noting, however, that unlike what will be accepted in Europe, Australia will view a claim that is in

the format “product X for the treatment of disease Y (second medical use),” as being “suitable for use” in treating a disease, thus, such a claim will likely not be viewed as novel.

With respect to diagnostic-kit claims in Australia, diagnostic-kit claims styled as in the United States are often rejected as merely specifying a collection of known reagents and not being directed to a novel article of manufacture. For example, a claim drafted as “a kit for diagnosing disease Y comprising reagent A and B,” is not patentable in Australia if reagent A and B are known. Diagnostic-kit claims comprising known reagents can be amended upon filing in Australia to recite a kit “when used in a particular diagnostic method” to circumvent a rejection.

Canada

Any new and useful art, process, machine, manufacture, or composition of matter or any new and useful improvement in any art, process, machine, manufacture, or composition of matter is patentable. Methods of medical treatment and surgery are not patentable, as they are considered by Canadian courts to produce no economic result relating to trade, commerce, or industry.

However, Swiss-style claims are patentable under Canadian law. The following styled claims are acceptable in Canadian practice:

1. Use of X in preparation of a medicament for the treatment of disease Y
2. Use of X for Y
3. Use of X for treatment of Y

Importantly, if the use claim includes any active method step, the Canadian Patent Office will consider the claim to be a method claim and unpatentable. For example:

1. Use of device X for making an incision in tissue Y (acceptable)
2. The use of claim 1, wherein following the incision, device X is inserted into the incision site (not acceptable)
3. The use of claim 1, wherein the incision is semicircular and at least 2 cm in length (acceptable)

The action of inserting device X in claim 2 above would be considered to be a method step and would render claim 2 into a method claim directed to surgery. Claim 3 would be acceptable, as it introduces no method steps, only limitations regarding the shape and size of the incision.

With respect to diagnostic claims, methods of diagnosis are patentable in Canada. The recited method steps must not comprise a treatment or a surgery step, however.

Drafting International Patent Applications and Claims

It is important for practitioners to understand the differences in style between different countries. Thus, in drafting PCT applications, care should be taken to include claims drawn to all these differing styles. For example, including both method-of-treatment and use-of claims. You should have multiply-dependent claims depend upon multiply-dependent claims to help with support for various combinations. It is also advisable to copy the claim set into the specification to ensure for such combinations in the event that claims are cancelled or amended.

It is also advantageous in your PCT application to place the claims with the most import first. This is because if the PCT issues a lack-of-unity rejection, the claims that will be automatically examined are the first set. If you want additional claims examined, you have to pay additional fees. Also, if the EPO is the designated search authority, it is better to avoid listing method-of-treatment claims first as such claims are not patentable in Europe.

Conclusions

The necessitated differences in claim drafting between foreign countries arise mainly due differences in unpatentable versus patentable subject matter in the respective countries. Although it is not possible to draft a claim set that meets every requirement of all countries without some amendment, a claim set can be drafted that requires relatively few amendments at the time of submission to the national patent office, e.g., only deletion of inappropriate claims. Applicants may adopt different claim-format styles depending on what countries the applicants wish to enter.

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Notes

1. Paragraph 1 of Article 52 EPC.
2. Art 54(5).
3. EPC Article 53(a)
4. See, e.g., Miyako Okada-Takagi, 6 Eubios J. Asian & Int'l Bioethics, 166-68 (1996).
5. *Patents throughout the World*, Thomson West, 2007.

Introduction to Patent Portfolio Building and Management

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Introduction

There are numerous factors for university technology transfer offices to consider when devising a strategy for managing a patent portfolio. One solution does not fit all cases. This is particularly true because most offices have limited patent-expense budgets. If the technology is likely to be licensed by a startup company, the strategy may be more complicated and expensive than if the technology will be licensed nonexclusively to a number of major corporations.

Likewise, if the invention is the result of industry-sponsored research, there will likely be some rights granted back to the sponsor, which can impact and/or obligate a specific patent-filing strategy. In the ideal case, where the technology is the platform for an entirely new field, then using the strategy of filing a first foundational application with an eye toward future filing should be considered. Unfortunately, sometimes with brand-new-field technology, it's difficult to determine if the field is really going to be worth patent protecting.

Patent Family Filings

When it comes to building patent portfolios, perhaps the most straightforward way of thinking about them is in terms of patent families or cases that claim priority to or from each other. In the United States, these patent families typically fall into three categories: continuation, divisional, and continuation-in-part (CIP) filings. Provisional applications in the United States are also used as priority filings, but do not themselves ever issue. Finally, foreign applications stemming from U.S. applications can also be considered part of a patent family.

Use of Provisional Applications

Since their introduction into U.S. patent law in 1995, provisional patent applications have been used by many university technology transfer offices as a starting point for protecting new technologies, when the ultimate patent portfolio strategy is not yet clear. They can be filed with less formality than a regular utility filing and with lower U. S. Patent and Trademark Office (USPTO) fees.

Provisionals are never examined, so if licensing opportunities do not become apparent within the provisional year, the provisional application can be left to expire without ever accumulating prosecution costs. In this way, they can be a less expensive option than a regular utility application. However, over the last decade, as patent prosecution and litigation has occurred on applications stemming from provisional applications, it has become increasingly clear that the time and thought put into drafting the provisional application itself should not be significantly less than the effort for drafting a utility application.

U.S. vs. Foreign Rights

A provisional application used as a priority document in foreign jurisdictions must meet all of the requirements for priority filings. For example, in the European Patent Office (EPO), your priority document must clearly indicate what invention you are claiming. In this instance, simply slapping a coversheet on a manuscript that is about to be published and filing a provisional application may not adequately protect your patent rights in all foreign countries. Additionally, such filing may not be necessary to protect your rights under current U.S. patent law, so filing a provisional may not, in the end, accomplish anything.

In fact, one could argue that this practice gives a false sense of security and could, in the end, be just a costly exercise in futility. If you file a provisional of this nature, then later proceed to file a Patent Cooperation Treaty (PCT) application, then years later file a national phase application in the EPO or other foreign patent office, you may spend quite a bit of money only to find out during prosecution, the priority document you are relying on is not sufficient and that the published paper serves as prior art against your pending application.

Patent Term Optimization

One of the major benefits of filing a provisional first is that patent term (expiration) is not calculated from the date the provisional application was filed. It is calculated from the date the first nonprovisional application stemming from the provisional was filed, which is likely your U.S. utility application date. This means that your invention is protected in terms of public disclosure and an early filing date to eliminate prior art of others, but the patent that ultimately issues will not expire for twenty-one years from your provisional filing, rather than just twenty years, as would be the case if your first filing was a utility application.

In fact, the U.S. provisional application was created to maintain parity in U.S. and international patent terms. In 1994, the General Agreement on Tariffs and Trade Uruguay Round patent legislation changed U.S. patent term from seventeen years postissuance to twenty years from the filing date to create parity with other countries. It also introduced the provisional application to provide U.S. filers with the benefit of an earlier priority filing date that would not begin the patent term clock. Without the provisional application, foreign filers could have an advantage by filing first in a PCT country other than the U.S. and later filing a U.S. application stemming from the PCT application.

For example, if you file first in Germany, then twelve months later, you file a PCT and enter U.S. during national stage, your U.S.-issued patent expires twenty years from your PCT filing date, not your German filing date. The introduction of the provisional was an attempt to provide a PCT priority date for U.S. filers that would not start the clock ticking on patent life earlier than the PCT filing date.

It is still important to make sure your provisional application contains enough disclosure to meet all the requirements for patentability, including utility, enablement, and written description. In addition, if you plan to rely on your provisional for priority in international filings, such as the EPO, you must make sure to meet their requirements as well.

Utility Applications

In general, if the invention is fairly well-formed and proven, it may make sense to go ahead and file a U.S. utility application as the first filing, rather than starting with a provisional application. There are several reasons for doing so. First and foremost, your patent will be examined and should issue faster than if you start with the provisional applications. In university-based technology transfer, having an issued patent gives you a stronger bargaining position than a pending application. Likewise, many companies have the perception that universities tend to file weak provisionals, so even if the patent has not yet issued, showing that you have a well-supported pending utility application may also provide more value in licensing negotiations.

Converting from Provisional

If your first filing was a provisional application, you must decide within one year whether to file a utility and/or PCT application claiming priority from that provisional. Alternatively, U.S. patent law does provide a direct route to convert a provisional filing to a regular utility filing. In practice however, most patent attorneys and agents procedurally file new applications with a priority claim to the provisional, rather than doing a direct provisional conversion. Often the impending expiration of the provisional application provides an opportunity to review the provisional application with the inventors to see if any additional or differing data exists.

For many technologies, particularly in the biological and biotechnology areas, the utility application is an expansion of the provisional, which includes more experimental data to supplement what was already included in the application. This is data that will be useful in convincing the patent examiner that the invention disclosed, supported, and claimed in the provisional application does in fact function as previously described. This data should be incorporated in a way that does not cause it to be viewed as new matter.

When drafting a utility or PCT application claiming priority to a provisional, be cautious about what you add. Anything you add could be considered new matter and not be accorded the filing date of the provisional. This is important for determining what constitutes prior art and what does not. While there is no limitation on adding more disclosure

at this juncture (and, in fact, it is common practice to do so), if you plan to rely on your provisional filing date, be strategic about what you add and why, when filing the utility application.

It is also a time to consider whether the inventors feel there is a new best mode that needs to be added to the application to meet the best-mode requirement. The inventors are required to include in the application the best mode for practicing the invention *at the time of filing*. A new utility application sets forth a new time of filing for the purposes of meeting the best-mode requirement.

Finally, in some portfolios, a number of provisional applications are in essence rolled together into a single utility filing prior to the expiration of the first filed provisional. This rolling together of multiple filings can be a cost-saver down the line, in that prosecution costs are limited to a single application rather than several independent applications. In addition, you may find that, in the course of filing multiple provisional applications within a year, the invention you want to claim becomes more clear, but is supported and described in multiple provisionals; in that case, it makes sense to claim priority to all of those provisional applications.

Continuation and Divisional Applications

When combining multiple provisionals into a single application, bear in mind that, in many instances, USPTO examiners are issuing restriction requirements to limit the number of claims they have to examine in any one filing. It is useful to consider this when drafting your utility application claims, so that when faced with such a restriction, you can decide which claims will be most valuable today and if and when to file divisional applications for the unelected claims. Continuing applications (i.e., continuations, divisionals, and CIPs) can be filed as long as at least one application in the patent family is still pending (not issued.) For unlicensed technologies, you may want to wait until just before issuance of the first application before you invest additional filing and prosecution costs into another application.

You may decide the first set of claims issuing are broad enough to provide you with a solid licensing position. While having additional claims would be nice, they may not enhance the licensing revenue for your technology. As a result, it may make sense not to pursue further divisional applications.

Continuation applications serve two primary functions. First, you may need to pursue a set of claims to an invention described in your application that you did not originally claim. As you work toward commercializing a technology after filing the application, you or your licensee may recognize aspects of the invention that will be commercially valuable that would not have been obvious to you at the time of filing. As long as the invention is adequately described and supported in the original patent application, you can add new claims without adding to the specification and file a continuation application.

Another common reason to file a continuation application is to pursue a set of claims that you cancelled after filing. For example, you might file the application with many claims and shortly thereafter license the technology to a company. It can be important for the licensee to have a license to claims in an issued patent rather than pending claims, as is often the case for startup companies seeking financing.

If your first or final office action indicates that some, but not all of your claims are allowable, it might make sense to cancel those claims that stand rejected, amend any that are objected, and wait for a formal notice of allowance. Then, prior to paying the issue fee, file a continuation application for the claims you just cancelled. This strategy will likely result in one issued patent and one pending application. It will allow you additional opportunities to file arguments in favor of allowance, without the risk of delaying issuance of the allowable claims.

Continuation-in-Part Applications

Continuation-in-part applications are those where there is a need to add new matter to support new claims that you wish to pursue. A CIP application often looks like a similar, but completely new patent application that has a priority claim to an earlier filed nonprovisional patent application.

In a university research setting, it is all too common for the inventors to come to you with an invention and, after filing the utility application, come back with a modification or improvement to the original invention that was not disclosed or supported in the original filing. Use of a CIP may be an appropriate route for protecting the new invention. This is also an opportunity to consider whether the new claims render the claims in the original application obsolete or far less valuable. If this is the case, rather than proceeding with prosecution costs for two cases, you may consider abandoning the original application in favor of the new one.

In a university research setting, use of CIPs may be quite different than in industry, because of the frequent publication of scientific papers by inventors. CIP practice is fairly specific to U.S. patent law. As a result, claims supported by the new matter in a CIP must meet all of the criteria for novelty and nonobviousness in light of all prior art, including the inventor's articles published more than one year prior to the filing date of the CIP. If claims in the application are fully supported by the priority application, these claims are examined with respect to prior art as of the filing date of the priority application; any claims not fully supported by the priority application are not afforded a priority date of the earlier application.

If an inventor presents a paper at a conference just before your priority patent application is filed, and then just over a year later, the inventor comes back with a modification or improvement to the invention, you might be tempted to file a CIP application. However, there will be no benefit in terms of patentability due to his or her presentation more than a year ago. There is typically no cost savings in a CIP versus a standalone utility application and, in fact, there is patent life to be lost. If you believe you can argue that the new claims supported by new matter are novel and nonobvious in view of the inventor's public disclosure more than a year ago, you might as well go ahead and file a brand new utility application that will expire twenty years from your new filing date, rather than a CIP, which would expire twenty years from your priority date about a year earlier.

A final point on this subject is that, regardless of when the CIP application is filed, the resulting issued patents expire twenty years from the filing date of the earliest-filed non-

provisional application to which they claim priority. For this reason, you may want to pursue such filings sooner rather than later, so your effective enforceable lifespan for the resulting issued claims is maximized. On the other hand, you can delay the costs of filing and prosecuting continuing applications by filing them serially, each one just before issuance of the previous case.

Additional Filings on Follow-on Disclosure

Often in university research, inventors will submit follow-on inventions, which are related to a technology filed earlier. These follow-on disclosures may fall into the category of potential CIPs or may represent separate new inventions. Either way, making the decision about whether or not to file on such disclosures can be simple and straightforward in some cases and complicated in others.

If you have a good relationship with a licensee for the original patent, you may wish to get his or her input on the value of additional follow-on intellectual property. Keep in mind, you may be able to extend the life of your relationship with the licensee by having additional patent protection for the improved inventions. This could be positive or negative to the licensee, depending on his or her perspective. In some cases, he or she may be thrilled to extend his or her exclusivity in the market space. In other instances, he or she may not be thrilled to have continued obligations to pay you for freedom to operate.

Dominating Claims in the Patent: Are Follow-on Applications Worth it?

If extended patent life is not a large factor in additional intellectual property protection, other factors must be considered. Has your first patent issued? If so, are the claims broad? If the answer is yes, do you believe you can argue for a higher royalty rate or additional licensee fee for the new technology? If not, you may choose not to file on the new idea. Some licenses have *royalty-stacking provisions*, which limit additional royalties for follow-in inventions. Be sure to consider this when making decisions about additional filings.

If the patent has not yet issued or the claims are not as broad as you would like, having another patent on a follow-on invention may give you a better intellectual property position, as well as a stronger bargaining position.

Picket-Fence Filing Strategy: When Another Entity Holds Dominating Claims

The decision to implement a picket-fence patent-filing strategy should be considered differently in the realm of university technology transfer than in industry. This concept describes the practice of filing multiple patents on various aspects of a product that circle around the broad claim that would read on a single technology or invention.

A broad, dominating patent claim would read on every version of the invention that could be produced. However, sometimes such broad dominating claims are either not available, have expired, or are owned by another entity. In industry, a picket-fence strategy is often used for defensive purposes when a competitor holds rights to the base or dominating intellectual property. When discussions about infringement are raised by the holder of the dominating intellectual property, a cross-license for the narrower, yet still valuable *picket-fence* intellectual property is a common scenario. For a company, this is not only cost-effective, in terms of not having to pay a royalty, but can also allow the company access to the dominating intellectual property to stay in the market. A company might also employ this strategy when a broad dominating claim is not patentable or was patented but has expired to maintain a competitive advantage in the market space.

For a university however, the goal of patenting typically is to license. Cross-licensing, while useful in industry, is not typically a factor in the university setting, because a university does not make products. As a result, it is worthwhile to determine if there are broad dominating claims owned by another entity. If so, that entity may be your only potential licensee for any picket-fence style claims.

On the other hand, such dominating claims often are broadly licensed within a particular industry segment, in which case, your narrower picket-fence style claims could warrant a solid licensing revenue because of the competitive advantage they provide to your licensee. If you are lucky enough to own the dominating intellectual property, you might want to consider picket-fence claims surrounding this intellectual property as a way of extending your patent life, and thus, your licensing revenue for that technology area.

Methods of Use/Treatment vs. Composition/Device Claims

In the area of composition and their methods of use, the application of picket-fence type strategies is quite common. For example, an early patent may cover a new compound and its use in a particular application. Later, your inventors discover a new use for that composition. If you are successful in attaining patent claims covering that new use, frequently in the form of method of treatment style claims, you can prevent anyone from marketing that compound specifically for that new application. Such claims can prove to be quite lucrative. The same can be said for devices and new applications, but such use claims in these instances are not likely to generate licensing revenues of the same magnitude.

Foreign-filing Strategy Basics

In terms of patent portfolio management, it is wise to think about international filing at the time of your first filing. Filing and prosecuting international patent applications can take many years and cost hundreds of thousands of dollars. As a result, university technology transfer offices are often appropriately cautious about such filings. You have to weigh a number of factors carefully prior to making these expensive decisions.

Do you internationally protect a new platform invention? Ideally, yes; however, if you anticipate a big hurdle for patentability, it may make more sense to wait for a licensee and/or wait for the more specific but commercially important follow-on inventions, and pursue international protection for one or two key inventions.

For example, if the first filing contains key broad claims that may be difficult to prosecute toward allowance, and you anticipate the inventor may develop many follow-on inventions, it might make sense to consider international coverage for the later, narrower, but commercially important applications.

PCT

One way to hedge your bets with international protection is to file a PCT application at the twelve-month deadline and wait until the national phase to determine whether you wish to invest the substantial costs into further international filings. Generally, you will spend five to six thousand dollars for a PCT application, which basically buys you another

eighteen months to attempt to license the technology. Then, prior to the national phase deadline, you can discuss with your licensee its interest in international filings and use its desire and willingness to pay for such filings as a driver in your decision making.

National-Phase Filings

One strategy you may wish to consider is direct national-phase filings. If you already have a licensee or if you already know you will only be interested in pursuing international filings in a specific country or two, you might choose to skip the PCT and file directly in the regional office(s) for those countries, thus saving the expense of the PCT application.

Conclusion

Many factors should be taken into account when devising a strategy for managing and building a patent portfolio at a university-based technology transfer office. One size does not fit all; one solution is not the best choice for every invention. The best strategy could depend upon the technology, the goals of the inventors, the objectives of your university and/or its licensees, and of course, your budget. In general, for cash-strapped university technology transfer offices, filing early but perhaps not often is the most effective strategy. Each strategy offers unique advantages and disadvantages, and these can be combined to build and maintain a strong portfolio over the long term.

Validity and Invalidity of Patent Claims

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Introduction

An invalid patent claim cannot be infringed. This statement has far-reaching implications whether you are a patent owner or a party accused of infringement, albeit each situation involves very different analyses and results. As a patent owner, the validity or invalidity of patent claims provides a basis for whether the owner has any leverage in enforcing a patent against an infringer and negotiating or maintaining the terms of a license agreement.

However, this chapter will address validity or invalidity of patent claims in the context of finding yourself in the undesirable position of dealing with the possibility or even the reality of an infringement lawsuit naming your institution as a party.

Once issued, a U.S. patent is presumed valid, as mandated by the U.S. patent statutes (35 USC § 282). This means that courts will deem each claim of the patent as meeting the statutory requirements of novelty, nonobviousness, utility, written description, definiteness, enablement, and best mode, which places a heavy burden to overcome this presumption on those challenging issued patent claims.

It also means that each claim is presumed valid independently of any other claim, which, in most cases, means that, even if an independent claim is rendered invalid, a claim dependent therefrom may still be valid and enforceable. Thus, each claim of a patent requires a separate validity analysis.

The examiners at the U. S. Patent and Trademark Office (USPTO) cannot comment on the validity or invalidity of claims in a U.S. patent, unless it is necessary to do so in the context of a reissue request, a re-examination request, or an interference proceeding (MPEP § 1701). Re-examination and interference proceedings are proceedings available

through the USPTO under certain circumstances for challenging another party's claims, as discussed in more detail below. In some situations, however, the only venue available for challenging the validity of a patent that is or may be enforced against you is the courts. This chapter discusses the different options for addressing claim validity issues before getting to court, once before the court, and outside the court.

Before Going to Court: Invalidity Opinion Letter

There are various ways in which your institution can become aware that it could be named as a party in an infringement lawsuit. In one scenario, a patentee (Company A) sends a registered or certified letter providing notice to you that it has one or more patents and extends an invitation to discuss licensing or other agreement options.

If Company A is savvy about its intellectual property rights, the letter (or at least the first letter sent) will not expressly accuse you of infringement or even threaten you with litigation, because to do so would allow you to file a *declaratory judgment action* with the court, wherein you as the plaintiff ask the court to declare that the claims of the patent are invalid or that the claims are not infringed. Declaratory judgment actions are discussed in more detail below.

It is more likely that Company A will word the letter carefully, providing notice of its patent(s) and documenting your receipt of the notice (by registered/certified mail or otherwise). This allows Company A to start the clock on calculating damages (i.e., monetary remuneration for the financial harm caused to the patentee by your institution's activities) if Company A brings a patent infringement lawsuit against your institution. This presuit notice to your institution will also be relevant to Company A's potential claim of willful infringement, which can result in a tripling of any damages award. Company A would likely base its willful infringement claim on the fact that your institution had notice of its patent(s) and, thus, was allegedly aware that it was infringing and continued to do so nonetheless.

An institution should not ignore such correspondence because it puts the institution in the position of having knowledge or places an expectation on the institution of having knowledge (i.e., the institution knew or should have known) of one or more patents it

may be infringing. A patentee could use this correspondence at trial to demonstrate that your institution was reckless in failing to avoid infringing a patent of which it was aware.

A different scenario whereby your institution may become aware that it is possibly infringing a patent is through a faculty member or other employee informing you or other administrative officials of a patent that he or she believes is related to activities he or she is carrying out. In either situation, whether by notice from a patentee or through information from an employee of potentially infringing activity at the institution, the institution needs to consult a patent attorney at this point.

In some situations, the best course of action by your institution may be a dialogue with the patentee to work out terms of a license or other agreement so that the patentee will not pursue litigation against your institution.

If this is not a feasible option for the institution or if your institution's patent attorney has provided you with reasons why the institution's activities may not be infringing, your institution may instead choose to have its outside patent counsel provide a letter providing a legal opinion letter addressing one or both of these positions.

After reviewing the facts and the patent(s) at issue, your patent attorney may propose either the preparation of a noninfringement opinion letter, which explains that the claims of the patent(s) involved are not infringed by the activities at the institution, or the preparation of an invalidity opinion letter, which explains that the claims of the patent(s) involved are invalid and, therefore, cannot be infringed.

Which type of letter to pursue is dependent on the circumstances of the institution's allegedly infringing activity or technology. If, after reviewing the patent(s) at issue, including their complete file histories, and gathering information and discussing the details of the allegedly infringing activity or technology with those involved in it, the patent attorney decides that reasonable legal arguments can be made that the institution does not infringe the patent(s), either literally or under the doctrine of equivalents, then an opinion of noninfringement would be appropriate.

If after such an analysis, however, the patent attorney is not able to reach this conclusion, generally no letter or other written record addressing infringement should be prepared. Instead, the patent attorney may suggest analyzing claim validity to establish a basis for writing a letter explaining why the patent claims at issue are invalid.

One should obtain an invalidity opinion letter before becoming involved in litigation and use outside patent counsel to prepare the opinion letter to avoid issues of conflict of interest and bias that could arise if such an opinion is prepared by an inhouse attorney or someone with a financial or other incentive to provide anything other than a fully objective analysis. The letter should provide an explanation of the legal standards for patentability and set forth the facts regarding the prosecution history of the patent under analysis, including rejections that were made and how they were overcome.

The letter should then provide a discussion of each claim and why a court would not consider each claim valid. Such reasoning can be based on various factors, such as disclosures in prior art references, particularly those that were not considered during the prosecution of the patent and that provide teachings that would anticipate or render obvious the claims of the patent (35 USC §§ 102, 103).

Other factors can include an analysis of the language and scope of each claim and a legal discussion of why the language of the claim is not in compliance with statutory written description requirements and/or why the scope of the claim is not adequately enabled (35 USC § 112). Arguments can also be presented explaining that the claims should be deemed invalid for failure of the specification to disclose the best mode for carrying out the invention at the time the application was filed. Although less common, an analysis can also be made regarding whether the claims meet the utility requirements set forth in the U.S. patent statutes (35 USC § 101).

If relevant, an invalidity opinion letter can also address other bases for invalidating claims of a patent or rendering the patent unenforceable, including such issues as incorrect inventorship or inequitable conduct before the USPTO. To raise these issues in an invalidity opinion letter, a detailed analysis of the facts surrounding these issues must be

included, as well as an explanation of how the legal standards for asserting invalidity or unenforceability due to such improper conduct have been met.

An invalidity opinion letter must be a competent and well-reasoned analysis of the facts and legal bases that lead to a conclusion of invalidity of the claims at issue. It does not provide any guarantee or assurance that your institution will not be sued for infringement or found by a court to be carrying out acts of infringement. What it does provide is a basis for the institution to believe in good faith that its activities are not infringing because there is no valid patent claim to infringe, which allows for a defense against a claim of willful infringement that is likely to accompany an infringement claim. Once such a defense against willfulness is raised, the opinion letter is no longer protected by attorney-client privilege and its contents become available to the opposing party and to the court. Accordingly, all such opinion letters should be written with this possible outcome in mind.

One final point on invalidity opinion letters is that, in some circumstances, this good faith belief of no infringement can also be used to improve your leverage in negotiating a license or other agreement. However, care must be taken to maintain the privileged status and confidentiality of the legal opinion.

Once Before the Court

If it becomes necessary for your institution to use the court system to address the issue of whether a patent claim is invalid, there are typically two routes that can be pursued: that of a proactive plaintiff in a declaratory judgment suit or that of defendant in an infringement suit. Different ways to address claim validity in either of these situations are discussed below.

Declaratory Judgment

Traditionally a patentee could wait to file a patent lawsuit at its convenience. The patentee could decide to sue customers of a competitor for the customer's infringement without suing the patentee's competitor itself. This allowed the patentee to pick the venue for the lawsuit. A patentee could target the competitor's customers to disrupt the relationship between the competitor and its customers. The competitor, however, could not force the

patentee to engage the competitor itself in litigation. Thus, the competitor could not know when, where, or even if the patentee would file an infringement suit.

To remedy this situation, Congress in the 1920s enacted the Declaratory Judgment Act, which gave the Federal Courts jurisdiction to hear cases brought by someone whose interests (i.e., a competitor or other potential infringer) were affected by threat of a patent suit. This provides a potential infringer or other interested party the opportunity to proactively seek a judgment from the court that the patent at issue is invalid and/or not infringed without having to wait for a lawsuit from the patentee.

The Declaratory Judgment Act gives standing (i.e., the legal right to bring a lawsuit) to sue a patentee where the plaintiff (i.e., the potential infringer) has a threat of injury from a patent infringement accusation. This occurs in a situation where the plaintiff wishes to take action but taking that action may subject it to a patent infringement lawsuit.

For example, standing can arise if the plaintiff has been accused of infringement or threatened with legal action by the patentee. Another example is where the plaintiff is operating under a license agreement for the patent but believes it should not have to be bound by the license or pay royalties due to noninfringement or invalidity of the patent claims.

Formerly, where there was no risk of suit (e.g., a covenant not to sue was in place), the plaintiff lacked standing to bring a declaratory judgment suit against the patentee. As noted above, a patentee will typically try to insulate itself from the threat of declaratory judgment suits by couching its communications with a potential infringer in terms of offering a license under the patent as opposed to accusing the recipient of infringement.

The Supreme Court, however, recently altered the law in this area (see *Medimmune Inc. v. Genentech Inc.*, 127 Supreme Court 764 (2007)), with the result that, arguably, even a letter giving a patent number and suggesting that there will be licenses available may give a potential infringer standing to file a declaratory judgment suit. Similarly, even a promise or intent not to sue may be insufficient to avoid a declaratory judgment suit. In circum-

stances where the patentee still has the right to sue, even if it indicates its unwillingness to, grounds for a declaratory judgment suit may exist. Thus, this change in the law lowers the threshold required to have standing to pursue a declaratory judgment action in certain circumstances.

Further, it likely does not matter whether the potential infringer has yet to engage in the allegedly infringing activity. A recipient of an infringement charge, even under the guise of an offer to license, likely can file a declaratory judgment suit to remove any cloud over its ability to engage in activity in light of the patent(s) at issue. Previously, a plaintiff would have had to engage in the arguably infringing activity before it had standing to bring such a suit. Recent court decisions are more favorable for standing where the plaintiff has not actually engaged in the allegedly infringing activity but has intentions or plans to engage in the activity.

In sum, as courts interpret the law, a potential infringer can file a declaratory judgment suit before a threat or without a threat of suit as long as a patentee states that an activity or technology of a potential infringer is covered by its patent(s). A declaratory judgment action can ask the court to decide not only whether the patent claims are valid, but also whether specific activity constitutes infringement.

In such a declaratory judgment suit, the patentee has the burden to show that the plaintiff's activity is infringing and the plaintiff has the burden of proving that the patent is invalid and/or unenforceable (if alleged). In other words, the same burdens exist as in a normal infringement suit filed by the patentee, as described below.

Infringement Suit

Given the numerous requirements for the grant of a patent by the USPTO, any patent is subject to attack on the basis that it violated or did not meet one or more of the legal requirements for patentability. Thus, in an infringement lawsuit, the accused infringer can raise a defense that the patent did not meet the requirements for patentability, i.e., the patent is invalid. The accused infringer then has the burden of showing that the patent is invalid.

Each accused infringer also has the defense of denying that the scope of the patent claims covers the accused activity, i.e., that the patent claims are not infringed. It is the patentee who then has the burden to prove infringement of one or more claims. An accused infringer can also defend the suit by alleging that the patent is not enforceable under the principles of equity including unclean hands and certain other specific defenses relating to enforceability, such as inequitable conduct arising out of the patentee's conduct before the USPTO. These defenses, some of which are more accurately described as counterclaims, typically are directed to individual claims in the patent. Some defenses, such as enforceability, can affect the entire patent.

As noted above, when the USPTO issues a patent, by statute it is presumed to be valid, which includes the presumption that the patent claims have met all of the legal requirements for patentability. Discussed below are the more commonly occurring bases for invalidity. Specific fact situations could give rise to more or different invalidity allegations than described here.

Invalidity Due to Prior Art

In examining the patent, the USPTO makes a determination of whether the subject matter claimed in the patent application meets the requirements of being new (novel) relative to what was known in the art before the application was filed (the prior art). Likewise, the subject matter of the patent claims must be nonobvious in light of the state of the prior art.

Novelty of an invention refers to whether the subject matter in a patent claim is described in or known from a single piece of prior art, e.g., a single document, prior patent, public disclosure, etc. The question of obviousness usually rises in the context of combining more than one prior art reference to determine if the subject matter of a claim would have been obvious to one of ordinary skill in the art at the time of the invention.

During the application process, the USPTO examines the claims of an application for novelty and nonobviousness in light of the prior art available to the examiner. The examination process at the USPTO, however, has its limitations; the examination of the claims is only as good as the information available to the examiner handling a given application.

The prior art search conducted by the examiner typically consists mostly of a review of other patents and printed publications available in various patent collections and publication databases. In addition to overlooked patents and patent publications, an accused infringer may be aware of other public disclosures, such as journal articles, theses/dissertations, or other documents not included in the examiner's review that nonetheless constitute prior art to the patent claims.

The accused infringer can also rely on prior art activities, including, e.g., the sales of devices or public uses of processes. Such new prior art, which may not have been available to the examiner during review of the patent claims, is available to the accused infringer for use in meeting its defense burden of demonstrating the invalidity of the patent claims at issue in the lawsuit. Specifically, on the basis of these sources of new prior art, the accused infringer can argue that the patent was improperly granted because these materials show that the invention (what is claimed) does not meet the statutory requirements that the invention be new or nonobvious over what was known or available to the public before the patentee's invention.

Other Invalidity Defenses

Besides novelty and nonobviousness over the prior art, other legal requirements of patentability mandate that the patentee fully disclose the invention in a patent application to fulfill the patentee's part of its bargain with society of getting the benefit of exclusivity of the patented subject matter in return for contributing to the body of knowledge involved in making and using the claimed invention. Thus, the patentee's disclosure of the invention as set forth in a patent application must be sufficient so that the public gets the full benefit of the invention at its expiration.

These other legal criteria include (a) enablement, which requires that the patentee teach one of ordinary skill in the art enough to be able to make and use the invention (35 USC § 112); (b) utility, which requires that the patentee disclose a specific, substantial, and credible use for the claimed invention (35 USC § 101); (c) written description, which requires that the patentee provide adequate written details of the full scope of the claimed invention in its patent application (35 USC § 112); and (d) best mode, which

requires that the patentee disclose the particular embodiment of the claimed invention the inventor believes to be the most useful or best way of using the invention at the time of filing (35 USC § 112).

As these are legal criteria for patentability, the claims of an issued patent presumptively meet all of these requirements. This presumption of validity, as with the presumption of validity based on novelty and nonobviousness, is rebuttable by the accused infringer. It is not uncommon that once a litigation has commenced, there is often much more evidence available on these issues than that which was before the examiner during prosecution of the application. For example, inventor testimony, the court's definitions in interpreting the patent's scope and other information revealed during pretrial discovery may provide new evidence that was not available to the USPTO and the accused infringer can use such evidence to rebut the presumption of claim validity.

Unenforceability

Other defenses to a patent infringement charge include certain equitable defenses along the lines of inquiring whether the patentee has unclean hands due to failure to deal honestly with the USPTO while obtaining its patent(s). These defenses deal with the patentee's state of mind during patent prosecution.

The patent applicant has a duty to deal honestly with the USPTO during the prosecution of patent claims. Patent prosecution is known as an *ex parte* procedure between the applicant and the USPTO with no direct representation by the public or any competitors. The examiner's role is to protect the public by seeing that the conditions for patentability are met before any patent issues. The examiner, however, has limited resources and, therefore, the applicant has a duty to interact honestly with the examiner and provide certain information that may be material to the patentability of the applicant's invention.

The issue of inequitable conduct can arise in the context of whether an applicant has met its obligation to disclose material prior art or other information to the examiner or has misled the examiner during prosecution. In some situations, failure to meet this obligation is referred to as fraud on the USPTO, though the legal standards for inequitable conduct are not as limited as for common law fraud.

Inequitable conduct most often occurs where the patentee, as applicant, did not reveal to the USPTO examiner the most relevant prior art of which the applicant knew. Without this knowledge of material prior art, the examiner is prevented from making a decision on patentability on the best record. Similarly, if the applicant made misleading representations regarding what is or is not in the prior art, that too can constitute inequitable conduct. This is especially true when the examiner is not in a position to independently ascertain the true state of affairs or test the accuracy of the patentee's representations. Thus, inequitable conduct can take the form of misleading arguments made by the applicant, misleading affidavits filed in connection with the prosecution, or other misleading or incomplete assertions to the USPTO made in the course of obtaining a patent.

An inequitable conduct defense has two primary elements: materiality and intent. First, an inequitable conduct defense requires the patent challenger to show that the information not given to the patent examiner or the misleading nature of the arguments to the patent examiner were material to the examination of the patent claims. This is usually evaluated under the test of whether a reasonable examiner would have considered the information important in assessing patentability.

Second, the party asserting inequitable conduct has the burden of showing that the relevant prior art was withheld or that relevant representations were made with intent to deceive the USPTO. If the patent challenger is successful in proving that material prior art was withheld from the USPTO with intent to deceive, the result is unenforceability of the patent at issue. The patent is not technically invalid (for example, the claimed invention may still have been otherwise patentable), rather the patentee can no longer enforce the patent against any alleged infringers. The unenforceability of a patent due to inequitable conduct cannot be cured after the fact, so the patentee will never be able to enforce the patent against competitors, third parties, etc., after such a holding by the court. Also, an inequitable conduct determination usually affects the entire patent even if the inequitable conduct was limited to certain claims.

Invalidity or Unenforceability Due to Incorrect Inventors

As a further requirement to obtain a patent, the applicant is also required to identify the proper inventors of the subject matter of the patent claims. There are technical rules for

determining who should be named as an inventor. For example, in some situations, persons assisting the main inventor may have made a conceptual contribution that rises to the level of inventorship and must be named in the application or patent. Conversely, a technician who carried out experiments at the direction of another, or a senior-ranking individual in an organization, either of whom may have been involved in discussions about the invention but who did not make a conceptual contribution, may not necessarily qualify as inventors.

Inventorship is normally correctable, even after a patent has issued or after a potential infringer has raised an allegation of incorrect inventorship. Inventorship is not correctable, however, where inventors were listed or not listed with deceptive intent. For example, in a situation where the patentee had something to gain or lose by listing or not listing inventors, the court may hold that the incorrect inventorship was stated with deceptive intent and, thus, cannot be corrected, resulting in an invalid patent.

Compare, for example, a situation where an inventor was not listed on a patent because he or she was otherwise entitled to a royalty that would increase the cost to the patent owner verses the situation where an inventor was omitted who was under a preexisting obligation to assign the patent to the patent owner who would divide a set royalty among all the inventors regardless of how many there were.

Raising Invalidity or Unenforceability Defenses in Litigation

A determination of whether or not a patent is valid is separate and distinct from a determination of whether or not an accused process or product infringes the patent.

Sometimes the outcome of only one of the two determinations can end the case.

However, if the case goes to trial, the court may be required to render a decision on both questions.

One possible outcome when both questions are considered is a finding by the court that the claims of the patent do not meet the requirements for patentability and are, therefore, invalid. This is evaluated on a claim-by-claim basis. Once the claims are rendered invalid, they cannot be infringed, as there is nothing left to infringe. The accused

infringer or third parties no longer need to be concerned about infringing the claims of an invalid patent, as the patentee will no longer be able to assert these claims. Invalidity cannot be subsequently cured. There may, however, be other patents owned by the patentee or even third parties that contain valid claims directed to similar subject matter.

A second possible outcome is a finding by the court that the patentee's claims are valid but that they are not infringed by the accused product or process. This outcome reflects that the patent does meet the requirements for patentability or, more technically, any challenge to the patent's validity did not meet the burden of showing that the USPTO incorrectly issued the patent with its claims. While the patent may be valid, the decision of not infringed means that the accused product or process does not come within the scope of the patent's claims.

While these products and/or processes do not create liability for the accused infringer under this patent, it does not mean that the products or processes may not infringe other patents owned by this or another patentee. It must also be kept in mind that a different product or process, for example, a change in the accused product or process, may bring the product or process within the patent scope, i.e., result in infringement, thereby subjecting the accused infringer to liability.

The remaining option is for a court to find that the patentee's claims are indeed valid and infringed by the accused party's process or product. This result reflects that the patentee meets the requirements for patentability and the accused product or process comes within the scope of the patent's claims. In this situation, the patentee is entitled to a remedy for this infringement, for example, reimbursement of economic damages incurred as a result of the infringement and/or an injunction to prevent the infringer from continuing its infringing activities. At this point, the court may also consider the issue of whether infringement of the patentee's claims was willful, a finding of which can result in a tripling of the previously calculated damages. As discussed above, should an accused infringer find itself in this situation, a previously prepared invalidity or noninfringement letter should be considered as a possible defense, with consideration of the associated advantages and disadvantages as described above.

Outside the Court: Options to Invalidate Claims within the USPTO

Although as noted above, a USPTO examiner cannot publicly discuss the validity of an issued claim, there are certain situations that arise in which the USPTO can be the venue for addressing claim validity, which can occur either before or after a patent issues. These opportunities include: (1) an interference proceeding, (2) a third-party request for re-examination, and (3) a submission of relevant prior art to the USPTO by a third party, each of which is discussed below. One should note that as of September 2007, Congress was considering legislation that could provide additional avenues for challenging the validity of a patent even after issuance.

Interference Proceeding

The USPTO's Board of Patent Appeals and Interferences (BPAI) conducts interference proceedings to determine which of two competing applicants or patentees is entitled to a patent. When the USPTO determines that a patent and a pending application claim the same invention or that two pending applications claim the same invention, the USPTO uses an interference proceeding to determine who is technically the first inventor and is thus entitled to a patent. The successful party gets or retains its patent and the patent of the unsuccessful party is rendered invalid or, in the case of an application, the losing party loses the ability to receive a patent on the claims at issue in the interference proceeding.

An advantage of pursuing an interference proceeding as a venue for invalidating claims is that the BPAI functions within the USPTO as a specialized court that is well-versed in the law regarding patentability. Likewise, the BPAI is not afraid to immerse itself in the technology of the invention. This is in contrast to a District Court proceeding involving a jury whose understanding of the law and technology may be suspect, leading to much greater unpredictability as to the outcome. Also, in most cases (but not all), an interference proceeding may be less costly and time-consuming in comparison to a litigation and an appeal of an unfavorable BPAI decision to the court remains an option.

A disadvantage of an interference proceeding is that you need to have your own application pending or a patent issuing during the pendency of the other party's application. Your application must include a description of your invention in sufficient detail to allow

you to claim subject matter that the USPTO will determine to be the same as or obvious in view of the subject matter claimed in the other party's application or patent. The timing of when claims are presented for the purpose of provoking an interference proceeding is critical (See 35 USC § 135), and if this requirement is not met, the opportunity to get an interference declared will be lost.

As noted above, the USPTO must also determine that the claims presented in the applications of the respective parties are for the same invention. Before an interference can be declared, each party must have subject matter in the claims that is in condition for allowance pursuant to the criteria for patentability as described above. That is, all other issues that must be resolved before patent issuance, such as utility, novelty, nonobviousness, etc., must have been decided in favor of patentability. Only then will the USPTO consider whether to declare an interference.

Once it declares an interference, the USPTO sets a tight calendar of due dates in the interference proceeding that are not easily extended.

The first stage (approximately the first half of the interference calendar) is directed to the filing of preliminary motions that deal with every possible issue except the actual priority issue. Preliminary motions involve the raising of questions such as whether the applicant is entitled to particular priority dates of any other patent applications, whether the subject matter of the interference count (the same invention) should be redefined or restated, etc.

For purposes of invalidating the claims of the other party, preliminary motions can be filed on matters directed to the unpatentability of the invention by the opponent, employing all of the arguments discussed above for invalidating a claim during a court proceeding. Some preliminary motions directed to unpatentability can result in a suicide squeeze play, in that, if granted by the BPAI against the opponent, the same evidence will stand as a determination that the movant's application is likewise unpatentable.

Once the preliminary motion phase concludes, the BPAI can render an opinion that the claims of one party are invalid, ending the proceeding at this point. If the BPAI fails to

find the claims of either party invalid at this point, the next phase of the interference proceeding is initiated. In this second phase, each party introduces evidence demonstrating when the claimed invention was conceived to determine who was first to invent what is claimed. The outcome of this phase of the proceeding is an opinion by the BPAI that one party made the claimed invention before the other party and is, therefore, the only party entitled to a patent on the invention.

Re-examination Request

A third party can challenge the validity of an issued patent directly through the USPTO by filing a request for re-examination and paying the requisite fee (which is currently more than \$2,500). A re-examination proceeding essentially reopens the prosecution of claims on the basis of new information brought to the attention of the USPTO.

However, the only grounds for challenging validity via this route is a demonstration that the claims of the patent at issue are unpatentable because they are anticipated and/or obvious in view of subject matter in the prior art that was not already considered by the examiner during prosecution of the allowed claims. Generally, issues related to other patentability criteria, such as enablement, written description, best mode, utility, or inequitable conduct, cannot form the basis for requesting re-examination.

Therefore, this route is only practical to consider if one has relevant public disclosures (which must be prior art, i.e., publicly available before the priority date of the patent) that have not been considered by the examiner in determining patentability of the patent claims and that provide a reasonable basis for the USPTO to consider reopening the case for further examination. In some circumstances, evidence that an invention does not work as claimed may be presented for consideration in a re-examination request.

If such art or evidence is available, the benefit of requesting re-examination is that it allows for the possibility that the claims of the patent at issue could be rendered invalid or at least narrowed in scope, such that the patent is no longer a problem for the third party.

The potential disadvantages of requesting re-examination of another party's patent is that the opposite outcome is possible; i.e., the original claims can be upheld and the relevant art or evidence is now on the record, invoking a strong presumption of validity in view of this information. In addition, under current law, a challenger may be estopped from raising in a subsequent challenge defenses it could have raised in a re-examination proceeding. In other words, if the claims are upheld, the re-examination may have the unintentional effect of actually strengthening the patent that is being challenged.

Third-Party Submissions to the USPTO

As an additional mechanism for the USPTO to minimize the issuance of claims that do not meet the criteria for patentability and allow the public to assist in the patent process, there are procedures in place at the USPTO whereby a third party can submit relevant information (typically public disclosures or prior art) to allow an examiner to consider such information during prosecution of a patent application. As noted above, the examiners are limited in their access to public information and, even with the duty to disclose what an applicant knows, there are times when information material to the patentability of claims in an application is only known by a third party, which is typically a competitor or other party with an interest in the outcome of the examination of a particular patent application.

Such submissions can be sent anonymously, and they can be sent during examination of claims of a patent application that has been published by the USPTO (37 CFR § 1.99). Alternatively, the submission can be made before a patent application is published, in the form of a protest (37 CFR § 1.291), but this latter option requires specific knowledge of a patent application that is not yet publicly available and the submission must include an explanation of the relevance of the submitted documents. In contrast, a third-party submission during examination of claims in a published application cannot include any written comments or explanation of the relevance of the submitted documents.

The USPTO has discretion over whether the submissions are included in the record of a patent application and the applicant must be given notice of the submission. If a submission is entered into the record of a pending application, it is up to the examiner handling

that application to decide if the information provided impacts on the patentability of the pending claims. Thus, there is no guarantee that a third-party submission will have any invalidating effect on a pending application and may have the consequence of allowing the applicant to amend the claims to get around any such submitted art.

An alternative way to get information into the record of a pending application is to send the information directly to the applicant, thereby triggering the applicant's duty to disclose such information to the USPTO. It is best to send such information to the applicant or the applicant's attorney by registered mail or other means to document that it was received, along with a statement regarding why the information is material to the patentability of the applicant's claims. This enhances the burden on the applicant to disclose the information to the USPTO to avoid the appearance of failing to disclose material information, which can be the basis for a charge of inequitable conduct, thereby rendering any resulting patent unenforceable.

Conclusion

In summary, if your institution is facing a possible patent infringement lawsuit or if you are aware of patent applications that may become problematic should claims issue, this chapter sets forth many of the avenues available to you to address such situations. Identifying these situations early and implementing some of the strategies described above gives you options for protecting your institution or at least minimizing any negative effects.

Soliciting and Managing Copyright Inventions and Copyright Licensing: Part 1 Creative Works

Giovanni Tata, PhD

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Introduction

Having agreed to undertake the task of commenting on soliciting and managing copyright inventions, a fairly obvious question comes to the fore: How is soliciting and managing copyright inventions different from soliciting and managing technology inventions?

First let's start with defining *copyright inventions*. Many technology transfer offices divide intellectual properties (IP) into two categories: technical works and creative works. Technical works include IP that is generally of a scientific, medical, engineering, or technical nature, such as patentable or unpatentable inventions, devices, machines, processes, methods, compositions, and computer software.

Creative works include all copyrightable IP that is of an artistic, scholarly, instructional, assessment, or entertainment nature. Examples of creative works include creative productions, such as works of art or design; musical scores; books, poems, and other types of scholarly or creative writings; films; video and audio recordings; and instructional materials, such as textbooks and multimedia programs. All computer software is usually included in technical works except that which includes content such as videos, graphics, text, etc., or which is clearly developed for entertainment or for instructional purposes, e.g., electronic textbooks and textbook supplements, virtual labs, classroom and self-study tutorials.

At Brigham Young University (BYU), like at most institutions of higher education, copyright inventions are the domain of the faculty member or developer who created them. In fact the university policy states that the university retains ownership right to all technical works but relinquishes ownership rights to the developers of creative works when nominal use of university resources are used in the production of the IP. It is only when substantial

university resources are used in the production of creative works that the university will retain its ownership position, and income from the project will be shared with the developers. Here is a link to the BYU IP policy <http://www.ipsinfo.byu.edu/ippolicy.htm>.

Soliciting Copyright Inventions

The BYU Technology Transfer Office (TTO) was established in 1989, and like most university technology transfer offices, it focused on technological innovations with lucrative licensing potential. Therefore, the staff of the TTO virtually ignored any IP that was not technology-based. There were only two licensing professionals, and they already had more than they could handle without adding books, videos, software, and other creative works to their overflowing in-boxes. The TTO director indicated to the administration that the TTO was not able to handle creative works and that a separate office was needed to allow dedicated staff to focus on many products the TTO simply would not have time to commercialize.

Following a major revision of the IP policy, BYU established the Creative Works Office (CWO) in 1996 to take advantage of commercial applications developed in the areas of instructional materials, software, and creative works such as art, music, and other media. The university administration had decided they wanted to tap into the copyrights and content developed at BYU, so they created an office specifically dedicated to the commercialization and licensing of creative works, separate and distinct from the TTO.

The newly appointed CWO director asked the BYU administration to place the new office in a central location for easy access by faculty members and an increased presence on campus. Not only did the arrangement relieve an already heavy workload in the TTO, but it also engendered specialized expertise BYU felt it needed when dealing with this very different form of IP. The administration realized that copyrights and creative works are different animals than what the TTO was handling.

The major task of the first director of the new CWO was to educate the academic community about the new policy and the inclusion of creative works as part of the disclosure process. By the time BYU formed the CWO, the TTO had been soliciting disclosures for

about seven years, but only in three of the ten colleges on campus: the College of Engineering, the College of Physical and Mathematical Sciences, and the College of Life Sciences, where all the technical disclosures originated.

Therefore, a deliberate effort was needed to reach the remaining colleges on campus to mine for creative works that the administration knew faculty members were developing. Several seminars were held in colleges and departments to provide information on: which creative works the new IP policy covered, the disclosure process, and the way the CWO would handle copyright inventions. Because the CWO was interested in only those copyright inventions where the university had invested substantial resources (e.g., university funds were used in the development of the creative work or the faculty member had received paid leave) it was critical to find the gatekeepers of the funding resources and identify university-funded projects.

Inventions vs. Copyright Innovations

One of the critical differences between technology-based innovations handled by the TTO and IP handled by the CWO is that the latter usually involves a finished product. Unlike many technologies that receive patents but still face a long road to the marketplace, as soon as a creative work is created, the IP is ready to be licensed and disseminated. It could be a video, CD, software program, or instructional material in the form of a book. When a product is disclosed to the CWO, it is usually only a few weeks away from being available for purchase by the public. The office uses an electronic disclosure form for copyright inventions that asks many detailed questions about the nature of the project. The department secretary provides assistance to the developer by answering all the developer's questions. Here is a link to the disclosure form used by the CWO:
<https://creativeworks.byu.edu/infocenter/newproject/>.

In addition, the CWO only handles IP where the university has invested substantial resources. Faculty members can continue to publish their own books as long as they do not use substantial university resources. For example, the School of Education has close to fifty products, the majority of which are video-anchored and have many books associated with them, but because they were developed with the use of university resources, they belong to the university.

That does not mean, however, that the authors are locked out of potential financial gain. In fact, the CWO uses the same compensation policies as BYU's TTO, with 45 percent of revenue going to the developers, 27.5 percent to the college where the faculty member works, and 27.5 percent going back to the CWO. Whatever revenue remains with the university goes to a scholarly support fund that helps underwrite other projects. In addition, if the faculty member decides to put any portion of his or her royalties into a designated research account, the university will match that amount dollar for dollar.

Managing Copyright Issues

While the CWO operates independently of the TTO, the two do share resources such as office space, an office manager, and a receptionist. There are actually three separate offices in the suite: Technology Transfer, Creative Works, and Copyright Licensing. Copyright Licensing advises the university about copyright violations and provides assistance in obtaining copyright permissions and registering copyrights and trademarks. For more information about this office, see the chapter "Soliciting and Managing Copyright Inventions and Copyright Licensing: Part 2, by Carl Johnson in the 3rd Edition of the *AUTM Technology Transfer Manual*."

Managing Copyright Innovations

The CWO is currently organized with a director, a marketing coordinator, a part-time secretary, two part-time student programmers, a part-time student graphic designer, and three part-time student marketing assistants.

The current director's responsibilities are primarily focused on advising BYU faculty on IP and creative works so as to properly prepare the works for commercial use. He meets with faculty members and developers about their disclosures, and he conducts regular seminars or one-on-one meetings to educate university faculty on BYU's new IP policy. He also prepares and executes contracts and licensing agreements with the assistance of the general counsel's office. Lastly, he is responsible for the overall functioning, direction, budgeting, and staffing of the office.

The current marketing coordinator is responsible for the development, marketing, adver-

tising, and overall promotion of projects that are accepted by the director but are not licensed to companies outside the university. She assists faculty, staff, and students with the final conversion of their projects into a mass-marketable product that can be sold through the online Creative Works Catalog. Advertisement and promotion of the catalog fall under her responsibilities, as do the nuts and bolts of database development and administration. She also oversees the Web site programming and design that support the functioning of the catalog.

The part-time employees provide various services and forms of support to the director and the marketing coordinator. For example, the part-time student secretary assists with collection of royalties and front-office administration. The two programmers develop and maintain online storefronts for specific product lines and the general online catalog. The part-time student graphic designer assists customers in formatting and designing their products and helping to prepare the products for printing and production. Lastly, the three part-time student marketing assistants help to develop a marketing plan, generate potential licensee contact lists, and make initial contacts.

Assessing Marketing Potential

In all, the CWO brought in more than \$1 million to the university in the last fiscal year. However, the majority of the products garner between \$2,000 and \$10,000 a year. Publishing those works is part of the office's mission but likely dilutes its overall financial performance. That's the crux of the problem; the CWO staff see themselves as a service to the academic community on campus. If there is any way at all they can distribute a product, they will do it. Accordingly, the office has devised a series of marketing options to give some sort of distribution to any product developed on campus. A faculty member would be happy to get even a couple of thousand dollars for something from which he or she did not think he or she would get anything at all. The CWO's main focus is to provide a venue outside the campus for any copyrighted IP developed on campus.

In order to find such a venue, when the CWO has entered a disclosure into its database, the director meets with the developer or developers and quickly determines what path the invention will follow according to the CW project management flowchart (see Figure 1).

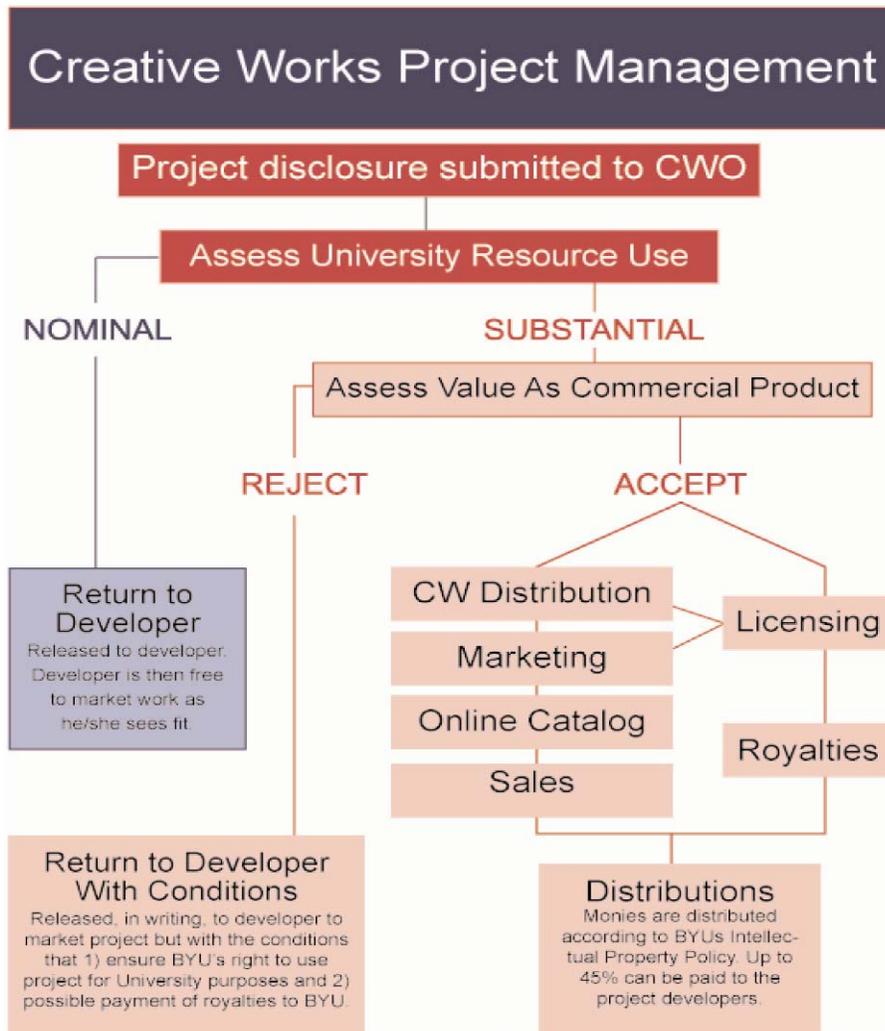


Figure 1: Project Management Flowchart

Since the CWO is dealing with finished products in most cases, the first priority of the director is to see if he can license the IP through a publishing house. BYU prefers to interest publishing houses in taking on the titles because they can do a much better job of marketing and selling the product than university staff can.

In some cases, however, because of the nature of a product, the CWO itself makes the product available through its Web site at www.creativeworks.byu.edu. This happens when

the product may be too narrow in scope, may not fit with any established publishers, or may have revenue possibilities that are too small to be attractive to an outside company. The CWO has been very successful making such products available.

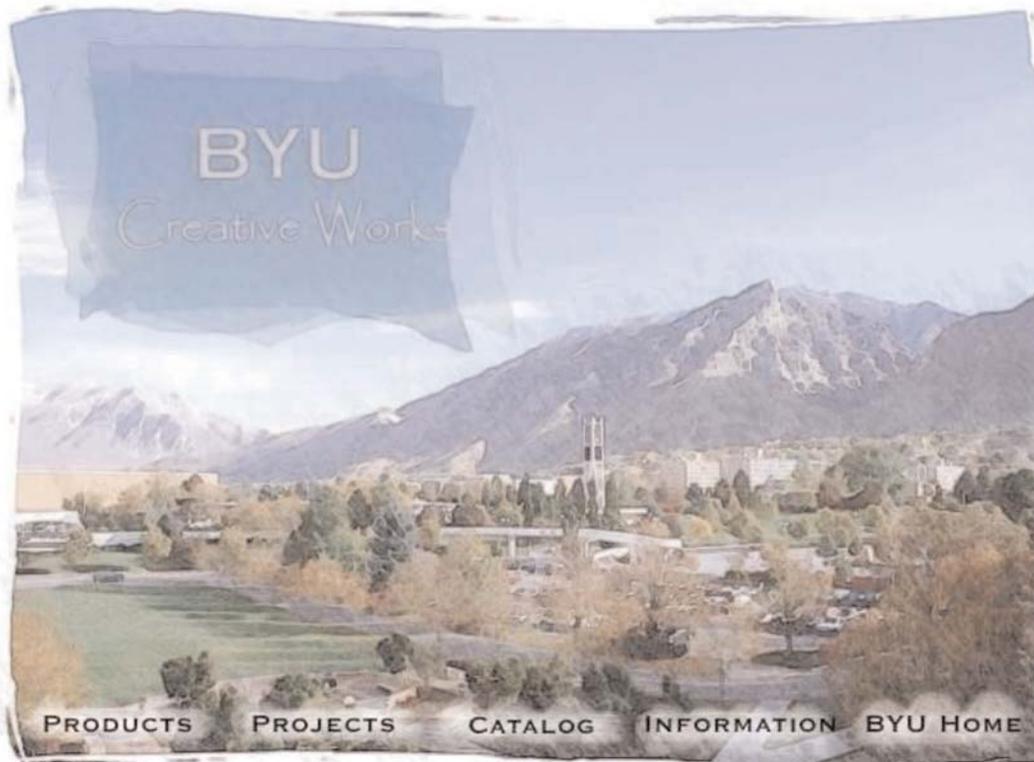


Figure 2: Creative Works Web Site

In 1997 the CWO established an online storefront for the software programs developed by the Humanities Technology and Research Support Center. One of these programs, Computer Adaptive Placement Exams (CAPE), uses state-of-the art computer testing techniques to accurately and efficiently place students in the first two years of college language courses. This product has been marketed for several years through online portals such as the one shown in Figure 3. Because about 600 institutions of higher education in the U.S. and overseas use CAPE exams, these exams generate close to \$100,000 a year in

revenue for the university.

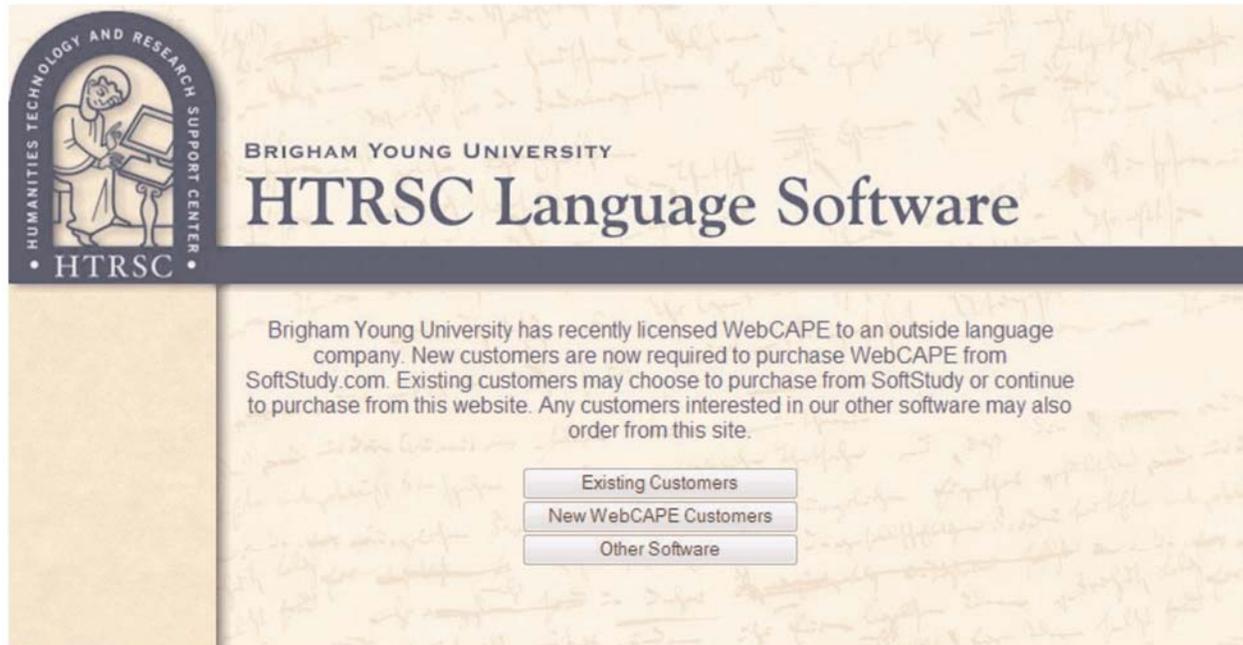


Figure 3: Computer Adaptive Placement Exams

Some of the CWO's greatest successes in licensing have involved virtual labs. A faculty member with the assistance of the Center for Teaching and Learning has developed Virtual ChemLab, a sophisticated and realistic simulation of instructional chemistry laboratories that covers high-school-level chemistry as well as freshman- and sophomore-level college chemistry. It was licensed to Pearson Publishing, a major UK-based education publisher, and it has become the most popular virtual lab in the United States.

By 2009, nearly 200,000 students across the country will be using it. To build on that success, the CWO has just released a virtual physics lab and a virtual physical sciences lab with the same publisher. Revenues from the virtual lab concept are close to \$200,000 a year, but that will probably increase with the launch of the new labs. Next on the development schedule will be a virtual biology lab, perhaps in 2010.

Other popular products licensed to publishers include OrganTutor and StatTutor. OrganTutor is a CD-ROM or online course developed by a music professor to teach organ

techniques; licensed to Rodgers Instrument Corp. and the Allen Organ Co., it has sold thousands of copies nationwide. StatTutor is an online tutorial for first-year statistic students. BYU licensed it to W. H. Freeman Publishers to be sold as a companion to some of the most popular statistics textbooks in the country.

Another highly popular product marketed by the CWO involves what are called “Culturegrams”—brief descriptions of daily life and customs covering 187 countries throughout the world. This product was initially marketed and distributed by BYU, but, in 2001, it was licensed to ProQuest. Last year it brought in about \$150,000 in royalties.

As mentioned previously, the School of Education also markets many popular products through the CWO. BYU markets products from the School of Education directly to school districts. For these products, the CWO needed a different Web site to meet the ordering needs of school districts. Royalties from the School of Education have brought in more than \$1.5 million in revenue in the last six years.

Setup, Production, and Distribution Resources

Prior to the establishment of the CWO, the TTO was managing the existing creative works. These included CAPE and some training videos from the College of Nursing.

The rest of the creative works developed by faculty members with BYU support were for a BYU audience. Prior to the establishment of the CWO, there was no centralized way of marketing the products coming from the School of Music, KBYU, the Department of Theater and Media Arts, and other departments on campus. It was decided that the best way to market these products would be through a BYU catalog that could be sent to mailing lists available on campus.

The first catalog was mailed in December 1997 and sent to 160,000 alumni. Setting up a mail-order fulfillment center is a costly endeavor, and given the limited resources available to the newly formed CWO, the option of setting up a fulfillment center on campus was not feasible. The CWO initially opted to work with a small entity on campus that was running its own fulfillment operation. The results were satisfactory, but after a few years, a new partner was selected because the small entity was not capable of expanding as

needed to accommodate the CWO's increasing number of available products. The CWO then decided to partner with the campus book store. CWO takes the orders and automatically redirects them to the bookstore, and the bookstore fulfills those orders. In turn, the bookstore charges the CWO 15 percent of sales. Initially the catalog was available in printed form and online, but after three years, the printed catalog was discontinued due to rising printing and mailing costs. It was replaced completely by an online catalog as shown in Figure 4. Since its inception, the Creative Works Catalog has generated sales of more than \$1.3 million.

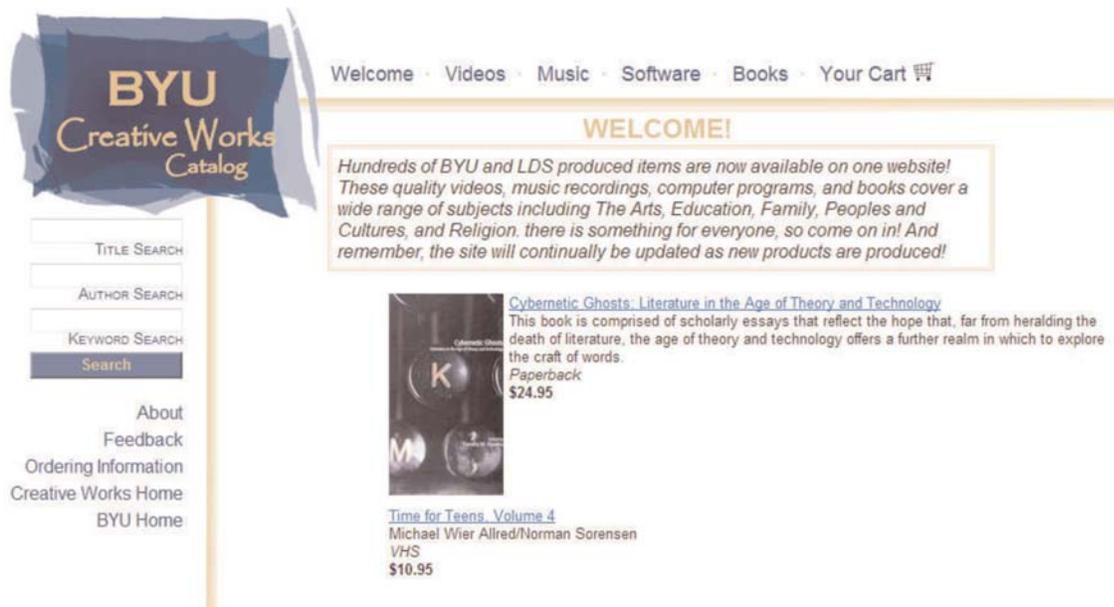


Figure 4: Creative Works Catalog

Any university that is considering opening its own CWO or setting up a similar operation should first examine what resources are available on campus in the way of distribution. One of the main problems is that the office must be able to do some fulfillment. Most departments are not set up to handle the details of sending books and other products to customers who order by mail or on the Web, as many of BYU's orders are received. Other logistics of concern include how to handle the warehousing, inventory, and accounting for the products involved.

Enterprise Centers

The CWO does not manage all creative works at BYU. If a commercial activity, such as manufacturing products, selling products, or services to end users or distributors, and/or providing customer support other than through CWO or TTO, is deemed consistent with the educational mission and academic programs of the university, an enterprise center may be authorized by petition through the chair and dean to the associate academic vice president for research. The enterprise center must have a center director and will require the involvement of university personnel. On occasion, a would-be center may not initially have the resources to hire a director or other personnel; in such cases the CWO handles the project until such times as there are enough funds for the new center to do so.

BYU currently has five enterprise centers that develop and market creative works. Sales from centers totaled \$757,182 in 2006. The CWO also functions as an incubator to a few projects that could eventually become enterprise centers. An example is the Chaucer Studio (see Figure 5), which produces solo or group dramatic readings of the works of Chaucer and other medieval authors. The Chaucer Studio's latest catalog lists 72 separate items. The CWO now manages this project, but if and when the funds permit, a full-time manager could be hired and the English Department could take over the project as an enterprise center.

Figure 5: The Chaucer Studio



When BYU first established the CWO, the CWO director encouraged the School of Music to market more aggressively the music developed by the department, and the CWO prominently featured School of Music products in the new Creative Works Catalog. In the year 2000, Tantara Records officially became the first enterprise center as envisioned by the new IP policy. Tantara's primary mission is to record and promote the music of BYU—its top ensembles, faculty artists, and composers—and allow selected students to experience the internal day-to-day operations of a small recording company, with Tantara's officers and producers acting as mentors. Tantara's revenues for the year 2006 were more than \$200,000.

Statistics and Rankings

BYU, founded in 1875, is one of the largest private institutions in the country, with a student population of 33,000. Even though BYU is primarily a teaching institution with only \$30 million in external funding, it has a fairly successful IP commercialization program. Cancer cures, environmental modeling software, hearing aid improvements,

computer programs that teach and test people's knowledge of foreign languages, and other inventions have placed BYU in the top ten universities when it comes to turning research into realized products, according to a new study. BYU ranked seventh in what the California-based Milken Institute calls "academic entrepreneurial capitalism." The institute issued this study, "Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization," on September 20, 2006.

Each year the Association of University Technology Managers conducts a survey of all universities and research hospitals in the United States and Canada. Among 151 institutions that responded to the 2005 survey, BYU ranked 139th according to the amount of sponsored research funding they received. That same year, however, BYU ranked 38th in the "amount of licensing revenue received" category. This high relative return on investment places BYU 5th in the nation for revenue per million dollars of sponsored research. BYU has consistently maintained this high performance for seven years. In the past, BYU has ranked 3rd four times, 4th twice, and 6th once. There are several benchmarks that illustrate the activity of the TTO and CWO at BYU for the year 2007:

	TTO	CWO	TOTAL
Disclosures	58	43	102
Licenses issued	9	16	25
Active licensees	38	59	97
License agreements in force	43	136	179
Revenue	\$2.5 million	\$1.1 million	\$3.6 million
New companies formed	4	1	5

Closing

While having an office that solely handles creative intellectual property may not suit every university, such an office can provide many benefits. It enables professors to distribute their products and research more widely, because the office's intent is to help professors produce their works, even if the revenues for the project are modest. Also, so long as the office is able to provide order fulfillment or effectively outsource order fulfillment, the organization of a CWO can be large or small, depending on the needs of its

parent university. Lastly, by marketing creative works to the public, professors bring recognition to themselves and their university, which helps the university to gain prestige and respect among other academic institutions. BYU has benefitted greatly from its own CWO, and it will only continue to do so.

Soliciting and Managing Copyright Inventions and Copyright Licensing: Part 2

Carl Johnson

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Managing Copyright Issues

United States and international copyright laws provide the legal basis for owning, licensing, and using creative works. Within the role of universities and colleges of creating, discovering, and disseminating knowledge is the opportunity to confront and resolve many copyright ownership and use issues. As individual authors, creators, and those representing institutions become more knowledgeable of copyright law, policy, and practice, more effective management of the ownership and use rights (copyright) is realized.

When thinking about the possible use of works protected by copyright, keep in mind the perspective of both the owner and the user of the material—the golden rule of copyright, What kind of respect and observance to copyright law would I want others to follow if I were the copyright owner of the material they are about to use?

Copyright Overview

Copyright is a collection of rights provided by law (Title 17, U.S. Code, referenced by section in this document) to the authors of original works of authorship, expressed in any tangible medium of expression. Copyright ownership is vested in a work if three requirements are met:

1. *Fixation*: The work exists in a tangible medium, from which the author's expression can be read, seen, or heard, either directly or by the aid of a machine. Fixation must be more than transitory (e.g., more stationary than sandcastles on the beach or cloud drawings by airplanes in the sky).
2. *Originality*: The work owes its origin to the independent creation of the author. An author who creates a work that looks identical to another work, if created completely

without reference to any other copyrighted work, would satisfy this requirement. A work does not have to be new or novel, but it simply must not be a created by copying a protected work known to the author.

3. *Minimal creativity*: The work possesses at least a modicum of creative expression. Most works meet this standard. Works that do not generally are common, everyday, and traditional forms of expression (e.g., organizing a telephone directory in alphabetical order).

Ownership of Protected Works

A work may contain many different inter-related elements, but only the elements of the work that meet the requirements of fixation, originality, and minimal creativity receive copyright protection. For example, a novel by S.E. Hinton called *The Outsiders* quotes a poem by Robert Frost entitled, “Nothing Gold Can Stay.” S.E. Hinton’s copyright in the novel would not extend to that poem. In fact, many parts of a novel are not protected, including general ideas about life, stock characters, basic elements of plot, and so on. Only the expression (actual writings) describing those things is protected by copyright.

A second author could write a story with background similar to S.E. Hinton’s novel, involving rivaling teenagers in different social classes, without violating copyright. The second author could even give the characters similar features like letterman jackets, greased hair, and pocket knives, but the closer this author comes to using the same exact elements with the same words (expression), the closer this author is to infringing copyright. An exception to this concept is the merger doctrine, which states that certain specific expressions are not copyrightable if there are only a few ways to express one idea.

Copyright ownership begins automatically at the time the author fixes a work in a tangible medium. Thus, if a person wrote a poem on a napkin while eating lunch today, the person would own a copyright to the poem immediately upon its completion. Protection of the copyright in a court of law requires additional steps such as registration and deposit. Registration is a prerequisite for bringing an infringer to court, and timely registration provides additional benefits strongly in favor of the copyright owner.

The requirements for copyright protection and ownership have changed over the years, but previous requirements remain important. Previous requirements include publication, notice, and renewal. These requirements are important today in determining whether a work is still protected under copyright. If copyright owners of older work have not followed these requirements, their works may have entered the public domain. For more information, see the section, “Duration of Protection.”

Selling a copy of one’s copyrighted work does not result in the transfer of copyright ownership. When an author sells a copy of his or her work, the copy becomes the possession of the buyer. Though other rights of the author remain protected, the buyer may subsequently sell the copy without consulting the copyright owner. The buyer may lend, rent, or lease out the copy, unless it is a phonorecord (material object in which sounds are fixed—CDs, tapes) or computer software.

Nonprofit libraries are exempt from this rule and may lend out phonorecords and computer software for nonprofit purposes as long as notice of copyright is given. Copyright owners may also contract with buyers to limit these rights—as is common practice in software distribution with shrink-wrap and click-wrap licenses.

Copyright ownership can be shared by two authors or owned by someone other than the original author. If two or more authors create a work together with the intent to create one unitary final work, then all authors retain joint ownership. Each author must contribute something independently copyrightable, more than just ideas.

If a work is created for an employer, the employer owns the copyright. These works are denoted as works made for hire. A creative work becomes a work made for hire if it is

1. Prepared by an employee within the scope of his or her employment or
2. Specially ordered or commissioned for use as a contribution to a collection of works.

A work created within the scope of employment occurs automatically if there is no agreement to the contrary. A specially ordered or commissioned work occurs when there is a written agreement signed by both parties and applies only to the following types of works:

1. Motion pictures or other audiovisual works
2. Translations
3. Supplementary works
4. Compilations
5. Instructional texts
6. Tests
7. Answer materials for a test
8. Atlases

Universities define their own intellectual property policies with employees to clarify what creative works will be considered as works for hire. Employment contracts with professors, students, and other employees give general guidelines for what works are considered works for hire, but some final discretion often remains with the university. Textbooks and other scholarly publication, which might seem to fall under the scope of employment of a typical professor, are generally not considered as works for hire. Universities tend to retain copyright ownership if the works are made for the university, under the direction of the university, with the substantial use of university resources, or in some cases, as collaborations between members of the university community.

Categories of Protected Works

Copyrighted works are created in many different physical mediums, requiring slightly different applications to carry out the general principles of copyright law. The U.S.

Copyright Office categorizes copyrighted works as follows:

1. Literary works (e.g., books, articles, software)
2. Musical works, including any accompanying words
(e.g., melody and harmony embodied in any form, such as sheet music or a recording)
3. Dramatic works, including any accompanying music (e.g., play scripts, theatrical performances)
4. Pantomimes and choreographic works
5. Pictorial, graphic, and sculptural works (e.g., paintings, sculptures, photographs)
6. Motion pictures and other audiovisual works
7. Sound recordings (e.g., particular rendition of a musical work recorded as performed)
8. Architectural works (e.g., design of a building in drawings, plans, or an actual structure)

Rights of the Copyright Owner

Section 106 grants the owner of a copyright the *exclusive right* to do and authorize others to do the following:

1. Reproduce or copy the work
2. Prepare derivative works based upon the work
3. Distribute copies of the work to the public by sale or other transfer of ownership, or by rental, lease, or lending
4. Perform the work publicly
5. Display the work publicly
6. Perform the work publicly by means of digital audio transmission (sound recordings only)
7. Control rights of attribution and integrity (works of visual art only)

The rights of the copyright owner are limited in scope by statute. Unless one or more of the limitations (called *exemptions* in the statute) apply, a person must obtain permission from the copyright owner before exercising these rights. The copyright owner is the person or entity who owns the exclusive rights mentioned above. The copyright owner can be the author, the publisher, or another person or entity having legal ownership of one or more of the exclusive rights described above.

Duration of Protection

Copyright protection is limited by time. Congress has changed the length of protection multiple times, leaving behind a complicated system of rules for determining the duration of works created in different time periods. There are two general rules to keep in mind:

1. Works created on or after Jan 1, 1978:
 - a. If created independently, protection extends for the life of the author plus 70 years
 - b. If created anonymously, under a pseudonym, or as a work made for hire, protection extends 95 years from publication or 120 years from creation, whichever is shorter
2. Works created before 1923 are no longer protected and are in the public domain.

Additional complications arise depending on whether the work is published, unpublished, or has been properly renewed. In all cases, copyright protection ends after the last day of the year. For more information see Sections 302-305.

Unprotected Materials

Copyright protection does not extend to the following:

1. Works for which the copyright has expired
2. Works produced by federal government employees within the scope of their employment
3. Works clearly and explicitly donated to the public domain
4. Works that have not been fixed in a tangible form of expression (e.g., choreographic works that have not been notated or recorded, spontaneous speeches, or performances that have not been written or recorded)
5. Titles, names, short phrases, and slogans; familiar symbols or designs; mere variations of typographic ornamentation, lettering, or coloring; mere listings of ingredients or contents
6. Ideas, procedures, methods, systems, processes, concepts, principles, discoveries, or devices, as distinguished from a description, explanation, or illustration
7. Works consisting entirely of information that is common property and contains no original authorship (e.g., standard calendars, height and weight charts, tape measures and rulers, and lists or tables taken from public documents or other common sources)

Copyright Law Related to Higher Education Institutions

Copyright Exemptions (Limitations on Exclusive Rights)

Copyright law grants several important limitations to the rights accorded copyright owners. While there are many exemptions in copyright law, the following paragraphs mention three main exemptions useful to universities: fair use, the library and archive exemption, and the face-to-face teaching exemption. To qualify for these exemptions, the requirements of each must be strictly followed, except in the case of fair use, which has no strict requirements.

The Fair Use Exemption: Section 107

Section 107 grants a fair-use privilege to use copyrighted works without permission when certain conditions are met. A reasoned fair-use analysis requires consideration of four factors as explained below. These factors are difficult to consider in isolation of each other and, thus, should be explored and weighed together. A fair-use analysis is fact-driven, and each unique set of facts regarding a proposed use leads to its own reasoned conclusion.

These factors are explications of the core intent of this exemption to encourage “purposes such as criticism, comment, news reporting, teaching...scholarship, or research.” Fair-use analysis applies to all formats and mediums, including the digital environment, and applies not only to the right of reproduction but also to the rights of performance, display, adaptation, and distribution.

Purpose and Character of the Use

In analyzing fair use, courts examine the purpose and character of the use. This factor has three distinct areas of inquiry—whether copying is transformative, commercial, and in good faith.

A work that is transformative is one that is not merely superseding of the original work but “instead adds something new, with a further purpose or different character, altering the first with new...meaning...or message” (*Campbell v. Acuff-Rose Music*). The classic example of transformative use is a parody because it contains new material added to an original work and has a different purpose with a different message than the original work. If a court finds a work to be transformative, it will often find in favor of fair use for the other factors as well. For this reason, this factor is considered one of the most important factors of fair-use analysis.

If the use is for a commercial purpose, this factor may weigh against fair use. This factor is important especially in the absence of a transformative use. If a work is transformative, however, this factor may still be in favor of fair use even if it is commercial. A parody, for example, is intended for a commercial purpose but still clearly a fair use. Most usage of copyrighted works in the university environment can be characterized as nonprofit edu-

cational uses, but educational use alone does not automatically result in a finding of fair use, just as a commercial use does not always result in a finding against fair use.

Finally, fair use presupposes good faith and fair dealing. If the court perceives that the infringer's use was deliberately underhanded, it may find a way to make these factors weigh against fair use.

Nature of the Copyrighted Work

A second factor examined by the court is the nature of the copyrighted work. This factor will generally weigh in favor of fair use if the work is factual in nature (technical, scientific, etc.), instead of a work involving more creative expression such as a play, poem, fictional work, photograph, painting, and so on. Fair use does not apply to some works, such as standardized tests, workbooks, and works that are meant to be consumed. The case for fair use becomes even stronger when there are only a few ways to express the ideas or facts contained in a factual work. The line between unprotected facts and ideas on the one hand and protected expression on the other is often difficult to draw. Fair use applies to unpublished works as it does to published works, but the author's right of first publication may be a factor weighing against fair use if a work is unpublished.

Amount and Substantiality of the Portion Used in Relation to the Copyrighted Work as a Whole

A third factor examined by the court is the amount and substantiality of the work taken. Although there are no numerical or percentage limits, the larger the amount of a work one uses, the less likely it will be fair use. This deliberate flexibility in the statute allows each situation to be judged on its specific facts and permits the doctrine to be practical in the higher education setting.

This factor also takes into consideration the quality of the portion taken as well as the quantity. Sometimes, even if only a small amount is taken, this factor may weigh against fair use if the portion can be justly characterized as the heart of the matter. This factor and, the fourth factor, market effect, work in tandem; the more of the original work taken, in amount and substantiality, the greater the negative impact on the market for the copyrighted work.

The Effect of the Use on the Market for or Value of the Copyrighted Work

The last factor examined by the court is the effect on the market of a copyrighted work. This factor identifies the anticipated effect of the use on the publisher's market. If the proposed use is likely to become widespread and would negatively affect the market for or value of the copyrighted work, this factor might weigh against fair use. Similar in importance to the first factor, this factor is often highly determinative of the outcome.

In defining the affected market, courts look at the current market of the infringed work, the market for derivative works, and potential future markets. Harms to any three of these markets may weigh against fair use. Though difficult to prove, showing a clear harm to the current market weighs heavily against fair use.

Harm to the current market might be inferred when the sales of the infringed work drop significantly while the sales of the infringing work increase. Harm to a market for derivative works is demonstrated when customers that would have paid for a license to adapt the original work choose not to or when sales decrease for licensed works while sales increase for infringing works. The threat of harm to potential future markets can also be persuasive regardless of whether a company has plans to exploit a new market, but the presumed market must be traditional, reasonable, or likely to be developed.

Not all harms to plaintiff's market will result in a finding against fair use. If a work causes harm by becoming a replacement for the original to fulfill the same type of purpose as the original (i.e., nontransformative) then it weighs against fair use. For example, an author who writes a book with the same characters as a Harry Potter novel has created a similar work with a similar purpose. Thus, the author is trying to gain some of the market share for Harry Potter novels and such usage would likely result in a finding against fair use.

A transformative work, such as a parody, may actually cause harm to a market by criticizing the original work of authorship. Returning to the Harry Potter example, suppose instead that the infringing author used the Harry Potter characters in a documentary film criticizing society's acceptance of magic. Even if it erodes the current market for Harry Potter books, this type of harm resulting from transformative works is less likely to weigh against fair use.

Weighing and Balancing the Factors

Fair-use analysis is a flexible doctrine that Congress intended to be tested and adapted for changing needs and circumstances. The law provides no clear and direct answers about the scope of fair use or its meaning in untested and unproven situations. If most factors lean in favor of fair use, the proposed use is probably allowed; if most lean the opposite direction, the action will not fit the fair-use exemption and may require permission from the copyright owner. Reliance on a reasoned analysis and using a Checklist for Fair Use is helpful to claiming a good-faith effort.

Libraries and Archives Exemption: Section 108

For libraries and archives (libraries) and their employees, Section 108 grants exemptions to the reproduction right (the right to make copies) and distribution right. This section is somewhat complex because of the difficult tension between the need for copyright protection and the need for making ideas available for educational purposes. Exemption is primarily related to the library's purpose in making a copy and the availability of the work.

The general rule is that libraries and archives may make one copy of a work and distribute it so long as (1) it is not for a commercial purpose or advantage, (2) the library is open to the public, and (3) the copy displays a copyright notice. The general rule applies primarily to literary works and specifically excludes:

1. Musical works
2. Pictorial, graphic, or sculptural works
3. Motion pictures or other audiovisual works other than an audiovisual work dealing with news

This section grants broader rights than the general rule depending on the library's purposes. The library may reproduce up to three copies of any category (including those excluded by the general rule) of work in certain cases:

1. If the work is unpublished, copying must be for *preservation, security, or for deposit for research in another library*. To fall under this exemption, the library must also own a copy of the unpublished work.
2. If the work is published, such use must be for replacement of a work that is *damaged, lost, stolen, deteriorating, or in an obsolete format*. Before copying a

published work, the library must give a reasonable effort to determine the cost of replacing the work and come to the conclusion that a new copy cannot be obtained for a fair price.

Any of these three copies may be in digital format as long as digital copies are not accessible outside the physical premises of the library.

The amount that may be copied depends on the circumstances and purposes for making a copy. If the library makes a reasonable determination that a copy cannot be obtained at a fair price, then it may copy an entire work and distribute it to a library patron. Otherwise, the library may only copy and distribute an article or similar contribution from a periodical, or a small part of any work, such as a chapter from a book. In both cases, the library must not have reason to believe the patron will use it for something other than private study, scholarship, or research.

This section grants even broader rights for a work in the last twenty years of any term of its copyright protection. Upon a reasonable determination that a work is not subject to commercial exploitation and cannot be obtained at a reasonable price, then the library may reproduce, distribute, display, or perform a work in facsimile or digital form. As with the other areas of this section, the library may exercise these rights only if its purpose is related to preservation, scholarship, or research.

Finally, most libraries provide copiers or other reproducing equipment for its patrons. A library will not be liable for copyright infringement done through the unsupervised use of such equipment by its patrons so long as the equipment displays a notice that making a copy may be subject to copyright.

Face-to-Face Teaching Exemption: Section 110

Section 110 (1) gives exemption to the performance and display rights in specific circumstances applicable to universities. A student or professor can present a work protected by copyright without permission if the following criteria are met when performed or displayed:

1. During face-to-face teaching activities
2. At a nonprofit educational institution

3. In a classroom or similar place devoted to instruction
4. With a lawfully made copy of the work

Generally, a university will have little trouble meeting these four requirements, but the fourth requirement may cause problems. For example, a faculty member or student might want to use a video/film from an online source such as YouTube. This material may be an unlawful copy and such use would not be allowed under this section.

An additional way to violate the fourth requirement is when a copy is made from a DVD or other audiovisual work that is protected by digital rights management. For more information on this topic see the section, “Circumvention of Copyright Protection Systems.”

Other Copyright Considerations

Reducing Liability by Expediently Removing Infringing Material

Section 512 grants a university exemption from liability in its role as an online service provider for copyright infringement occurring through its computer network. This section divides network activity into three sections:

1. Transitory digital network communications
2. System caching
3. Information residing on systems or networks at direction of users

The first two types of network activity, transitory digital network communication and system caching, only involve the university because the infringing material is temporarily passing through its network. For example, students offering illegal material from their own computers to users on the Internet by means of the university’s physical network would fall under this first type of activity. A university is not liable for these transmissions assuming the material is not made available, modified, stored for a long period of time, or initiated by the university (for specifics see the statute).

A university is more likely to be liable for the third type of activity—harboring infringing materials on one of its computers. To avoid liability for this type of activity, a university must have a system for removing infringing material from its network when notified by a

copyright owner. The university must notify the U.S. Copyright Office of its designated agent to receive notices from copyright owners. Upon proper notice from a copyright owner, the university must “respond expeditiously to remove, or disable access to, the material that is claimed to be infringing or to be the subject of infringing activity.” If the notice does not meet the standards of Section 512(c) (3), then the university is not obligated to do anything.

The notice generally contains the infringer’s Internet protocol address, name of the allegedly infringing file, and a time associated with the allegedly infringing transaction. Universities respond to these notices in a variety of ways, but generally, they identify the network user and communicate with the user until the infringing material is removed.

Copyright Compliance with the Higher Education Opportunity Act

On August 14, 2008, Congress signed an amendment to the Higher Education Opportunity Act requiring universities to pursue copyright polices to remain eligible for federal student financial aid programs. The university must provide an annual notice to students with the following information:

1. Notice that unauthorized distribution of copyrighted material, including unauthorized peer-to-peer file sharing, may subject the students to civil and criminal liabilities
2. Summary of the penalties for violation of federal copyright laws
3. Description of the institution’s policies with respect to unauthorized peer-to-peer file sharing including disciplinary actions that are taken against students who engage in unauthorized distribution of copyrighted materials using the institution’s information technology system

The university must certify to the U.S. secretary of education that it:

1. Has developed plans to effectively combat the unauthorized distribution of copyrighted material, including through the use of a variety of technology-based deterrents
2. Will, to the extent practicable, offer alternatives to illegal downloading or peer-to-peer distribution of intellectual property, as determined by the institution in consultation with the chief technology officer or other designated officer of the institution

Universities have responded to this amendment in a variety of ways. Many universities already have strong copyright programs in place. Some employ network software to detect illegal activity (usually targeting peer-to-peer file sharing), while others focus on education and actively pursuing Digital Millennium Copyright Act notices related to Section 512. Little information is given as to what the statute actually requires in terms of how actively a university must combat infringement and how far it should go in offering alternatives, but, at the time of this writing, administrative regulations were scheduled to be released as early as November 1, 2009, and will become effective as early as July 1, 2010.

Circumvention of Copyright Protection Systems

Section 1201 prohibits the circumvention of technological measures designed to control access to a copyrighted work. Circumvention means to “descramble a scrambled work, to decrypt an encrypted work, or otherwise to avoid, bypass, remove, deactivate, or impair a technological measure, without the authority of the copyright owner.” For example, a professor may violate this part of the law by creating a compilation of audiovisual clips for teaching purposes from a DVD, digitally protected by a technology called CSS. Though a professor’s usage of copyrighted works for teaching purposes might normally qualify as a fair use, Section 1201 prohibits such usage if it requires circumvention. Another popular access control is called digital rights management technology often used to control sound recordings (MP3s) purchased from online music distributors.

Access controls may differ from encoding. National Television System Committee (NTSC) and Phase Alternating Line (PAL) are simply encoding standards, while region encoding, CSS, ACSS, Apple’s Fairplay, Microsoft’s WMV, and Sony’s OpenMG are examples of access controls.

The Library of Congress, upon recommendation of the register of copyrights, has authority to make exceptions to Section 1201 through a rulemaking procedure that occurs every three years. As of this writing, the current exceptions are effective until October 27, 2009. The current exception most relevant to universities grants film and media studies professors permission to circumvent access controls, specifically for works meeting the following description:

Audiovisual works included in the educational library of a college or university's film or media studies department, when circumvention is accomplished for the purpose of making compilations of portions of those works for educational use in the classroom by media studies or film professors.

Anyone can submit comments for these rulemaking procedures. A handful of universities regularly take an active part in this procedure, and further participation from other universities would continue to help shape this area of the law. Information about the current rulemaking procedure and previous ones may be found online at the copyright register's Web site at <http://www.copyright.gov/1201/>.

University and Campus Copyright Advisory Services

Many universities and colleges have established a central office (or at least designated an individual) to address copyright issues, provide copyright resources, and otherwise promote copyright awareness and compliance. The following is a brief overview of what Brigham Young University (BYU) has done in this regard.

Copyright Services at BYU

The Copyright Licensing Office (CLO) exists to assist faculty, staff, and students with all aspects of copyright and licensing. The CLO works closely with the Office of the General Counsel to ensure fair and consistent compliance and interpretation of the United States Copyright Law. Specifically, the CLO provides the following services:

1. Online copyright education
2. Classroom presentations on copyright and fair use
3. Staff and department training
4. Individual consultation (appointment preferred)
5. Copyright policy review and clarification
6. Copyright law applied in collaboration with the BYU Office of General Counsel
7. Copyright registrations

Licensing Services

The CLO can do the following to help faculty and staff with licensing issues:

1. Assist with researching the source of material
2. Identify copyright owner information
3. Request permission for use
4. Obtain and sign license agreements
5. Process payment of licensing fees
6. Offer licensing tutorial and training

The CLO maintains a repository for licensing documents. It manages actions and restrictions of licensing agreements; produces reports for renewals, residual payments, conditions, etc; and is a central source for publisher and copyright owner information.

Copyright Tutorial

The CLO developed an online educational tool to help the campus community understand the basics of copyright. Found at www.copyright101.byu.edu, this online tutorial is designed to assist faculty, staff, and students learn what rights a copyright owner has; the legal exemptions that exist for educators, such as fair use; and case studies to analyze and solve. It is also available on CD, by request, at no charge. The tutorial was developed in three interactive modules and includes short videos, case studies, reference material, and an online game (final test). After faculty have taken the tutorial, they are encouraged to have their students also take the tutorial as part of their coursework or offer it to students for extra credit. The tutorial takes less than two hours to finish and can be completed in one sitting or in sections.

A certificate is generated upon the successful completion of the tutorial's game, which is sent directly to the professor who is using it in his or her course. When the professor receives the e-certificate, it can be assigned a pass/fail value, a specific point value, or any other value the professor prefers to use. Several faculty members have incorporated the tutorial into a section on ethics, but it can easily fit into other areas of study. A printed certificate can also be generated and picked-up at the CLO if an individual (including faculty) requests it in place of an e-certificate.

For more information about BYU, specifically, its Creative Works Office, see the chapter “Soliciting and Managing Copyright Inventions and Copyright Licensing: Part 1 Creative Works, by Giovanni Tata, PhD, in the 3rd Edition of the AUTM Technology Transfer Practice Manual.”

Obtaining Permission: Licensing Works Owned by Others

If you are seeking permission on your own, a license should be received from the copyright owner or his or her representative and obtained in writing. Keep a copy of all permissions received and any related correspondence.

Requests for permissions should include the following information:

1. Your name, address, telephone number, e-mail, and fax number
2. Your title/position and name of your publisher, university, or other entity
3. The date of your request
4. Complete and accurate source citations for the material you are requesting permission to use
5. A precise description of the proposed use of the copyrighted material as well as when and for how long the material will be used
6. A signature line for the copyright owner including title if he or she is representing a company and the date

Summary

When considering the possible use of material protected by copyright, keep in mind the golden rule of copyright, “What kind of respect and observance to copyright law would I want others to follow if I were the copyright owner of the material they are about to use?” In addition, your answers to the following questions will help you determine if permission is needed.

1. Is the material you are about to use protected by copyright?

- A. Copyright protection does not last forever. For example, anything published in the United States before 1923 is in the public domain, which means it can be used without permission or the payment of any fees.

- B. Materials created and published by employees of the federal government are in the public domain and not protected by copyright.
- C. Materials clearly and explicitly donated to the public domain can be freely used without permission.
- D. Materials clearly licensed (permission given) by the copyright owner for your planned use. There are a number of Web sites, such as Creative Commons, providing such licensed uses. Most home page Web sites will include a link to *copyright information* or *use information* or similar wording; click on these links and read the permitted uses; often nonprofit educational uses are permitted.

2. Does your institution or related entities own the material?

Often your institution or individuals working for your institution may own the material you are planning to use and existing policy may allow your use without seeking formal permission.

3. How will the material protected by copyright be used?

Your proposed specific use of material protected by copyright will effect whether you can claim an exemption (limitation on exclusive rights) thus not needing permission. Generally, the larger proportion of the copyrighted work you use and the broader the copying and distribution of the copyrighted work, the more likely you will need to seek permission. For example, posting a complete copy of a copyrighted work on a public Web site would in most instances require permission.

Whenever your proposed use of material protected by copyright goes beyond what is allowed by exemptions (limitations on exclusive rights) contained in the U.S. Copyright Law, permission should be obtained.

4. Will your proposed use clearly qualify as an allowed exemption (limitation on exclusive rights), thus not needing permission?

Refer to the previous sections under “Copyright Exemptions (Limitations on Exclusive Rights)” for information to answer this question.

5. Does your institution's copyright ownership and use policy provide useful guidance?

If you do not have an institutional copyright ownership or use policy, this is a good place to start. Discuss and meet with other university personnel and begin the exciting journey of further defining and clarifying the copyright policies, procedures, and practices at your institution.

Software Licensing

Doug Hockstad

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Introduction

Software-related technologies comprise an ever-greater fraction of the inventions disclosed by university faculty and staff to technology management offices. Unfortunately, these technologies present challenges to the primarily patent-based intellectual property (IP) policies of most universities. In addition, the unique issues that surface during negotiations involving software often require even experienced technology managers to explore new and innovative approaches to licensing.

Software Protection: Copyright and Patents

Copyright law (the details of which are covered elsewhere in the *Technology Transfer Practice Manual*™) protects “original works of authorship.” The types of original works protected by copyright include just about anything written, including plays, music, software, works of art, certain aspects of databases (as described below), and other tangible media. In the United States, the Copyright Act gives the owner of the copyright the exclusive right to (*and to authorize others to*):

- copy the work,
- create derivative works,
- distribute the work, and
- publicly perform or display the work.

How does all this apply to software? Software is, at its core, a written work. In that sense, copyright laws cover the *source code*, or the natural language version of the software. This gives software developers the ability to license their copyrights in the source code to interested parties.

Copyright Registration

Although confusing to many, it is important to understand that you do not need to register a copyright with the government to own a valid copyright. In fact, copyright exists at the moment the creator fixes the work in a tangible medium; that is, as soon as the written work is completed. Whether to actually register copyrights is a decision institutions approach in various ways.

The primary value in registering a copyright pertains to lawsuits: A copyright *must* be registered to bring an infringement suit in federal court. So, it might seem as though owners should always immediately register their copyrights in software (or any covered works).

However, copyright holders can register a copyright at any time...even *after* infringement has occurred. The primary benefit of registering a copyright before any infringement is the ability to seek statutory damages and attorney fees. In industry, this could be a significant consideration. In academia, however, this is not usually a vital consideration.

Another value in early registration is clarity: It marks a specific point in time illustrating copyright ownership, establishing a public record of the copyright claim. Registration can be valuable in any discussions or disagreements over copyright. In the end, if the software is licensed to a company, it might be best to get the licensee's position on registration.

How do you go about registering your copyright? The process is straightforward, if not easy. The process is fully described on the U.S. Copyright Office Web site <http://www.copyright.gov> and includes filling out one of several registration forms and sending it to the U.S. Copyright Office along with an inexpensive filing fee and some other depository requirements (described in detail on the Web site). Depositing software without appropriate redaction, however, may constitute a "public" disclosure of the code that could harm the potential for patent rights or allow others to create unauthorized copies of the code.

Patents

Software authors will often request that the licensing office “patent” software. Owners of inventions will often seek patent protection for software through patents covering the process embodied in software. The Court of Appeals for the Federal Circuit recently clarified the standard for whether processes (such as those found in software) are patent eligible. The court in *In re Bilski* ruled that a process is patent eligible if it either (i) is tied to a particular machine or apparatus or (ii) transforms a particular article into a different state or thing.

The U.S. Patent and Trademark Office (PTO) and courts need to further interpret the practical meaning of this standard that will apply to most patents aimed at protecting software. In the meantime, before filing a patent on any software, it is worth discussing with your patent prosecution counsel whether the invention embodied in the software not only has commercial value, but also whether it can be claimed in a patent in compliance with the new *Bilski* standard.

In many, if not most, circumstances, the value of a particular software package lies in (a) the fact that someone took the time to create it and (b) how hard it would be to re-create. In general, if time and money were no object, a person could write his or her own version of most software programs that otherwise would be purchased.

Why doesn't this happen more often? Usually not because of patent protection (although in some cases this might be a deterrent), but more often because the software is priced lower than the value of the time and resources required to re-create it. It is simply more cost and schedule effective to purchase the product than to re-create it. In addition, it is often more cost effective to use established software product maintenance, based on product support of multiple customers. Accordingly, quite often, a university can adequately protect its software inventions through copyright and does not need to pursue costly patent protection to effectively commercialize the software.

Patents on software *do* have value in certain situations, however. In some cases, the software itself is trivial to write, but what the software does, and how it does it, is so unique

and unforeseen, that a patent is the best way to capture that value. In other words, the value of your technology may lie more in the novel function the software performs, rather than in the source code itself. In these cases, when there is something unique about what or how the software works, a patent may be the best choice, even though the time and expense of getting a patent is considerably greater than that of establishing the copyright.

Another consideration about patenting software: enforceability. Source code is often invisible to the user. Therefore, if you cannot easily detect whether a third party is practicing your new process, then your patent will have little value to your university or a licensee, and filing for a patent is likely not worth the cost.

Finally, you should also consider the foreseeable life of the software when deciding the best IP protection to pursue. Patents, in general, take a relatively long time to obtain, and software patents take even longer (currently it takes approximately four years simply to receive the first PTO office action on software-related applications). Accordingly, licensing staff should consider whether patent protection might be definitively obtained during the period of time when the software still has commercial value in the market. If not, copyright protection (which, as discussed above, is immediately effective upon writing the software) is likely the more effective method of protection.

Databases

Databases, while not necessarily software, are usually embodied in software and, therefore, such invention disclosures often fall under the responsibility of the software licensing professional. In actuality, databases are one (or both) of two items: an organization methodology (the structure of the database) and the data (facts) stored within the database. Under this framework, the data themselves are not protected by copyright laws.

However, the organization of the data, the uniqueness and layout of the database structure, is potentially protected by copyright. There must be some original authorship reflected in the organization and layout of a database. While the alphabetical listing of names in a phonebook does not constitute original authorship, a database that categorizes or relates data in a thoughtful manner may contain a copyrighted organization or

layout. In that case, it is important to remember that copyright will only protect that particular layout, and not the underlying data.

While difficult to protect by copyright, databases can be protected in other ways. Most often they are protected and exploited simply through contract law. That is, access to, and use of, the database (whether meaning the structure for storage or the data contained within) is controlled by a usage license, restricting what the licensee can do. These licenses can be extremely valuable, both in terms of revenue and simply institutional and author acknowledgment, which is often an under-appreciated benefit to universities.

When licensing data, it is important to ascertain and verify the sources of the data. Data are often not just “created” by faculty, but gathered and collated from a variety of sources. Many of these sources might have contractual restrictions on use, or even restrictions on data derived from its use! Individual faculty members will often not be aware of such restrictions, and, therefore, you run the risk of licensing software containing third-party IP, exposing the university to legal liability.

Ownership and IP Policy

Scholarly Work

Since Bayh-Dole, and at some universities even prior to Bayh-Dole, IP policies attempt to address the typical situations in which the university would claim ownership of IP and how it might protect and commercialize such IP. Many policies describe these ownership principles in terms of patentable technology. They do not anticipate other forms of IP protection that may be better for different types of technologies that were potentially unforeseen at the time the institution drafted the policy (such as software).

In addition, there may be confusing overlap between university copyright policies drafted long ago to address faculty ownership of scholarly work (such as books and curriculums) and more recent IP policies (aimed at technology transfer or patent issues). Absent any direction from the institution’s IP policy, copyrighted works, and software in particular, present some unique opportunities for confusion and misunderstanding that licensing offices are left to address on a case-by-case manner.

One of the most common misunderstandings is related to what is commonly referred to as *scholarly work exceptions*. In industry, employment agreements usually clearly state that employers own any employee creations related to their work, consistent with work-made-for-hire requirements in copyright law. Universities often have similar agreements, but almost always also have scholarly work exceptions allowing faculty to retain ownership of such work.

The term *scholarly work* has the trouble of being, relatively speaking, undefined. Historically, the term covered such things as journal articles, books, works of art (e.g., music, paintings, sculptures, etc.) and instructional materials (unless, of course, any of these materials were the specific results of either a funding source or a specific assigned duty) created by faculty at the university. The problem is that, often, this scholarly work exception is not clearly defined, and various software works could be interpreted to fall into the definition of scholarly works. In many cases, universities have been slow in clarifying the issue, often leaving their faculty (and the technology transfer office) in undefined territory.

As an illustration, consider the following situations at hypothetical University X. For these examples, University X has an IP policy stipulating the university owns copyrighted material outside the definition of scholarly work as long as the material is either related to the employee's position at University X or involved use of University X facilities. Under this policy, if a physician writes software related to medicine, likely he or she used some amount of university resources to accomplish this and/or used his or her experiences at the university in developing the software. Accordingly, the likely result is that University X owns such software.

Similarly, if a radiologist writes a program to manipulate digital medical records, likely University X also owns that software. If, on the other hand, the same radiologist publishes a journal article describing a new system for manipulating digital medical records, then the radiologist would likely maintain ownership of that article as a traditional scholarly work.

In either situation, regardless of who owns the software or journal article, if either were created as a deliverable under a government grant, the university is responsible for compliance with reporting requirements and ensuring the government receives a retained government use license in such software or article.

Alternately, if an emergency room physician writes a new golf simulation program, University X might not own that program because it falls outside of the physician's employment and experiences at University X.

Because of this lack of clarity, disputes may arise and should simply be worked out on a case-by-case basis. Faculty members often feel strongly that the software they create should be their own. In addition, it often takes lengthy conversations and review of the funding sources to determine who really *does* own or have rights to such software. The best course of action is to review and, if needed, revise an institution's IP policy to clarify software ownership.

Revenue Sharing

By policy, custom, and, ultimately, the Bayh-Dole Act, universities share licensing revenues with inventors (in stark contrast to most company policies). This can make inventorship (authorship) a contentious issue because identifying the inventors (authors) can be difficult. By law, the author of a copyright work is the person who created it (or his or her employer if this is work made for hire), not the person with the idea or the person who led the project. Such problems often lead to confusion over who should be listed as the inventors of software.

Most universities take one of two positions. The first is that revenues related to software will be shared with the idea originators and any others who materially contributed to the concept and development of the software...except for the programmers. In this model, the programmers are being paid to program, offering little in the way of intellectual content and, therefore, not eligible for royalty sharing.

The second model includes programmers as *contributors* to the software invention who are eligible for royalty distribution. Most institutions appear to be converting to a model that includes programmers as contributors. The reasoning behind this is two-fold: Most often the other authors subjectively believe that the programmers significantly contributed to the software invention and should share in any proceeds; and in most cases, objectively speaking, it would be hard to envision a case where the programmer did not significantly contribute to the software invention. This appeals to both a sense of fairness and practicality.

Software Development

Software is developed under many scenarios, but most often either as a result of someone needing specific tools he or she cannot find commercially (or can't afford) or as a specific planned outcome of a funded project. Regardless of the circumstances of development, software developers usually possess at least one of three desires concerning financial remuneration associated with their software:

- for revenues to support ongoing development of the software's parent project
- to provide the software for free (most often seen when software is part of a collaborative effort with others)
- to personally profit

License Revenue-Supported Projects

Commonly, academic software developers desire to support further development or support of the project through license revenues. While laudable, there is often a reason to discourage this: If there are authors (or inventors) associated with the project, there will be tax implications to waiving their revenue share to an account in the university that they control. In most situations, this is considered first as revenue they have earned (taxable) and then as a donation to the university (tax deductible)—the two transactions do not simply cancel out, and the personal liability of the authors remains. Many institutions avoid this problem by disallowing the direction of waived revenue: Such revenue goes to the department and is not in the control of the inventors. It is then up to the department to decide whether or not to fund the project from such revenues.

Third-Party Software

Finally, note that much of the software disclosed to university technology transfer offices will contain third-party components. These are the utilities, libraries, functions, and more that programmers find on the Internet, or purchase, to accomplish a specific task within their own work. For instance, someone writing a word processor might use a publicly available spell-checker rather than create one from scratch, saving substantial time and effort.

Usually, there is no malicious intent in including the third-party component code. Programmers often believe the code is free: free to use, free to distribute, free to do with whatever they please. In many, if not most, cases, this is *not* true. There is almost always a license associated with the use of the component, and it is the responsibility of the technology manager to carefully assess these licenses and determine the best course of action.

In some cases, it is permissible to include the software in the end product for certain purposes (e.g., open source or academic purpose versus commercial use). In other cases, the component should be replaced with another having a more flexible license or be completely rewritten from scratch. All too often, academic software is released without removing these hidden traps, much to the consternation of the licensing reps as well as the general counsel's office.

A Special Note on Open Source in Development

Open source software continues to become more prevalent in the university setting, presenting significant issues when faculty or staff incorporate it into their software. While *open source* is a term used differently from situation to situation, it commonly refers to software licensed under specific terms meant to encourage its open use. Some of these open source terms include unrestricted redistribution, access to source code, and rights to derivative works.

Some examples of commonly referenced open source licenses include the GNU General Public License (GPL), the Berkeley Software Distribution (BSD), the MIT License, and

the Mozilla Public License. If a faculty member has used any open source software during the course of developing his or her software, it will be important to analyze the terms of the relevant license to determine whether the faculty member's own software must be released under the same license as well. While open source licenses share many common principles, they often differ in important ways and should be analyzed individually. (For more on open source licenses, see "Open Source Software Licensing," in Volume 3 of the *AUTM Technology Transfer Practice Manual, 3rd Edition*.)

Software Licensing

While similar to any license from a university, software license agreements should contain some unique attributes. One unique aspect of software licensing is the wide potential range of commercialization paths, including third-party development firms, end users, and distributors. As addressed below, each of these potential commercialization paths has pros and cons, and the nature of the particular software to be licensed will suggest the appropriate licensing path to pursue. In particular, some points to consider in selecting one path versus another include:

- How robust is the software?
- Will it require support?
- How much ongoing development is planned?

Which licensing path you elect to pursue (through in-depth discussion with the involved faculty) will drive the particular form of the license and the important terms to consider.

One potential commercialization path is a software development firm. The majority of software developed in the university setting is not of commercial quality. That is, the software has not gone through extensive debugging, optimization, and quality-control phases, or does not have extensive documentation. This possibly makes the best commercialization path a third-party software development firm, which would put the software through a rigorous release process. In the end, this path provides a better product to the market. Such license agreements are similar to traditional university patent agreements, providing the licensee the right to create its own works based on the university's work (e.g., derivative works), requirement to indemnify, no warranty clauses, etc.

Another potential commercialization path is direct to end-user. This path is not typically available to early-stage university technologies. Software that is already successfully used internally, and/or has high ease-of-use, might be a good candidate for such licensing, as might software with limited appeal outside of small markets. Such licenses are typically shorter in length than traditional university licenses, not requiring much of the reporting and diligence sections.

However, these agreements should contain the same warranty disclaimer clauses. In addition, care should be taken that the university is dealing with qualified licensees (whether from a financial perspective or from an export controls perspective), and that individuals within an organization are not able to inappropriately accept a license on behalf of their company (e.g., there should be language that covers either the individual or acceptance on behalf of an organization). In some cases, extra care should be exercised when the software has the potential to do harm to either the licensee or the licensee's equipment.

Distributors are yet another commercialization path for software, where the licensee simply acts as a sales agent for university software. Although software following this path may have already achieved a relatively high-quality state of development, similar to the end-user example, this software might have a steep learning curve, or be prone to significant support requirements, and likely requiring more resources (e.g., ongoing support and consulting) than a university could, or is willing to, supply.

A reseller or other distributor would better serve this type of software market.

Distributor/reseller agreements are similar to the traditional developer agreements above; but these licenses would not include the right to create derivative works. Instead, the licensee's business model is one of margin on sales and support fees.

Open Source Licensing

There is a large movement by universities and other software developers to support distribution of free software. Free can mean anything from free to make derivatives, to no cost, or many things between. As noted above, faculty creating software are often driven to create solutions for the public good and have little or no desire to obtain personal

profit. Further, if the software was created as part of a collaborative effort with others, there may be expectations or requirements to contribute such software back for use by others. (Note, there is not a statutory equivalent to Bayh-Dole for copyright.)

In these cases, it is the technology manager's responsibility to (a) ensure faculty and staff understand the value of the material they have, (b) understand the consequences of their decision to have the software provided for free, (c) protect the institution from harm, (d) and ensure appropriate institutional or author acknowledgement or credit. Also, it's important to explain the different types of free, or open-source, licenses available.

Prior to using any specific free-use, or open source, agreement, it is important to discuss with the creators their overall objectives for the software as well as the consequences of this choice. The official open source definition by the Open Source Initiative is found at <http://opensource.org/docs/osd>. In essence, open source software meeting this standard has the following attributes (among others):

1. Freely re-distributable
2. Source code available
3. Ability to create derivatives
4. No discrimination against any user group or use

A commonly referenced open source license is the GPL (GNU General Public License). Often referred to as *copy-left*, this type of license is viral in that it requires any software that uses, incorporates, or is derived from software licensed under it be released under the same license. [Note: The GPL is currently undergoing a significant revision (version 3.0) and should be reviewed by counsel to catch differences from the prior, well-known version 2.0.]

However, free software doesn't have to be released under the GPL. There are many styles of free use and open source software licenses. The most important thing is to clearly understand what the goals of the faculty are:

- Do they simply want it to be free of charge?
- Do they want to distribute executable code or source code?

- Do they want to allow derivative works?
- Do they want to allow licensees to distribute it further?
- Do they want licensee derivative works *back*?
- What is their real goal in making this open source?

Technology managers should discuss all of these issues carefully with faculty prior to releasing software under any open source (or free) license.

A Final Note...Click-Wrap Licensing

Software and other digital media are often protected by what are called *click-wrap licenses*. Such licenses are typically for use as end-user licenses and allow licensees to simply accept a license electronically rather than in written form, with no negotiation of the terms. Click-wrap licenses are presented to the user at various points, usually while downloading the application, installing it, upon first running it, or in the case of online databases, upon first accessing it.

Generally, the user must affirmatively consent to the terms of the license agreement (the entire license presented, with the user required to scroll through it) to become bound by it. These agreements are a useful tool for the licensing professional due to their inherent reduction in negotiations required for each licensee. However, consultation with attorneys is recommended prior to using them, as they have not been diligently tested in court yet, and some software might be more risky than other software.

But that Author Moved to a Monastery: Proactively Managing Intellectual Property to Enhance Choice for Distribution in Academic Technology Transfer

Dana Bostrom

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Innovative software with a unique title is disclosed to your office. The list of authors is ten people. Some of those listed are former and current students, and the disclosure mentions that the software was tested against data created by this same team. Now your office must determine who is an author, of which kind of right, where ownership lies, and gain appropriate assignments. Given my experience, this process can take many months, and—in one actual case—my colleague had to express mail assignment documents to a monastery in rural China prior to executing a license. The time it takes to retroactively manage intellectual property rights can discourage authors and potential licensees, such that distribution opportunities are lost.

Complex software, digital media, and portfolios of assets are becoming more common. That DVD, Web site, or software that was developed by a team on campus can have far-reaching impact—as well as users around the world. Thus, the rights within those assets—copyright, trademark, data, and other associated rights—are increasingly being managed by technology transfer professionals. Many universities manage academically and financially successful copyright portfolios. The University of Washington managed several technologies based solely on copyright and trademark, and each amassed more than \$10 million in licensing revenue over a six-year period. Gatorade is one of the best-known trademark cases in the world. These are not isolated cases.

We do not have to ignore patent rights and can acknowledge that patent rights are critical to some businesses. However, enterprises are successfully launched and maintained without patent rights—or with patent rights as a smaller component of the value proposi-

tion—every day. Managing technologies, with a broader focus than on patents, can save time and money while still achieving substantial public benefit and income. Managing nonpatent rights can require more advance work to set a distribution strategy, collect intellectual property rights, manage third-party obligations (which can be easier to accrue than working with patent rights), and identify assets that are useful to distribute.

This chapter will focus on managing intellectual property and associated rights to enable distribution of intellectual assets that have a substantial nonpatent basis. It will not discuss the licensing of these rights or creation of a strategy for the distribution of these rights, but rather suggest mechanisms to proactively manage intellectual property rights and expectations such that licensing and distribution of these rights is easier. By managing these rights while they are being created, institutions can focus on choosing distribution channels for the works, rather than tracking down authors to collect rights.

Potential Rights

Trademark Rights

Trademark rights are one of the most powerful rights, given that they may have no expiration date as long as the mark is used with the goods or services. In addition, trademark is more widely understood by the public at large when compared to other intellectual property rights. Research institutions generally have some built-in awareness and knowledge of the importance of trademarks and the management techniques for them, given the official insignia most research institutions carefully manage. Research projects and technologies can also use trademark; names of particular research results, the whole team's name, or a name of a new technology area are all potential trademark names.

While state trademark registration can be sought (in the U.S.), federal registration is often all that is necessary to protect the underlying rights in the marks obtained through use with the goods or services. International trademark registration can also be sought, although the methods to apply for and enforce marks under international law may vary. The most common trademarks from research institutions are words, colors, and designs.

To have value, trademarks should be used consistently and denote a certain level of quality of the goods (or services for a service mark) with which the mark is used. Trademarks, in the U.S., must also be “used” in commerce prior to issuance. Use in commerce appears to be an issue still under debate in the U.S. given educational institutions’ concern about when others’ trademarks are infringed (and used) by them, but have less concern about the use of new marks created by the institution.

In addition to filing for registration for actual use of the mark, institutions may also file intent-to-use applications in the U.S. to seek federal registration for marks that may not have yet been used at all or may not have yet have been used in commerce. Such use in commerce may later be shown once the mark is used with goods that have been distributed across state lines. There is great flexibility in managing trademarks.

Trademarks can be useful to include in a package of other rights (copyright, patent, etc.) to associate the licensed rights with the licensed products. The research institution can accrue benefit from association with a product that the public values, regardless of any financial gain.

Many institutions shy away from trademark licensing because quality management is required. Research institutions need to devote resources to ensure that, if the research institution is still using the mark, concurrent use by licensee(s) of the mark does not create conflicts or confusion. Resources to achieve this purpose do not often pre-exist in research groups or institutions. In addition, trademark owners must watch for potential infringers of the mark and new registration filings for marks that may be confusingly similar and may require challenges in the U. S. Patent and Trademark Office or in court to avoid decreasing the value of the owners’ mark.

Trademark Management Methods

Sometimes researchers are extremely keen to seek trademark rights and protection for descriptive names of every research result from a project (“Collaborative Information Retrieval” or “CharityWeb”). Often these groups have little desire to commercially exploit or use the trademark in commerce; rather the name is seen as a defensive mechanism—a

trophy or asset without value to create relationships or financial return. Since trademarks need to be distinctive (for example, arbitrary, fanciful, or suggestive), descriptive names may not be granted a trademark registration without showing that the mark has acquired distinctiveness (also known as *secondary meaning*) through what is typically extensive use of the mark (usually a minimum of five years) with the goods or services. This concept can be challenging for researchers who are trying to establish an entirely new field or way of thinking about a scientific problem. I encourage researchers to think of compound words (those that are fanciful or coined) rather than relying on the descriptive term alone.

With groups that desire trademarks as a defense, as well as those where there is the potential for distributing results from the research, I usually begin by talking with them about creating and managing identifiers—logos, words, and/or phrases—that would be eligible for trademark registration, but the university has chosen not to submit applications for trademarks. Since, in the U.S., trademark rights and value are acquired through use (i.e., one does not need to register a trademark to accrue rights), I encourage groups to establish and use terms of use for their identifiers. Creating and managing terms of use provides users practice with the activities necessary if the university did register and license a trademark, and it can begin building value in a mark without any expense. Most large corporations have terms that they require others to use when they allow use of their brand name or logo. Terms usually include items such as:

- size and location of the word and/or logo in comparison to other items on the same page, product, etc.
- color of the word and/or logo
- quality standards of the product, event, etc., being promoted

These corporate guidelines can be examined to create a template that researchers must complete. Gaining an assignment from the trademark creator(s) is also important.

With terms of use established and either a trademark registration application filed or a plan for a future application, a strategy for managing infringement is appropriate. Law firms and search engines are able to set alerts for possibly competing marks, but someone must be tasked with learning more about the potentially infringing use and bringing

in legal counsel when necessary. If a trademark registration is filed, the owner should consider whether the registration is competing and should be opposed so that the value of the original mark is not diminished. If the mark becomes the common name for the product or service, the mark may become generic and, thus, no longer provide trademark rights in it. This has happened with *aspirin*, *cellophane*, and *escalator*, as well as many other terms.

The Bottom Line

1. Technology transfer professionals must seek assignment from trademark creators—but must make sure the assignment is for something that would be eligible for trademark registration.
2. Applications for registered marks or intent-to-use applications may be filed, but do not need to be filed.
3. Terms of use must be established to create and maintain value.
4. Someone must be charged with assuring compliance to the terms of use and scout for potentially infringing marks and competing registrations of marks.

Copyright

In the United States, copyright happens when someone creates any copyrightable work and places it in fixed form. Copyright in research institutions is most usually associated with scholarly works such as journal articles. However, copyright attaches to almost all written works at a research institution, as well as works of music, art, computer programs (software), etc. Copyright also has an extremely long life, of approximately one hundred (or more) years, and its rights can be divided up and licensed separately.

Copyright is a bundle of at least five rights: copying a work, modifying the work (commonly known as *creating a derivative work*), distributing the work, performing the work, and displaying the work publicly. For example, modification rights can be granted, but without granting rights to distribute the modified work.

The most common copyrighted items that a technology transfer manager will see are software, digital media, Web sites, curricula, assessment tools, and technical information.

While all of these have special opportunities and problems, I will generally review copyright of these here. Open source software management and digital media have extremely complex issues that could emerge, depending on how much pre-existing material the researchers use in the new works.

Copyright can be registered in the U.S. with the Library of Congress. Registration is extremely inexpensive and allows one to sue others for infringing upon the registered work, provides a review of whether notice affixed to the work is correct, and allows for recovery of statutory damages and attorneys for infringement occurring after registration. Registration can be difficult, though, if one has to seek information about the appropriate authors who should be listed on the copyright registration application.

Copyright Management Methods

Because U.S. law says that copyright ownership normally accrues to authors and not to their supervisors, it is too often the case that students who wrote a curriculum, took a photograph, designed a logo, or wrote software and have left the research institution must be tracked down to assure that the institution does obtain ownership in the work. Because each institution's policies vary, identifying where ownership lies in all generic cases is not possible in a chapter such as this.

In addition, employer-employee relationships and contract law may impact what works can be deemed works for hire, which is what most companies use to automatically achieve ownership of works their employees create (with the company becoming, in effect, the author). Conversely, if a work is created by an outside contractor, there is normally no work for hire except under very limited circumstances. Research institutions often have as a default that employees own copyright, but must assign it to the institution under particular circumstances. One of the most difficult tasks for technology transfer professionals managing copyright is clearing title, as research is extremely collaborative and the legal definition of *author* is different from how scholars work with each other, and, thus, different from how scholars talk about their colleagues' contributions.

Given the distinctions between corporate and research management of copyright, I recommend managing copyright, in particular, as proactively as possible. Because copyright happens instantly but it can take numerous copyrightable instances to create something appropriate for broad public distribution, authors should be informed of the expectations for work creation, rights consolidation, and distribution so that there are fewer problems once authors are asked to assign work or authors see their names associated with a public use of a work to which they contributed.

Managing expectations of research team members can be handled in a number of different ways. I have used several customizable forms to help research leaders identify their expectations, formalize them, and share them with other team members. I have found two types of documents to be helpful:

- *Information about local policy and laws:* While institution policy and relevant state and federal laws are accessible to potential authors, it is unlikely that the authors have read them, understood them, or believe that they apply to them. A simple list, reference, or recitation of some of the key points is useful to ensure that everyone is on the same page with regard to what can and cannot be done within the relevant policy and law framework. This document is created by the technology transfer professional. Depending on the institution's policy, this document may allow advance assignment of rights or a promise or notice that assignment of rights will be required at some point.
- *Information about the local conditions of the research team:* What has the team decided to do about distributing and/or sharing work from the project? I ask groups to consider who can share work created by the team, when, and with whom. For example, can students use related work in class projects? Can individual contributors publish their portions or does one need to wait for the entire item to be complete? The technology transfer professional can provide a template, with the choices that would be allowed under policy enabled, but the unique content of this kind of a document should be designed by the research team.

With these kinds of documents in place, members are aware of what the grand plan is for the work they are creating. Making the principal investigators aware of the challenges of copyright can make seeking assignment when works are created or prior to someone's departure from the institution easier. I encourage researchers to put these two documents in place as soon as possible after the research team is in place, but certainly when external funding to support the work is in place. A documentation of these informal expectations and what works are planned to be shared (and with whom, when) helps make sure that all project participants share the same understandings.

The Bottom Line

1. Copyright happens automatically when the work is created, and rights can be distributed across numerous individuals. This can be challenging if the research team wants to distribute a work (such as software) that was developed over a number of years.
2. Rather than tracking down authors across the globe several years after departure from the institution, proactively managing the author's expectations for how his or her work will be used and gaining assignment prior to departure, makes everyone more comfortable with the plan for sharing copyrightable works.
3. Most complications arise when research-institution employees create copyrightable works. However, relationships with vendors (or other third parties) hired to work on particular components must also be managed to assure the research institution appropriate rights to achieve the purposes of the work.

Data Rights

Few institutions have specific data rights policies, and there are as many definitions of data as there are data creators. Granting organizations sometimes ask for rights, institutions and authors sometimes each believe that they own data, and data are unevenly covered by statutory methods in the U.S. Foreign jurisdictions sometimes have better mechanisms for managing data than the U.S.

Data are most commonly shared within databases, and the database as a whole is usually managed by copyright and contract. Data and databases can have a variety of uses: experimental results, data to validate against, disparate data made easy to search through a structured system, patterns to look for, historical data, etc.

Data Rights Management Methods

Data can be created by individuals or machines, and the structure of the data has the same options. Research teams that are planning to create data and/or databases could use methods similar to those mentioned in the copyright section. Care should be taken to assess where any non-original data are from to avoid questions about ownership. Data generated by machine may have special concerns if they involve use of other copyrighted information, and parties should be cautious if they use spider, search, or compilation techniques that are legally defensible given the final purpose of the data. Technology transfer professionals may need to examine trespass laws, copyright laws governing circumvention of protection measures, or related laws.

Other Rights

Privacy and Publicity

Laws managing an individual's privacy, use of name, likeness, voice, and signature vary by state. More than fifteen U.S. states have laws that regulate privacy—other states have common-law rights, as well as both statutory and common-law rights. Technology transfer professionals should be concerned about privacy and publicity law when using information, pictures, or other regulated assets about technology the institution promotes. The developer's names and likenesses are the most obvious instances of personal information, but photographs of others embedded in a work may also need to be reviewed. Factual information can certainly be used, but technology transfer professionals should consider if additional permissions are required when using assets other than factual information.

Privacy also impacts the use of data that a research team collects, especially if the data are about individuals or from a Web site. Other laws, if the data involve medical patients or minors, may need to be examined. Some research teams construct a privacy policy to let users know how data will be collected, managed, and shared.

Conclusion

This chapter briefly reviews issues technology transfer professionals should consider in copyright, trademark, data, and other related rights and focuses on how to manage rights

proactively to avoid ownership disputes or title clearance issues at the time of licensing. Closely tied to intellectual property rights is revenue management, which can be contentious with numerous authors contributing to a common work over a long period of time.

Technology transfer professionals are often caught managing ownership disputes of copyrightable works, when the concerns of the authors are more often about how revenue, credit, or other elements will be distributed. Providing research teams a mechanism to discuss these issues, document them, and develop a plan to distribute their work will allow a research institution to more easily share their work to achieve public impact while minimizing risk.

Open Source Software Licensing

Edward Kelly, JD

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Introduction

Open source describes a software development strategy; essentially it is a way to write computer programs. The OS model develops software in an open environment with the source code distributed for peer review and peer modification: See Eric Raymond's *Cathedral and Bazaar* (<http://www.tuxedo.org/~esr/writings/cathedral-bazaar>). The idea is to publish the *source code*, the human readable form of the program, for review and comment by anyone and everyone interested. The open and public scrutiny of the code will result in bugs being found more quickly and solved with greater elegance.

Thus, the intrinsic parallelism and free idea exchange inherent in the open source software development process has benefits over the traditional proprietary software development process. To get these benefits, the source code needs to be freely available and free to use and modify. These needs have led to the development of license agreements that make freely available the source code and the right to use and modify the source code: open source licenses.

But there is more to the OS model. There is a philosophy promoted by most open source developers that the knowledge and information provided in the published code is for public use, and the public should have the right to use the source code as the public sees fit. Still others go further. They take the position that copyright laws have failed to benefit actual software developers and instead benefit only corporations that take ownership of copyrights from employee-developers and use the copyright to control distribution of the software for company profit.¹ To address this, these developers promote releasing code to the public to be used by the public but only with an agreement from those using the code that they too will release any work derived from the code for public review and use.

To this end, the open source community employs copyright laws and software licenses to distribute code for public use, and some in the community have taken significant effort to leverage copyright law and licenses to ensure that code released to the public remains publicly available, even if that code is subsequently improved, modified, or expanded. This chapter discusses two families of OS licenses that differ in the requirements placed on the licensee and which, consequently, serve different members of the software development community.

Commonly Used Terms in OS Licenses

Before going any further, it may be helpful to review some of the terms commonly used when discussing open source licensing of software. Some of the terms are technical and some are legal. It may be best to discuss these terms in the context of a simple example.

When computer programmers first start learning to program they often start with the simple example computer program called Hello World. Written in one popular computer language, the program looks like this:

```
#include <stdio.h>
main()
{
printf("Hello World!\n");
}
```

The Hello World program will cause the words “Hello World!” to be written on the screen. Indeed, the line `printf(“Hello World!\n”)` clearly suggests that this program will print out the phrase “Hello World!” This program code set out above is called the *source code*, a version of the program that a human can read and understand and change. For example, you can easily see that if you wanted this program to welcome AUTM, you could edit the program to read `printf(“Hello AUTM!\n”)`; and now the phrase “Hello AUTM!” will print out on to the screen.

The modification you made is called a *derivative work*, which is a term provided by the U.S. Copyright Statute that says that the holder of a copyright (which is the right to copy) is also the holder of all rights to prepare derivative works; that is, altered, amended, or supplemented versions of the original work. What is and is not a derivative work is often a complex question, but the analysis often begins by looking to see whether the new work was made by modifying a copy of the original work. If it was, this is a large factor in finding the new work to be a derivative work prepared from the original.

Although you can read this source code, a computer cannot. To put this program into a form that a computer can understand and run, the program sends the above source code for this Hello World program to a special program called a compiler that will compile down the source code into *object code*, essentially the 1s and 0s (binary form) that a computer can understand, but that is all but impossible for a person to understand.

Looking again to the source code for the program, you can see that the very first line is `#include <stdio.h>`. This is a statement that tells the compiler to link to a library called `stdio`. The `stdio library` is the standard input/output library, and it contains all the computer code necessary to carry out the `printf` command used in the Hello World program. A library contains sets of common computer operations, like printing to a computer screen, or math functions like quadratic equations.

Using standard libraries reduces the development time of software products by eliminating the need to repeatedly code these common operations and debug the result. The compiler will *link* the `stdio` library with the Hello World program and generate all the object code the computer needs to actually print the phrase “Hello World!” to the screen.

One or more of the terms *source code*, *object code*, *derivative work*, *library*, and *linking* appear frequently in most open source licenses, and the preceding should provide some useful description of the meaning of these terms.

The Legal Structures of the Open Source Model

As noted above, there are two basic and related philosophies that drive open source software licensing. The first is that the value of the information and technology built into computer code is realized most effectively when it is published for everyone to see and released for everyone to use. This philosophy guided the development of several common licenses used by the OS community, which arose in the late 1990s, in response to the concerns of the hacker and free software communities. These licenses, discussed more fully below, grant to the license holder a right to use the code as the license holder wishes and disclaims all warranties and liabilities.

A second related philosophy is that programmers, at least certain types of programmers, are best-served when source code is freely available for review and use, and, further, that traditional notions of copyright restrict creativity and innovation and fail to compensate the creative party. This philosophy led to the development of the *copyleft license*, a license providing published code for use but requiring any modifications, amendments, or derivative works resulting from that published code remain publicly available for review and use. To this end, the copyleft license requires that, to the extent that any derivative work is released, that derivative work will be released with the published source code and with the right to use that derivative work for any purpose.

In essence, the open source licensing environment breaks down along these two types of licenses, with the first type being referred to generally and in this chapter as *less restrictive* and the second type being referred to generally and in this chapter as *copyleft*.

Moreover, the open source licensing environment includes a robust and vigorous membership that takes seriously these licensing issues and, to this end, have established organizations that offer examples of open source licenses and suggestions on how to use the correct license. Further, the open source community has added some teeth to these agreements by establishing organizations like the Free Software Foundation Inc. (<http://www.fsf.org>) that will pursue infringers, particularly companies that fail to comply with copyleft obligations.

As such, unlike other areas of licensing, the open source community has a rich body of available template licenses offered by organizations and communities for the purpose of helping developers create code under the open source model. These template licenses are commonly reviewed and selected by developers, including those at universities and research centers, as the licenses under which code is distributed.

Less-Restrictive Open Source Licenses

The less-restrictive open source license provides the source code to the licensee with the licensee agreeing to disclaim all warranties. Typically these licenses are publicly and freely available and are delivered as shrink-wrap licenses that the licensee obtains upon download of the code. As the point of the OS license is to give the licensee the actual source code, it is understood that many of the licensees will use the source code to operate computers, machines, and other devices. A good example is the Apache Web server software (<http://www.apache.org>). This code is released as open source code. The vast majority of licensees merely use the code to run Web servers.

However, a substantial number of licensees have actually made derivative works from the Apache server source code. These modified versions of Apache can be used for any number of applications, including running Web servers from small handheld devices. As the modified code actually takes control of the hardware and may have access to files stored on the hardware, it is important to disclaim all liability, as there is always the possibility that the software may damage the hardware and data on the system. But for the concern over liability, the source code could be released freely and without concern. However, under the adage of “No good deed goes unpunished,” developers releasing their code to the public with copies of the source are quite wise to use a shrink-wrap license to disclaim all warranties.

The Massachusetts Institute of Technology, Berkeley Software Distribution (BSD), and Apache licenses, classic open source software licenses widely used in many open source projects, are examples of the less-restrictive open source licenses: The text of these licenses can be found at the Open Source Initiative, <http://www.opensource.org>. These licenses are very flexible and compatible with almost every form of open source license.

The most well-known of such projects are probably the BSDNet and FreeBSD Unix-like operating systems and the Apache HTTP server.² These licenses, as applied to the original licensed code, allow the code to be used in proprietary software and do not require that open source versions of the code be distributed. Projects created under these licenses, or derived from such code, may go closed and released under a proprietary license.³

The following is a closer look at the BSD license template. As previously noted, the BSD license, and templates for licenses like the BSD license, are available from several organizations, including the Open Source Initiative.

A BSD-like license begins with a notice of copyright:

Copyright (c), Year., <owner>
All rights reserved

The next clause provides for the use and redistribution of the source code, along with certain minimal attribution obligations:

Redistribution and use in source form and binary forms, with or without modification, are permitted provided that the following conditions are met:

Redistributions of source code must retain the above copyright notice, this list of conditions and the following disclaimer.

Redistributions in binary form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and/or other materials provided with the distribution.

Neither the name of the <ORGANIZATION> nor the names of its contributors may be used to endorse or promote products derived from this software without specific prior written permission.

The license ends with a section of standard disclaimers that disclaim all warranties and liabilities:

THIS SOFTWARE IS PROVIDED BY THE COPYRIGHT HOLDERS AND CONTRIBUTORS “AS IS” AND ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED. IN NO EVENT SHALL THE COPYRIGHT OWNER OR CONTRIBUTORS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

The effectiveness of these disclaimers may vary from jurisdiction to jurisdiction, with different countries having different rules as to the extent warranties may be disclaimed. Consulting with an attorney is important when crafting disclaimers.

In the end, this license grants the right to use the software in any manner the license holder wants, including the right to make modifications to the code and freely use and sell the modified code. Thus, this less-restrictive license gives the right to make derivative works and keep that work as proprietary code for commercial sale.

Others of these less-restrictive licenses have similar language, some being quite clear that the license holder can use the code for his or her own proprietary, commercial endeavors, such as the Apache license, which states:

You may add Your own copyright statement to Your modifications and may provide additional or different license terms and conditions for use, reproduction, or distribution of Your modifications, or for any such Derivative Works as a whole, provided Your use, reproduction, and distribution of the Work otherwise complies with the conditions stated in this License.

Granting Patent Rights under Less-Restrictive OS Licenses

To encourage the software development community to work with code being distributed under an OS model, some commonly used less-restrictive licenses contain grants to any patent rights held by the developer and necessary to use the code being distributed. For example, the Apache license includes a grant to any necessary patent rights held by the contributors, a term defined in the license to include the licensor:

3. Grant of Patent License.

..., each Contributor hereby grants to You a perpetual, worldwide, non-exclusive, no-charge, royalty-free, irrevocable (except as stated in this section) patent license to make, have made, use, offer to sell, sell, import, and otherwise transfer the Work, where such license applies only to those patent claims licensable by such Contributor that are necessarily infringed by their Contribution(s) alone or by combination of their Contribution(s) with the Work to which such Contribution(s) was submitted. ...

The problem with this clause for a university is quite clear. It can reduce the value of any patents the university owns on inventions that are embodied in the open source code as it freely grants licenses to any party that also takes a license to the software. In the end, it is important to understand that many forms of less-restrictive open source licenses are offered for use by different organizations and communities. These licenses will differ in terms substantially, and the correct license for your purpose will depend upon your facts and intentions.

Copyleft Licenses

Although there is no single copyleft license, the GNU General Public License (GPL) is generally considered the prototypical license for copyleft licensing of open source software. The GNU GPL is the license under which the Free Software Foundation Inc. (FSF) licenses GNU software. Many other organizations follow its lead and release software under the GPL. The GPL has been available in one form or another for more than fifteen years; the latest version, GPLv3, was released in the summer of 2008 and is available from the FSF at <http://gplv3.fsf.org/>.

The GPL includes a preamble, terms and conditions of licensing, warranty disclaimers, terms and conditions that govern software produced by the licensee using the GNU software, and other miscellaneous terms and conditions. The preamble sets forth the purpose of the GPL, namely: “to guarantee your freedom to share and change free software—to make sure the software is free for all its users.” The GPL is intended to apply to most of FSF’s software and any other program whose authors commit to using it.

The GPL permits users to distribute copies of programs covered by the GPL (including derivative works) and charge a fee for the service of providing copies of such works. GPL licensees may copy and distribute copies of the source code of the software that is covered by the GPL.

In exchange for the licenses granted to them, licensees are required under the GPL to include specified copyright notices, warranty disclaimers, and licenses with each licensed software program and modified work that is based upon or that incorporates the licensed software. Licensees must also provide prominent notices of any modifications they make to software.

However, the key feature of the GPL, and any copyleft license, is that the GPL requires that any derivative work of the licensed software be licensed as a whole at no charge to all third parties under the terms of the GPL; that is, a licensee’s customers must be permitted to view and work with source code and to copy, modify, and distribute derivative works of the licensee’s programs without payment of a royalty (other than the permitted service fee for transferring a physical copy). This clause prevents the licensee from using the source code to create a derivative work that can be licensed as proprietary software under a commercial software license.

More specifically, the GPL includes the following statements, terms, and conditions:

Preamble

The GNU General Public License is a free, copyleft license for software and other kinds of works.

The licenses for most software and other practical works are designed to take away your freedom to share and change the works. By contrast, the GNU General Public License is intended to guarantee your freedom to share and change all versions of a program—to make sure it remains free software for all its users.

The GPL goes on to say:

When we speak of free software, we are referring to freedom, not price. Our General Public Licenses are designed to make sure that you have the freedom to distribute copies of free software (and charge for them if you wish), that you receive source code or can get it if you want it, that you can change the software or use pieces of it in new free programs, and that you know you can do these things.

The terms of the GPL allow you to charge for your software, although given that the GPL allows copies to be made freely, it is difficult to understand why someone would pay a meaningful royalty.

Turning to terms and conditions, the GPL implements the copyleft philosophy by using licensing clauses that restrict how you can *convey* copies of the original work or copies of any derivative work. The GPL, in Section 2, grants any person who “comes into possession” of the software the right to use the software, modify it, make copies for that person’s use, and provide it to others with the express purpose of having those others modify the work and provide the modified work back. Specifically, Section 2 of the GPL states:

2. Basic Permissions.

... You may make, run and propagate covered works that you do not convey, without conditions so long as your license otherwise remains in force...

All this can be done and none of it requires the release of the source code for the work or modifications to the work as all these activities are essentially related to mere use of the software by a person who has a copy of the software.

However, once a party chooses to begin *conveying* (i.e., providing) copies of the software, or modified versions of the software, to others for the others to have and use, then Sections 4 and 5 of the GPL become relevant and active. Sections 4 and 5 of the GPL require that any conveyance of the software or modified versions of the software be accompanied by copies of the source code, or by instructions on how to obtain the source, and with a grant of the right to use, modify, and copy the software or modified versions of the software.

4. Conveying Verbatim Copies.

You may convey verbatim copies of the Program's source code as you receive it, in any medium, provided that you conspicuously and appropriately publish on each copy an appropriate copyright notice; ...

5. Conveying Modified Source Versions.

You may convey a work based on the Program, or the modifications to produce it from the Program, in the form of source code under the terms of section 4, provided that you also meet all of these conditions:

- a) The work must carry prominent notices stating that you modified it ...
- b) The work must carry prominent notices stating that it is released under this License ...
- c) You must license the entire work, as a whole, under this License to anyone who comes into possession of a copy. ... This License gives no permission to license the work in any other way, but it does not invalidate such permission if you have separately received it.

As set out in the above clause c), additional terms and restrictions to use, modify, or copy the software or modifications of the software are strictly forbidden, or at least controlled. Section 7 of the GPL allows some very minimal modifications to the license, such as allowing for better warranties.

The result is that the GPL licenses the software with the right to freely use, copy, and modify the software, but with a restriction that prevents a user from redistributing the software or any derivatives as proprietary code under a traditional commercial license. Importantly, this restriction also applies to software that is incorporated into hardware devices, such as MP3 players, personal digital assistants, cell phones, and other devices.

The GPL explicitly requires that software licensed under the GPL and incorporated into a hardware device must be accompanied by the source code for that software and instructions for changing the software within the device. In this regard, companies incorporating GPL-licensed software must take care; a recent settlement between the Software Freedom Law Center and Verizon Communications Inc. required Actiontec Electronics, a supplier of Verizon hardware that violated the terms of the GPL, to appoint an open source compliance officer and to pay an undisclosed amount.

The Lesser GPL

The strictness of the GPL raises some concerns within the open source software development community. In particular, the use of software libraries that are licensed under the GPL has caused some particular concerns. Recall that the Hello World example included the `stdio` library, which was compiled along with the program. The concern is that using a library licensed under the GPL (such as a licensed version of the `stdio`) would bring the entire Hello World program under the terms of the GPL. In many cases, the library provides merely standard code and technology and its inclusion into the program is more for the convenience of not having to rewrite these standard libraries than to take advantage of any particularly innovative programming present in the library.

To address this concern, the GNU project offers a second principal license that can be used with any code, but is particularly suited to use for libraries. As opposed to the GPL, the GNU Lesser GPL (LGPL) permits use of the library in proprietary programs without having the entire program brought under the GPL (for the text of this license, see <http://www.opensource.org>).

The LGPL provides definitions to help more clearly explain the limits of the license. Specifically, the LGPL helpfully defines certain terms:

“The Library” refers to a covered work governed by this License, other than an Application or a Combined Work as defined below.

An “Application” is any work that makes use of an interface provided by the Library, but which is not otherwise based on the Library. Defining a subclass of a class defined by the Library is deemed a mode of using an interface provided by the Library.

A “Combined Work” is a work produced by combining or linking an Application with the Library. The particular version of the Library with which the Combined Work was made is also called the “Linked Version.”

In Section 4, the LGPL allows the library to be used with another application to create a combined work, and the combined work may be released under the terms of “your choice:”

4. Combined Works.

You may convey a Combined Work under terms of your choice that, taken together, effectively do not restrict modification of the portions of the Library contained in the Combined Work and reverse engineering for debugging such modifications, if you also do each of the following:

- a) Give prominent notice with each copy of the Combined Work that the Library is used in it and that the Library and its use are covered by this License.
- b) Accompany the Combined Work with a copy of the GNU GPL and this license document.
- c) For a Combined Work that displays copyright notices during execution...
- d) Do one of the following:
 - 1) Convey the Minimal Corresponding Source under the terms of this License, and the Corresponding Application Code in a form suitable for, and under terms that permit, the user to recombine or relink the Application with a modified version of the Linked Version to produce a modified Combined Work, in the manner specified by section 6 of the GNU GPL for conveying Corresponding Source.

- 2) Use a suitable shared library mechanism for linking with the Library. A suitable mechanism is one that (a) uses at run time a copy of the Library already present on the user's computer system, and (b) will operate properly with a modified version of the Library that is interface-compatible with the Linked Version.
- e) Provide Installation Information, but only if you would otherwise be required to provide such information under section 6 of the GNU GPL, and only to the extent that such information is necessary to install and execute a modified version of the Combined Work produced by recombining or relinking the Application with a modified version of the Linked Version. (If you use option 4d0, the Installation Information must accompany the Minimal Corresponding Source and Corresponding Application Code. If you use option 4d1, you must provide the Installation Information in the manner specified by section 6 of the GNU GPL for conveying Corresponding Source.)

Thus, the LGPL provides copyleft restrictions on the library code itself, but does not apply copyleft restrictions to a program that merely uses the library.

Conclusion

The open source development model, whether under less-restrictive licenses, the GPL, or the LGPL, appears to be here to stay, and it may work well for many projects and efforts where a royalty stream is unlikely or unnecessary. However, copyright holders should take care to understand the open source model before embarking on an open source strategy. In particular, universities should evaluate how their community currently uses open source software, whether the advantages of open source software development apply to them, and whether their licensing goals are consistent with the GPL.

Notes

1. See St. Laurent, *Open Source & Free Software Licensing* (O'Reilly 2004).
2. See St. Laurent, p.14.
3. See St. Laurent.

the public to be used by the public but only with an agreement from those using the code that they too will release any work derived from the code for public review and use.

To this end, the open source community employs copyright laws and software licenses to distribute code for public use, and some in the community have taken significant effort to leverage copyright law and licenses to ensure that code released to the public remains publicly available, even if that code is subsequently improved, modified, or expanded.

This chapter discusses two families of OS licenses that differ in the requirements placed on the licensee and which, consequently, serve different members of the software development community.

Sui Generis: A Unique Form of Intellectual Property Governing Compilations of Data

Bruce Goldstein

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Introduction

The well-used Latin phrase *sui generis* translates into English as *of its own kind* or *unique*. In the arena of intellectual property (IP) law, the phrase refers to a form of IP that does not derive from other, traditional forms of IP, such as patents and copyrights. Beginning in the mid-1990s, the European Union (EU) began trying to create such a sui generis system to govern compilations of data. Ten years later, the EU has returned to re-examine this new system, perhaps to change or repeal it, perhaps not. The two questions for this chapter are, what does the sui generis system do and how does it affect technology transfer (both in the United States and elsewhere)?

This chapter will review the history of the law leading up to the creation of the sui generis system. It will also examine the sui generis system in detail. Then the chapter will recount the EU's experiences with, commentary on, and international reaction to the system. Finally, the chapter ends with some suggestion of issues to consider in negotiating agreements with the sui generis system in mind.

Historical Perspective

U.S. Constitution: Patent and Copyright Clause

The United States Constitution enumerates the powers of the three branches of the federal government. Under Article I, Section 8, Clause 8, Congress has the following authority regarding patents and copyrights: "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Clearly, under this clause, Congress can create a system of copyrights designed to give the author of, say, a book of new, fictional stories the right for a limited time to market that new book exclusively. The question is, what about a book of facts?

Twentieth Century Case Law: Sweat of the Brow Doctrine

As a matter of metaphysics, if a person happened to be the first to record a given fact on paper, calling that person the *author* of the writing seems strange at best, and granting the person exclusivity to any paper reproduction of the fact would create a barrier to “the progress of science and useful arts.” This dynamic is reflected in the most fundamental axiom of copyright law, that “no author may copyright his ideas or the facts he narrates.”

At the same time, the history of copyright clearly allows that, when one collects a series of separate works (whether copyrighted on their own or not) and compiles them into a new work, that new compilation may be entitled to its own copyright. Thus, a collection of folk stories, sheet music, and reproductions of artwork all may involve sufficiently creative industry that the new work represents something more than the sum of its parts. As a result, the copyright laws in the United States (U.S.) have always expressly acknowledged that compilations may be protected by copyright.²

Between these two unassailable premises lies an apparent tension: When does a stack of individual facts become a unitary work protected by copyright? Most courts in the United States construed the Constitution’s Patent and Copyright Clause and the copyright laws to require that a person claiming to be an author of a work demonstrate that the work has some element of creativity or originality beyond the mere facts on a page. For example, the selection of which data to include, or how to arrange it in the work, could involve sufficient creativity to warrant protection. Merely being the first to write it down, however, would not, because the fact itself inherently belonged to the public.³

Some courts, however, asserted that copyright is a social trade-off—without the promise of exclusivity, people will tend not to invest as much in creating compilations and, because society is better off having such works in existence, copyright is a reward for that investment, even where the work fails to involve the kind of creativity that would normally warrant copyright protection. This reasoning became known as the *sweat of the brow* or *industrious collection* doctrine.

Paradigm Shift: *Feist v. Rural Telephone*

The Facts of Feist

During the 1980s, Kansas had eleven local telephone utilities, each with a monopoly in its region. State regulations required that each maintain a local white pages directory of residential phone numbers, organized by last name, which must be collected and distributed free of charge, but companies could charge advertisers for placing ads in the commercial yellow pages directory. These two directories were typically joined in a single book.

Feist Publications Inc. wanted to publish a directory of all residences in Kansas, which would also be distributed for free, but which would compete for advertisers. Feist received permission to copy the data from ten of the eleven utilities, but when Rural Telephone Service refused, Feist copied data without its consent. Because Rural had inserted four fictitious names in the directory, Rural was able to prove easily that Feist had copied. The Kansas courts followed the sweat of the brow doctrine, holding that Feist infringed Rural's copyright in the white pages, a decision affirmed by the Tenth Circuit Court of Appeals.

Supreme Court's Opinion

The United States Supreme Court, however, reversed unanimously. Looking at the Constitution and prior Supreme Court cases dating to the late 1800s, the Court held that *originality* is, and always has been, the constitutional touchstone of copyright. The Court noted that one who writes down facts is not an *author* and the work is not *original* because the act of recording a fact is not one of creating; at best, the writer has discovered a fact, but the fact itself is not created by its recordation.

This observation is consistent with the concept that granting copyright to certain compilations is constitutionally acceptable. After all, creating a compilation can involve a non-functional, creative selection of which facts to include, an artful arrangement of data, or an imaginative coordination of otherwise unrelated data. It is *these* elements of the compilation that are protected by copyright, not the underlying data.⁵

The Court expressly repudiated the line of cases relying on the sweat of the brow doctrine.

It may seem unfair that much of the fruit of the compiler's labor may be used by others without compensation. As Justice Brennan has correctly observed, however, this is not "some unforeseen byproduct of a statutory scheme." *Harper & Row, Publishers, Inc. v. Nation Enterprises*, 471 U.S. 539, 589 (1985) (dissenting opinion). It is, rather, "the essence of copyright," *ibid.*, and a constitutional requirement. The primary objective of copyright is not to reward the labor of authors, but "to promote the Progress of Science and useful Arts."⁶

The Court went further, observing that copyright protection does not necessarily apply to every selection, coordination, or arrangement of data. To be sure, the degree of originality is not large, and most compilations will pass muster; moreover, novelty is not required.⁷ Nonetheless, some compilations are so mechanical, utilitarian, and trivial that the spark of independent creativity is wholly lacking.

The Court noted that even *Feist* conceded *Rural* had a valid copyright in the book as a whole, as it contained both advertisements in the yellow pages and original, introductory text at the forward of the book. Nevertheless, the Court held that *Feist* did not infringe by copying the data in the white pages. *Rural* mechanically included all residents, functionally sorted by last name, and exercised no independent creativity in coordinating the phone number with each name. Merely associating that data with a separate yellow pages section did not render this mindless listing original.

Post-Feist Cases

After the *Feist* decision, several cases helped clarify exactly where the line of minimal creativity lies. In one case, involving a compilation of public laws, a court held that, while the laws themselves are in the public domain, the layout and pagination may be protected.⁸ Similarly, another court held that the formatting, organization, layout, and artwork in the yellow pages section of the phone book can be copyrighted.⁹ Where recording content requires the application of professional judgment (rather than merely reporting statistics), a court ruled that copyright is available.¹⁰ Finally, despite the

acknowledged principle that a recipe's mere listing of ingredients is not protected, the exact words used in a cookbook to articulate the process can be copyrighted.¹¹

Tangentially, the issue of news has continued to arise in the context of copyright, even after the decision in *Feist*. The National Basketball Association (NBA) has long tried to extract value out of the reporting of scores in basketball games. With the rise in the 1990s of inexpensive cellular telephones, Motorola began a service of sending updates of games directly to customers' phones. The Second Circuit noted that the score of a game is a fact, and so cannot be copyrighted by the NBA. At the same time, the court observed that a major value of that fact is in its entertainment function, which Motorola was diminishing without compensation. Accordingly, the court held that, under *Feist*, the NBA cannot sue for copyright infringement, but might have a claim for unfair competition.¹²

Impact of Feist on Other Common-Law Countries

Since *Feist*, the courts of Canada and Australia have had opportunities to examine the same issues, in light of their own versions of copyright laws (which follow principles and procedures very similar to those of the United States). These cases are also instructive.

In Canada, the Supreme Court faced a dispute between a library service, which offered photocopying services for research purposes, and publishers of scientific works and of compilations of data. The Court declined to hew to the reasoning in *Feist* and require creativity, but also declined to hold that anything beyond slavish duplication, such as sweat of the brow labor, is enough to warrant a copyright. Instead, the Court required that the writer have used some intellectual effort, skill, and judgment beyond a mere trivial, mechanical exercise.¹³

Australia has elected to follow the lead of the United Kingdom's (UK) long-held industrious collection approach.¹⁴ In *Desktop Marketing v. Telstra*, Telstra owned copyrights in a CD-ROM edition of the enhanced white pages and yellow pages for Australia, which included more data per person than merely the associated phone number and address. Because the Australian copyright laws were written on the basis of UK laws, the court found UK precedent much more persuasive than *Feist*, and so declined to follow *Feist*.

Instead, the court articulated the rule that sufficient work and expense could support copyright, provided that the author independently collected the data (i.e., did not copy it from any other source).

EU Directive on Sui Generis

1996 Directive

On March 11, 1996, the Parliament of the European Union passed a directive entitled, “Directive 96/9/EC of the European Parliament and of the Council on the legal protection of databases.”¹⁵ The directive required that member states pass implementing legislation by January 1, 1998. For convenience, a complete copy of the text of the 1996 directive is available as a separate PDF.

The directive sought to harmonize several competing theories and practices regarding compilations of data that do not clearly qualify for copyright protection. As noted above, the UK has long followed a sweat of the brow doctrine. France pioneered a droit d’auteur (author’s right) doctrine, which protected only original databases that required an element of “intellectual creation.” Also, some of the Scandinavian countries followed a catalogue rule, which gave a limited protection to factual compilations created through original labor.¹⁶

Scope of Application

The directive establishes that databases may be protected by either or both of two forms of intellectual property: traditional copyright (which needs no further elaboration here) and sui generis protection. Under the terms of the directive, the sui generis rights would apply to “[a]ny collection of independent works, data, or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means.” The directive imposes no qualification or limitation regarding originality, creativity, functionality, or the like.

Infringement

Under the directive, the owner of sui generis rights in a database may exclude others from extracting and reutilizing a substantial part of the database. *Reutilization* includes

any reproduction (even temporary or archival), adaptation (including to a new medium), alteration, or distribution to the public. *Substantial* can be measured either quantitatively or qualitatively, depending on context.

Duration

Once created, the sui generis rights last up to fifteen years.¹⁷ That term can be continued indefinitely, however, as long as the owner continues to update the database with “substantial new investments” of data.

Reciprocity

The EU included in the directive a carrot to induce other nations to follow suit. For a database made outside the EU, sui generis rights may be exercised in the EU only if the database was made in a country that offers “comparable protection to databases produced by nationals of [the EU].”

Optional Exemptions

Each EU member state may, at its option, exempt copying for teaching or scientific research, but only “to the extent justified by the non-commercial purpose to be achieved.” Also, each EU member state may continue to exempt other things “traditionally authorized” by that state.

Implementation

Officially, all EU members were required to have passed implementing national legislation by January 1, 1998, but only three actually met the deadline. All but Ireland and Luxembourg had finished by the close of 2000 and, as of January 2007, all but two EC members (Romania and Bulgaria) have implemented it. Norway, Iceland, and Lichtenstein also had implemented sui generis rights, even though they were not members of the EU.¹⁸ Although other nations have considered adopting legislation implementing sui generis protections comparable to the 1996 directive, apparently no other nation has clearly done so.

Follow Up: 2001 Directive (2001/29/EC)

In 2001, the EU passed a directive to harmonize “copyright and related rights in the framework of the internal market, with particular emphasis on the information society.”¹⁹ On its face, the 2001 directive did not amend any prior directive relating to copyright or sui generis rights; rather, it purports to focus on issues on the periphery, such as the proper scope of affirmative rights of owners, a long list of specific (but optional) exemptions that member states may implement, and the legal significance of technological measures used to control access to protected works.

EU Experience and International Reaction

Major EU Cases

In November 2004, the European Court of Justice (ECJ) issued four opinions limiting sui generis rights. All four shared a common theme: What is the nature and minimum level of resources that one must invest in the creation of the database to confer sui generis rights?

*British Horseracing Board v. William Hill Organisation Ltd (UK)*²⁰

The British Horseracing Board (BHB) has a crown-granted monopoly on reporting results of horse races. As of 1998, BHB maintained a large database on, among other things, the lists of horses running in all races, their respective handicaps, and their respective owners, trainers, jockeys, pedigrees, and racing histories. The data for the next day’s races are available by subscription (online or by satellite feed) and, afterward, the data are published weekly, in an official journal. William Hill Organisation Ltd. (Hill), a subscriber to both the live feed and the journal, launched an online betting service, which included both the list of which horses will be running and what odds Hill’s service was offering.

BHB sued Hill in the UK courts under the UK’s implementation of the 1996 Directive, and in 2001, won at the trial level. The UK Court of Appeals, however, stayed the judgment and referred eleven questions of interpretation to the European Court of Justice. The ECJ concluded that the sui generis right stemmed from investing in the creation of the database, mainly the act of seeking, discovering, and collecting disparate data from inde-

pendently existing sources—in contrast to the mechanical collection or creation of data that might happen to be deposited in a database incidentally or for convenience. BHB existed to collect its data for purposes of public reporting and BHB itself created the data on horses' handicaps; the simple act of putting the data into a database did not constitute an additional investment sufficient to confer sui generis rights in that compilation.

Fixtures Marketing v. Oy Veikkaus Ab (Finland),²¹ *Fixtures Marketing v. Svenska Spel Ab (Sweden)*,²² and *Fixtures Marketing v. OPAP (Greece)*²³

Fixtures Marketing Ltd works under an exclusive contract with the English and Scottish Football Leagues to compile all the details for all the games played in England and Scotland. Under these contracts, Fixtures owns all the IP associated with that data. OPAP, Oy Veikkaus Ab, and Svenska Spel Ab all operate national betting services. Toward that end, all three betting services reproduced data taken directly from Fixtures' database. Fixtures offered each betting service a license, but each refused.

Fixtures originally sued Veikkaus in 1996 under copyright infringement and won at trial, but the judgment was overturned by the Helsinki Court of Appeal, a decision affirmed by the Finland Supreme Court. After Finland adopted the 1996 Directive, Fixtures tried again in 1999. This time, Fixtures lost at trial, but the Helsinki Court of Appeal referred the case to the ECJ. Fixtures sued Svenska Spel in 1999, lost at trial and in the intermediate appellate court, but Sweden's highest court stayed the case and referred the question to the ECJ. Finally, Fixtures sued OPAP after Greece implemented sui generis in 2000. The trial court stayed the case and referred the matter to the ECJ.

In all three cases, the questions included whether the sports data was protected by sui generis rights at all, and if so, whether use by the three betting agencies constituted infringement. As with the *BHB* case, the ECJ reasoned that sui generis rights stemmed from investing in the creation of the database, mainly the act of seeking, discovering, and collecting disparate data from independently existing sources—in contrast to the mechanical collection or creation of data that might happen to be deposited in a database incidentally or for convenience. In each case, the compilation in question was created each year wholly independent from whether that data would ever be put into a database.

Merely putting data into a database does not represent a sufficiently significant investment to warrant sui generis protection.

*Directmedia Publishing GmbH v. Albert-Ludwigs-Universität Freiburg (Germany).*²⁴

In the *Directmedia* case, a German university professor laboriously selected 1,100 of 20,000 poems that he considered the most important written in German literature from 1730 to 1900. A database, which he built over the course of about two-and-a-half years and at a cost to the university of about €35,000, tabulated many aspects of the works, including information on the author, title, opening line, and year of publication.

Soon thereafter, Directmedia put out its own list of the 1,000 most important poems of German literature on CD-ROM. In this list of a thousand poems, 876 were written between 1730 and 1900, and 856 of these appeared in the professor's database. Directmedia conceded that it had looked at the data in the university's database in compiling its own, but maintained that it had used critical independent judgment on each work in deciding which poem to include, and drew the actual poem texts from its own digital resources.

The professor and the university brought an action against Directmedia for cessation and damages. The Regional German Court found infringement, but on appeal, the Bundesgerichtshof (Federal Court of Justice) referred the case to the European Court of Justice (ECJ) for guidance. The key question was whether "extraction" reached as far as using the primary work as a substantive guide in making a new version.

The ECJ began by noting that the Directive was written to be very broad, such that copying data into a different medium or transforming the structure of the work, do not rescue an act of copying content from being an infringement. Given this context, the ECJ was unimpressed with the argument that "copying" included only mindless duplication of content. If Directmedia transferred substantial data from the university's database to its own, an interim critical examination of the substance of the data did not excuse the transfer of that data.

In referring the case back for further factual findings, the ECJ cautioned that sui generis rights do not protect against mere consultation and may not be used to facilitate “abuses of a dominant position,” restrictive practices, or unfair competition. While a database owner may condition access on agreeing to certain terms, including restrictions on direct transfers of content, once the database has been released, the recipient may examine the work for informational purposes.

2005: EU Report

As the decennial anniversary of the 1996 Directive approached, the European Commission issued its first review of the impact of the 1996 Directive.²⁵ The report, based on surveys and public information on product development, focused on whether the rate of growth of the database industry in Europe increased, whether more databases were produced in Europe than would have been in the absence of sui generis rights, and whether the benefits accrued in areas targeted to encourage innovation.

Despite assertions by the publishing sector that sui generis rights were crucial, and despite survey responses suggesting that the 1996 Directive offered new legal certainty, the report concluded that the evidence did not support the position that the anticipated economic benefits of sui generis were realized. Ultimately, the report recommended neither repealing the 1996 Directive nor changing its scope (up or down), but leaving it as is. The report encouraged members of the public to submit comments, both on the report and on sui generis rights in general. As of the writing of this chapter, the EU has not taken any subsequent action regarding the 1996 Directive.

International Reaction to the 1996 Directive

WIPO Proposal of 1997

Following the EU’s passage of the 1996 Directive, the World Intellectual Property Organization (WIPO), an intergovernmental organization under the auspices of the United Nations, began discussing the creation of a worldwide treaty. The Committee on Copyrights drafted a proposed treaty in 1997, but WIPO never reached consensus on what the treaty ultimately should say. Moreover, the Trade-Related Aspects of Intellectual

Property (commonly known as TRIPS) Agreement came into force in 1995, and WIPO had just concluded another copyright treaty, both of which included terms concerning compilations of data.²⁶ Between these, the need for yet another treaty was unclear.

WIPO issued a report in July 2002 on subsequent developments. The report concluded that more work was needed to clarify open issues, that there would not likely be any major movement internationally soon, and that WIPO should continue to follow any and all further developments.

Academic and Publishing Communities

Most of the articles and reports published in response to the report,²⁷ as well as those written beforehand, have been critical of sui generis rights,²⁸ and some even criticized the report as being too limited in scope.²⁹ Only a handful supported the sui generis model.³⁰

Other Nations' Responses

It is difficult to be certain which countries have considered implementing European-style sui generis rights for databases but declined to do so and which have never considered it seriously. Either way, after the 1996 Directive, most countries failed to implement a similar system nationally. Based on a survey conducted by the International Association for the Protection of Intellectual Property, countries known not to have sui generis provisions as of 2007 include Argentina, Australia (which follows the UK sweat of the brow doctrine of copyrights), Brazil, Canada, China, Egypt, Japan, Paraguay, Singapore, South Africa, Switzerland, and the United States.³¹ India reported it does not have a sui generis system for databases, rather, India follows the logic of *Feist*.³²

The United States Congress has examined the question almost every year from 1996 through 2004. Congress' latest effort involved two competing bills: H.R. 3872, "The Consumer Access to Information Act of 2004," and H.R. 3261, "The Database and Collections of Information Misappropriation Act of 2004." Both bills died in committee, never reaching the floor of the House of Representatives for debate, and no subsequent bill has been proposed.

Issues to Consider in Negotiations

Access to Collaborative or Funded Works

Private Funding

In most cases, in the United States and other non-EU countries, worrying about sui generis rights to data generated under a collaborative project is not worthwhile. Such rights are only likely to have a substantial impact where the bulk of the raw labor is to be done in Europe. In such situations, those who negotiate with European counterparts should carefully consider how important access to that data may be over time. Indeed, merely preserving the right to publish may not be enough if the non-EU party wants to ensure continued free access to that data.

Government Funding

If government funds are involved (for instance grants from the U.S. federal or state governments), then the recipient of those funds may be required to adhere to additional rules about publishing and about sharing raw data.³³ If so, then an arrangement in which access by the public to the data is limited may be inconsistent with the spirit, if not the letter, of the government's policy. Careful attention must be paid to ensure that the collaboration agreement does not put the funding-recipient in jeopardy of violating the funding agreement.

Protection Strategies

Reliance on Traditional Intellectual Property

In some cases, a party seeking to reserve sui generis rights can be placated if much of the commercial value could just as easily be realized through traditional forms of intellectual property protection. For example, a party trying to protect a database such as the one cited in the *BHB* and *Fixtures* cases might have better chances if the owner of the database had relied on copyright to the content that they had independently created or trademark-related rights in certifying the authenticity and quality of the data. Databases governing genetic information may be useful for a time as a research tool but, probably, the commercially useful intellectual property rights in such a tool are neither large in scope nor infinite in duration. Moreover, the true blockbuster products likely to come out of

such work will be those designed *in light of* the data in the database. These products can be adequately protected by patents.

Trade secret protection is also a possibility. Not every collaboration requires that each shred of data generated be made public (whether free or for sale). Where this is the case, a party legitimately might preserve the right to keep a portion of the data it generates under the collaboration as a trade secret, particularly where that data are related to another product (such as data on manufacturing processes for a drug). If faced with such a situation, the most important thing for both parties to do is strive to identify clearly what their respective commercial plans are—sell the data (via *sui generis* licenses), publish the data outright, or keep (some of) the data confidential.

Contract-Based Solutions

As is true for most negotiation problems, successful resolution is limited mainly by creativity and willingness to compromise. Once the negotiators have clearly staked out what their interests are, common ground usually can be found.

Consider the following possible options:

- Each party provides complete copies of the data to each other at regular intervals;
- Each party has a nonexclusive, royalty-free, worldwide, irrevocable license (perhaps for internal use, perhaps for any use) to access, extract, reorganize, and otherwise use all data generated under the project;
- Commercial exploitation of *sui generis* rights (when consistent with the purposes of the collaboration) will be limited in scope to certain fields of use or applications;
- Access to a database governed by *sui generis* rights will be granted to all requesters via a nonexclusive license styled on the open-source licenses commonly used to share software.

Notes

1. *Harper & Row Publishers Inc. v. Nation Enterprises*, 471 U.S. 539, 556 (1985).
2. *Feist Publications Inc. v. Rural Telephone Service Co.*, 499 U.S. 340, 345 (1991).

3. See, e.g., *International News Service v. Associated Press*, 248 U.S. 215 (1918). Recognizing that § 5(b) of the 1909 Copyright Act specifically mentioned “periodicals, including newspapers,” the Court acknowledged that news articles were copyrightable, but rejected the notion that the copyright in an article extended to the facts in it: “The news element—the information respecting current events contained in the literary production—is not the creation of the writer, but is a report of matters that ordinarily are *publici juris*; it is the history of the day.” *Id.*, at 234.
4. *Jeweler's Circular Publishing Co. v. Keystone Publishing Co.*, 281 F. 83, 88 (2nd Cir. 1922), *Cert. denied*, 259 U.S. 581 (1922).
5. *Feist*, 499 U.S. at 348–49.
6. *Id.*, at 349.
7. *Id.*, at 358–59.
8. *West Publishing Co. v. Mead Data Central*, 799 F.2d 1219 (8th Cir., 1986), *Cert. denied*, 479 U.S.(1987).
9. *Bellsouth Adv. & Publ. Corp. v. Donnelly Info. Publ. Inc.*, 933 F.2d 952 (11th Cir., 1991).
10. *CCC Info. Svces., Inc. v. MacLean Hunter Market Reports Inc.* (2nd Cir, 1994).
11. *Publications International v Meredith Corp.*, 88 F.3d 473 (7th Cir., 1996).
12. *Nat'l Basketball Ass'n v. Motorola, Inc.*, 105 F.3d 841 (2nd Cir., 1997).
13. *CCH Canadian Ltd. v. Law Society of Upper Canada*, [2004] 1 S.C.R. 339, 2004 SCC 13.
14. *Desktop Marketing Systems Pty Ltd. v. Telstra Corp. Ltd.*, [2002] FCAFC 112. The UK's approach dates back to at least the case of *Walter v. Lane*, [1900] AC 539 (House of Lords), but was repeatedly reaffirmed after the passage of the 1911 Copyright Act, which is the foundation of the current copyright law in the UK.
15. Official Journal L 077, 27/03/1996 pp. 0020–0028.
16. *DG International Market and Services Working Paper: First Evaluation of Directive 96/9/EC*, Commission of the European Communities, Brussels (12 Dec 2005; hereafter “Working Paper”) (document available at http://europa.eu.int/comm/internal_market/copyright/prot-databases/prot-database_en.htm).
17. To be precise, the sui generis rights persist until the first day of the January preced-

- ing the fifteenth anniversary of the creation of the database.
18. *Working Paper*, supra n. 16, at 11. See also, The Database Right File, Institute for Information Law, 2007 (document maintained online, at <http://www.ivir.nl/files/database>). This document also summarizes local court cases interpreting the national implementation acts.
 19. Official Journal L 167, 22/06/2001 pp. 0010–0019.
 20. Grand Chamber Case C-203/02 (9 Nov 2002).
 21. Grand Chamber Case C-46/02 (9 Nov 2002).
 22. Grand Chamber Case C-338/02 (9 Nov 2002).
 23. Grand Chamber Case C-444/02 (9 Nov 2002).
 24. Grand Chamber Case C-304/07 (9 Oct 2008).
 25. *Working Paper*, supra n. 16.
 26. The WIPO Copyright Treaty implemented terms consistent with the standard for originality articulated in the *Feist* case (supra, n. 2).
 27. A complete, online list of comments to the European Commission’s Internal Market and Services Directorate General, with links to content, is available at http://circa.europa.eu/Public/irc/market/market_consultations/library?l=/copyright_neighbouring/database_consultation&vm=detailed&sb=Title).
 28. See, e.g., Hugenholtz, P.B., “The ‘Spin-Off’ Doctrine in the Netherlands and Elsewhere in Europe,” Paper presented at Fordham U. Sch. Of Law, 11th Ann. Conference on Int’l IP Law & Policy (14-25 April 2003) (document available at <http://www.ivir.nl/publications/ugenholtz/spinoffordham.html>); “Free and Open Exchange of Environmental Data,” 83 *Bulletin Amer. Met. Soc.* 452–56 (2002) (statement by the AMS Council); Maurer, S., “Across Two Worlds: Database Protection in the United States and Europe,” *Intellectual Property and Innovation in the Knowledge-Based Economy* (Industry Ministry, Canada, 2005); Langford, J., “Sui Generis Protection of Genetic Resources and Associated Traditional Knowledge,” International Expert Workshop on Access to Genetic Resources and Benefit Sharing (Cuernavaca, Mexico, 2004) (document available at <http://www.can-mexworkshop.com/documents/papers/III.3.1.pdf>).

29. Cardinale, P.J., “Sui Generis Database Protection: Second Thoughts in the European Union and What it Means for the United States,” 6 *Chi.-Kent J. Intell. Prop.* 157 (2007).
30. See, e.g., Mathur, A., “Working Paper No. 141, Missing Markets in World Trade: The Case for ‘Sui Generis’ Protection of Traditional Knowledge,” India Council for Research on International Economic Relations (Aug 2004) (document available at <http://ideas.repec.org/p/ind/icrier/141.html>); “Response from the European Publishers Council to the First Evaluation of Directive 96/9/EC on the Legal Protection of Databases” (10 March 2006) (document available at http://www.epceurope.org/issues/EPC_response_legal_protection_databases.shtml).
31. Report summary is available online at http://www.aippi.org/reports/q182/q182_summary_e.pdf.
32. Gupta, A., “Protection of Databases in India and Sui Generis Protection,” 10 *J. Intell. Property Law & Practice* 1093 (2007).
33. See, e.g., “NIH Principles and Guidelines for Sharing of Biomedical Research Resources,” 64 Fed. Reg. 246 (23 Dec 1999); “NIH Policy on Sharing Research Data,” Grants Notice #NOT-OD-03-032 (26 Feb. 2003) (document available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>).

Licensing Plant Varieties Developed at Universities

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Observations Regarding Plant Variety Licensing in a University Context

Plant breeding research and the associated plant variety development has played a central role within research universities, especially those in countries or regions where agriculture is key to the regional economy. In the United States, land grant colleges were established in the mid-nineteenth century, in part, to support the local agricultural economy as the nation expanded its geography and population. The plant breeding and related research carried out at these universities helped establish the agriculture infrastructure in these newly developing regions.

In recent years, the support for plant breeding from traditional government funding sources has decreased. Several factors contribute to this change, including a shift in funding to support molecular biology and genomics as applied to agricultural research. Without a doubt, the genomic revolution of the 1990s will change the face of agriculture, but the path to direct benefit in all but the most major of crops is uncertain. Researchers are using these techniques to understand some of the fundamental aspects of plant biology in important agricultural crops, which may lead to traits that enhance disease resistance, abiotic stress tolerance, and even the nutritional or wellness-enhancing attributes of common crop plants. Such enhancements will surely create value, but the timeline to value creation is long.

With the decrease in government funding, universities have become more reliant on funding from grower or marketing-based organizations. Often these commodity groups or marketing order boards are state-sanctioned with a charter to levy their membership and use those funds to support, in part, research to develop new varieties or markets. Such local funding creates expectations of direct local benefit from the research that can

impact the commercialization strategy for those charged with variety rights management on behalf of the university.

The local benefit demanded can take the form of discounted royalty rates for the contributors, preferred access to new varieties (that is, access in advance of broader commercialization), or even requests to share royalties from broad-based licensing programs. In making any such decision on behalf of the university, the licensing office must weigh the impact on faculty research and be cognizant that a strong relationship with such local groups is essential to ensuring future support for the research program.

University plant breeding programs also need to understand and manage their relationship with private breeding organizations. In certain crops, the market is dominated by large specialized corporations, and the outlet for university technology, by necessity, flows through them. However, in other crops where the market may be small, the product of the university research is the finished variety licensed to propagators, seed houses, etc., that become the distribution channel to the grower.

With the advent of more sophisticated marketing of specialty fruit and vegetable crops, private breeding companies have been established to capture this value. Traditional university research programs are now direct competitors to these private breeding companies, leading to questions on how best to support the local agriculture community. One question to be considered is whether a university should license advanced germplasm to private breeding companies or retain it for internal use only. While any decision regarding the research program is rightly the purview of the academic research enterprise, the outcome has an impact on the role and nature of the plant variety licensing program.

Also, universities may enter into sponsored research agreements with individuals or companies to develop plant varieties just as they would do in other research areas. In return for funding the research, the sponsor may secure preferential access to the varieties. The terms and conditions of such preferential access or the nature of the license itself would be subject to the university's overarching policies relating to sponsored research.

Another somewhat unique element of plant variety licensing at universities is defining the exact nature of the customer and/or licensee. In the majority of nonplant licenses, the university's primary relationship is with the licensee, and the royalty paid under the license agreement is an invisible component of the price paid by the final customer. In vegetatively propagated crops, in particular, universities license to nurseries that propagate and sell plants to the grower. Nurseries often perceive their role as a service provider multiplying what has been created by the university. Often, licenses are nonexclusive, and so the nursery has very little incentive to promote the university's variety over others in its catalog.

Ultimately, demand for the variety is generated by the success of the variety based on grower experiences. The royalty paid to the university may be explicitly stated on the invoice such that the grower perceives the royalty as a university-imposed tax. Such perceptions can create ill will, especially when the growers believe that they have paid for the research leading to the variety through fees paid to their commodity organization or marketing order board.

These observations point to the fact that managing a plant variety licensing program has some fundamental differences as compared to managing other technologies created through university research. The remainder of this article will concern itself with some of the practical aspects of protecting and licensing plant varieties. The reader is also directed to a recent publication, *Intellectual Property Management in Health and Agricultural Innovation*,¹ which contains a number of chapters that expand on aspects of plant variety licensing applicable to university technology transfer offices.

Types of Intellectual Property Protection Available

A range of options exist to protect the university's plant varieties. This section outlines the key options and highlights the context where they could apply. At no time should these comments be taken as a substitute for consultation with appropriately trained attorneys who specialize in the various forms of intellectual property protection.

Bailments and Tangible Property Rights

Most university technology licenses relate to intellectual property and occasionally deal with the tangible property of the university. Such tangible property could include cell lines or mouse models for disease for use as research tools either by industry or public-sector scientists. For plant varieties, bailment agreements for the tangible property consisting of the finished variety or the parental germplasm are a key part of the normal process of testing and evaluating the commercial potential of a new variety.

For logistical and pragmatic reasons, most universities cannot develop a finished variety without the help of outside collaborators. These collaborators provide the land and crop-management infrastructure, as well as market-informed analysis of the commercial potential of the new variety. Because filing for intellectual property protection on advanced germplasm selections may be undesirable due, in part, to the cost of seeking protection, especially considering that many lines may need to be tested to determine if any are commercially useful and also because the invention may not be considered complete until commercial utility is proven, the preferred way to secure protection for the university's asset is to transfer possession (but not title) to plant material to the grower under a bailment.

The limitations imposed in the bailment agreement protects against the testing being considered a bar to further protection using plant patents or plant variety rights. Should the variety not prove useful, the university can terminate the bailment agreement and recover (or destroy) its property to prevent unwanted propagation.

Bailments can also play a role in a hybrid licensing strategy (described later in this article) whereby a licensor can maintain control over proprietary germplasm beyond the term of the plant patent or plant variety rights. Also, enforcement of the tangible property rights granted under the bailment may be less cumbersome than enforcement under intellectual property rights.

For example, in the United States, enforcement of tangible property rights generally takes place in state courts, whereas enforcement of plant patents and plant variety protection certificates requires action in federal courts. Also, in certain other countries,

while plant variety rights legislation may have been enacted, a judicial precedent for enforcing those rights may not have been established, whereas the enforcement of tangible property rights may be well-established. The use of bailments alone does come with certain risks, most notably the inability to limit use of plant material that escapes from the contractual control. As such, bailments should be used with caution.

United States Patents

U.S. patents can be used to protect plant varieties. Unique to the U.S. is the ability to obtain a utility patent (as one would for any other invention), as well as a plant patent. The usual statutory requirements for patenting such as novelty, nonobviousness, and utility, as well as the requirement to correctly name the inventor(s), apply to plant patents. As such, it becomes important that any prerelease testing be carried out in such a way as to not create a statutory bar to issuance of the patent.

U.S. patent law allows for an experimental-use exception provided certain criteria are met. Included in these criteria is whether there was a secrecy obligation on the part of the testing party. Many of these criteria can be addressed by ensuring that the appropriate test agreement is in place prior to distribution of plant material to the testing party. Accurately naming inventors is also critical for any patent, but may be a more complicated issue for patenting plants, as will be discussed later in this article.

Filing and prosecution of a utility or a plant patent requires that the person have passed the patent bar and be registered to practice at the U.S. Patent and Trademark Office (USPTO), which means that universities generally retain outside counsel for this purpose.

Utility Patents

Utility patents are a useful option to consider when evaluating the appropriate intellectual property protection strategy for a new crop plant. Utility patents are available for all plants and are used quite extensively by the leading seed companies when protecting parental germplasm, including parental lines enhanced with biotechnology-derived traits. These utility patents are usually distinct from the patent that protects the technology underlying the particular trait (e.g., the mechanism of herbicide tolerance).

In most instances, the utility patent protects the parental line containing the enhanced trait and uses the claim structure of a utility patent to protect progeny of that line through conventional plant breeding. Utility patents are considerably more expensive to prepare and prosecute than plant patents, but the increased scope of the protection afforded by utility claims makes them a useful intellectual property management tool in high-value crops, especially those that employ a hybrid breeding strategy to achieve superior performance.

Utility patents do require the deposit of the claimed subject matter, which can create a challenge. Deposits of tissue-cultured plant material can suffice, but showing that the deposited material is sufficiently viable to meet the intent of the patent statute and finding a depository willing to accept and maintain the deposit for the duration of the patent can be a challenge. The American Type Culture Collection does provide depository services (<http://www.atcc.org>) for certain plant material claimed in utility patents.

Plant Patents

The practice of plant variety licensing in the U.S. differs from that in most other places in the world due to the fact that plant variety rights are controlled by two different laws managed by two different branches of the government. U.S. plant patents cover *asexually reproduced plants* (that is, plants where the multiplication for commercial production is asexual) *other than tubers*. A plant patent holder has the right to exclude others from asexually reproducing the plant and from using, offering for sale, or selling the asexually reproduced plant or its parts or from importing that plant or its parts. Amendments to the statute in 1998 added the concept of plant parts and the ability to exclude imports as a response, in part, to importation of cut flowers covered by a U.S. plant patent.

A plant patent has a single claim to the plant described in the specification. The patent application must describe the plant in sufficient detail that the patent examiner can determine that it meets the novelty, nonobviousness, and utility criteria, but unlike U.S. plant variety protection certificates and analogous plant variety rights elsewhere in the world (both discussed below), the USPTO does not require the applicant to deposit the plant or subject the plant to physical evaluation of its described unique features. U.S.

plant patents do not contemplate the saved-seed concept present in other forms of plant variety rights (see below), presumably because the concept is not relevant to vegetatively propagated species.

United States Plant Variety Protection Certificates

U.S. plant variety protection certificates (PVPCs) are issued by a division of the U.S. Department of Agriculture for a range of *sexually reproduced plants*. (For more information and a list of varieties for which PVPCs are issued, consult the Plant Variety Protection Office Web site at <http://www.ams.usda.gov/science/PVPO/CertificatesDB.htm>.)

The rights granted under PVPCs are equivalent to the rights granted under legislation that follows the Union for the Protection of New Plant Varieties (UPOV) treaty in other countries (see below). These rights include the right to control export, something not specifically granted under U.S. patent law. Regulating export is useful if one desires to manage the production and distribution of a variety globally. Absent specific restrictions in the form of a label or use license, a purchaser of a patented product can export that product, thus complicating a global marketing scheme. PVPCs also allow a farmer to save an amount of seed of a protected variety sufficient to replant the equivalent amount of that variety in subsequent years, but the farmer is not permitted to increase production nor transfer the seed to another individual.

Unlike patents, one does not need to be a registered patent attorney to submit an application for a PVPC, and universities can submit PVPC applications directly. Deposits of plant material are required for evaluation for distinctiveness, uniformity, and stability. As with U.S. patents, applicants must submit their application for a PVPC within one year of the first sale or offer for sale of a new variety in the United States.

Foreign Plant Breeders and Variety Rights

Outside of the U.S., plant varieties are protected by the national laws of each country. Increasingly, these laws operate under the basic principles set out by the UPOV treaty, an international treaty administered in Switzerland. The United States is a party to this treaty and, as mentioned above, U.S. PVPCs follow UPOV guidelines even though U.S.

plant patents do not. While UPOV creates a framework, legislation in each country may vary in the way in which the basic principles are implemented, which requires those seeking international protection to understand the exact nature of the protection afforded by local plant variety rights laws.

Outside of the European Union, no mechanism exists to file for plant variety rights protection in multiple jurisdictions. In the EU, the Community Variety Protection Office offers protection in all EU member states; however, protection in individual member states is still available through national offices in that country. Most UPOV-compliant laws give variety developers in other countries four years (or six years for trees and vines) from the domestic sale to seek protection in the foreign jurisdiction.

Not every species is afforded protection in every country, necessitating a thorough analysis before embarking on an international licensing strategy. It is possible to work within a national system to add a particular species to the protected list, but such endeavors do require a strong internal advocate and usually a compelling economic reason (such as access to an important new variety that could create value for the agricultural economy). Even if protection is possible, it is important to consider whether the rights granted will be enforceable. In countries with well-developed judicial systems, litigation of plant variety rights occurs rarely, if at all. Predicting the course or outcome of an enforcement action in countries with less well-developed judicial systems is exceedingly difficult. The complexity and cost of broad protection, combined with the uncertainty of subsequent enforcement, requires that decisions to seek broad protection be well-thought-out.

Trademarks

Trademarks provide another avenue to protect plant varieties that has application in certain circumstances. Trademarks identify the source of the good and protect the name or the brand, not the variety itself, and, except, in rare circumstances, should not be considered a substitute for plant variety rights protections. In the U.S., trademark rights can be created by use or by registration with the USPTO. In most other jurisdictions, trademarks must be registered with the appropriate authority.

A common misconception is that one can use the variety name as a trademark. In fact, the variety name can never be accorded the status of a trademark, no matter how well-recognized it becomes as that name is considered the generic name for that particular variety. Also, filing for plant variety protection in one jurisdiction using a particular name may preclude the use of that name as a trademark elsewhere in the world, irrespective of whether the variety is protected (or even protectable) in a particular country.

Trademarks are being increasingly used by commercial plant breeding organizations as a valuable part of a combined intellectual property rights management strategy, especially where the variety has some distinct consumer appeal. Like tangible property rights, trademark rights do not expire so long as they are used, and so afford a way to capture value beyond the traditional term of patent or plant variety rights protection.

However, the use of trademarks carries with it other responsibilities for the holder, such as ensuring that the trademark is used correctly by internal and third parties and that the goods bearing the mark meet quality standards specified by the holder. For a more comprehensive discussion of the use of trademarks in plant licensing, consult “Use of Trademarks in a Plant Licensing Program” in *Intellectual Property Management in Health and Agricultural Innovation*.²

Commercial Registration

In many countries, before a variety can be sold, it must be registered with a governmental agency. As with plant variety rights, the process for commercial registration varies by jurisdiction, but the process lacks the consistency afforded to plant variety rights protection by the UPOV treaty. Understanding the nuances of commercial registration is usually far beyond the scope of any university licensing office and not within the purview of law firms or like agencies retained to file and prosecute plant variety rights applications. Often, it is preferable to require the licensee in the particular territory to seek and pay for any commercial registration needed to sell or license the technology to propagators or growers.

Practical Aspects of Plant Variety Licensing

The following section discusses some practical aspects of protecting and licensing plant varieties.

Managing Intellectual Property Rights Prior to Release of a Variety

As noted earlier, developing a new plant variety is a long process that begins with the initial breeding event and proceeds through multiple stages depending on the nature of the plant variety. In seeded crops, the steps could involve rounds of recurrent backcrossing to introgress the desired trait into a well-known and understood parental background or sequential inbreeding and selection to identify varieties with stable characteristics.

For vegetatively propagated species, the process may require extended observation of the performance of the selection on different rootstocks or in different environmental conditions. While such activities could be carried out within the somewhat regulated environment of the university, more commonly, plant breeders engage the support of third-party collaborators to propagate, multiply, grow, harvest, and evaluate potential new releases.

Under UPOV-compliant laws, such testing, and the incidental sale of the crop, may be permitted without compromising the ability to seek protection of the crop in a future filing. Similarly, under U.S. patent law, incidental use of the selection as part of the testing is permitted without loss of rights with respect to future patent filings. However, as mentioned earlier, to protect future intellectual property rights, it is important that all such third-party testing be carried out under agreements that ensure the testing does not trigger statutory bars to future protection domestically and internationally.

Release of a New Variety

The decision to release a new variety from a university plant breeding program is complex. As the variety will be inextricably linked with the institution, it must meet a complex set of criteria and require institutional signoff. Who actually approves release will depend on the institution, but the technology transfer office may not be a required signatory to this process.

However, it does fall on such offices to manage intellectual property protection of released varieties, and some of the criteria addressed in the approval process have implications for patent and plant variety rights protection. Such criteria include the distinctiveness and stability as well as commercial utility of the variety and, often, the naming of the variety, which has implications if using trademarks is part of the overall intellectual property protection strategy. Ultimately, the decision on whether or not to seek intellectual property protection for the variety should be based on the best interest of the internal and external stakeholders.

For U.S. plant patents, a key requirement for protection is determining the inventorship for the patent. Because of the potentially long timeline between the initial cross and any final decision to release, identifying inventorship can be complex. One person may have initiated the process by deciding what parents to cross, another may have played a role in selecting particular progeny for further evaluation, and yet others may have perfected the invention by choosing the particular individual among the selected progeny for one that has the traits that make it useful in commercial agriculture. Depending on the circumstances, all such participants could rightfully be considered inventors. Because inaccurate inventorship can prejudice the validity of a patent, it is incumbent on a technology transfer office to accurately determine inventorship prior to filing a plant patent application.

For U.S. PVPCs and foreign plant variety rights, inventorship does not have the same legal significance, and so the driver for determining inventorship is ensuring internal equities with respect to royalty sharing. However, to maintain consistent treatment of contributors within the institution, inventorship determination for PVPCs should follow the same principles that apply to plant patents.

Postrelease Distribution of Plant Material

Once a decision to release a variety has been made, a matter to be considered is the process for distributing what is likely to be a limited amount of the plant material. If a university does not have the physical resources to maintain the germplasm in suitable quantities (e.g., a foundation plant service), then some alternative arrangements are nec-

essary. If third parties are used to multiply or distribute initial plant material, it may or may not be appropriate to license them under intellectual property rights as their role in the commercialization may be transient.

When providing initial plant material of a new variety, it is important to ensure that all material supplied complies with all phytosanitary requirements and be verified as true to type. The university has to be concerned about the liability associated with the distribution of disease-carrying or off-type material. The future value of a new variety could be seriously compromised if a grower's initial experience with it is colored by a bad experience due to poor quality plant material distributed by or on behalf of the university.

Another issue that sometimes arises upon release of a new cultivar is what role a university should have in the allocation of a limited supply of plant material. Sometimes, marketing order boards or commodity groups ask to play a role in allocating plant material amongst their members to ensure that all that desire access have it and prevent market pressures from driving up the price. In any arrangement related to distribution of plant material, it is important to ensure that the rules that govern allocation are clear and understood and that the arrangement not be subject to allegations of favoritism of one party over another.

Licensing Strategies and the Relationship to the Local Industry

Universities (land grant, or otherwise) may have a policy designed to give some form of preference to the local agricultural community. This preference may or may not arise due to direct funding of the plant breeding program by the industry. Local preference can take several forms, including preferential access (i.e., access ahead of a more widespread release) and differential financial terms in license agreements. The choice of whether or not to protect a variety may be influenced by the requirement of local preference, as the protection provides the legal basis for restricting access or differential pricing.

Beyond simple preferential treatment, the local industry may also demand input into broader national or international commercialization strategies where such commercialization is perceived to negatively impact the local industry. Simply delaying release or

charging a higher royalty may not be sufficient to allay such concerns. From the university's perspective, such industry concerns must be balanced against other drivers such as recouping the costs of intellectual property protection needed to support the local preference and meeting the overarching university mission of transferring its technology for the public benefit, both domestically and for humanitarian uses in developing countries.

Licensing terms

Many factors contribute to determining the most appropriate terms in a plant variety license agreement. A key factor is the goal of the licensing strategy. Often this goal is to provide the broadest possible access to the variety, which leads to nonexclusive licensing to propagators, such that growers can purchase their plant material from a range of possible suppliers. Nonexclusive licensing can ensure that the variety is priced through a competitive market. However, nonexclusive arrangements do not create an incentive for licensees to promote the variety and may result in a new variety languishing for lack of a strong advocate. For a variety with a limited market potential, an exclusive license may provide the incentive to pursue the niche opportunity.

The royalty base for plant licenses, especially for vegetatively propagated crops, is often the propagation unit, with a set royalty per unit (e.g., per tree, per 1,000 seedlings, per bag of seed) rather than a percent of the sales price. Per-unit royalties do not allow the licensor to benefit from price increases due to inflation, so for agreements with a per-unit royalty, including a clause that allows royalties to adjust for inflation, is advantageous. A per-unit royalty model does have the advantage that royalty base is less subject to manipulation (for example, a licensed product may be discounted to drive sales of other related products) by the licensee.

Ideally, royalty rates should be related to the value created by the variety, but traditionally, royalties on tree sales range from \$1 to \$2 per tree. Considering the price of the average fruit or nut tree, this amounts to a royalty of 5 percent to 10 percent of the sales price. Also royalties on sales of seed crops are often in the 5 percent to 10 percent range. Such rates are justified because plant varieties are effectively finished products with no further development required.

For perennial crops, a disadvantage of a propagation unit-based (i.e., one-time) royalty is that this structure does not capture the value of the final consumed or used plant material. To capture this value, a production or box royalty may be appropriate. Extracting such production royalties from commodity items can be exceedingly difficult, because the grower is not receiving premium price for the product and, thus, has no added value to share with the licensor.

However, if the licensing strategy includes exclusive or restricted distribution terms (also known as *managed production*) and the grower receives a premium price for the product, then it is quite reasonable to expect that the licensor capture some portion of that premium through a production royalty. Such production royalties can be levied on the units of product shipped from the packhouse (i.e., per unit weight, carton, etc.) or as an annual fee based on production area (i.e., per acre, hectare, etc.)

Collecting royalties at the packhouse can pose difficulties due to the need to ensure accuracy in accounting for units shipped, especially where the product could be combined with similar products. Production area-based royalties can be easier to police as the planting area can be determined based on the number of units actually purchased at the outset and is not subject to season-to-season fluctuations in production. Production royalties vary based on price premium over commodity product received by the grower or packer for the variety. The royalty rate may also take into consideration other support (such as technical assistance and marketing materials) provided as part of the license agreement.

In certain instances, a university should consider the applicability of a hybrid licensing strategy for a new plant variety. Hybrid licenses can combine tangible property, patent or plant variety rights, and trademark rights in a single license and allow the licensor to leverage the unique attributes of each form of right. Through the bailment provisions, the licensor can limit access to the tangible property, and, if necessary, enforce destruction of the material should the licensee breach the terms of the agreement. The tangible property and trademark rights may run indefinitely, and, thus, the licensee can continue to extract value created in a particular variety past the term of patent or plant variety rights.

Such hybrid agreements are complex and should be drafted very carefully to ensure that each grant of rights is separate and separable from the others. Royalty terms must reflect the fact that the patent or plant variety rights will expire and, thus, should be structured with a specific royalty associated with each right granted.

For example, such structure enables a licensee to sell off-grade fruit without using the trademark at a lower royalty. Generally, hybrid licenses are only applicable to very high-value products, where the return to all the stakeholders warrants the additional costs associated with administering and enforcing the license agreement.

Licensing Internationally

Varieties developed in one area are often well-adapted for similar climates and soils in other countries. Areas well-known for developing new varieties are regularly visited by growers from other countries looking for new varieties to enhance local agriculture.

Additionally, in the global production and marketing world of the twenty-first century, retail distributors are often searching for year-round supply of product in specific categories, so contraseasonal production opportunities exist for unique or valuable products to supply this year-round demand. For universities, this scenario provides an opportunity to explore international licensing in addition to licensing for domestic agriculture. For popular varieties, international licensing may surpass domestic licensing in terms of revenue.

For any university, licensing outside of its domestic market creates logistical challenges. For traditional utility inventions, international licensing is often the purview of the original exclusive licensee, and, thus, the university is not directly engaged in choosing the licensing partner or administering the license.

Because of the fragmented nature of agriculture, directly licensing a plant variety in another country can be logistically difficult. Undoubtedly one can license individual nurseries or producers directly, but postagreement management in such an environment is a challenge. An alternate approach is to select a master licensee for a particular country or region. The master licensee may be specific for the variety or crop type or may represent

a range of varieties. Effectively, this means the university has executed regional exclusive licenses with the right to sublicense.

In some countries, specialized plant variety management companies exist to manage university and private plant variety rights. In choosing a master licensee, one should take care to ensure that the master licensee can equitably represent the university's varieties. If the individual or company is representing competing varieties, the potential exists to favor one licensor over another based on the value the master licensee receives.

Another point to consider is whether the master licensee will use the university's variety as a way to sell other services for which the university receives no consideration.

Lastly, if the university's objective is broad distribution of a variety, choosing a nursery as the master licensee may be undesirable, as it would require the master licensee to enable competitors to meet the university's objectives.

These and other issues can be addressed by contract terms, but in general, it is preferable to choose the right partner at the outset than to be forced to terminate an agreement and find another partner down the road, especially in a foreign country where the laws and jurisprudence are different and potentially more favorable to the local party.

Often, testing a variety is the precursor to international licensing. Because of the costs of securing plant variety rights protection, such testing is often carried out under a bailment or test agreement. Determining when and where to test a variety does require careful consideration. Because of the long lead times between propagation and commercial production in certain varieties, testing may have to begin as soon as possible after domestic release to enable a reasonable determination of commercial utility prior to the end of the four- or six-year window to protect the variety.

If quarantine is required, it may even be necessary to start the process prior to the domestic release. Any delay in testing will mean that a decision to protect will be made without true knowledge of the commercial potential. Any prerelease testing should be

carried out under appropriate contractual terms that protect the ability to secure plant variety rights protection in the future.

Widespread testing without diligent controls can lead to uncontrolled propagation through unauthorized sharing (knowingly or through pilfering) of plant material. Once the plant material is widely distributed, it may be impossible to reassert control and this could lead to the loss of plant variety rights both within the test country and beyond. Where a master licensee is in place, all testing should be done under its auspices so it can determine whether the tester is a suitable business partner and the testing meets the broad goal of the licensing program.

When considering an international licensing strategy, one needs to determine where to protect the particular plant variety. Protection strategies may include both offensive and defensive protection. Protecting in the jurisdiction where the variety will be grown would be offensive, whereas protecting in jurisdictions where production is not anticipated but where, without protection, unregulated production could harm the market for the propagating material (due to import of propagating material from another country) or the crop would be defensive.

If the strategy relies on licensing propagation rather than production, protecting only in propagation regions may be sufficient. As protection in each jurisdiction requires a separate plant variety right application with its associated costs, the commercial opportunity must be carefully evaluated. Master licensees that are motivated primarily by commercial success and that understand the local market dynamics are often in a better position to determine the appropriate protection strategy. Once all such considerations are evaluated, the university may have to make the decision on whether or not to make the variety available internationally, and if so, whether or not royalty-bearing licenses are the best way to further the university mission.

If international licensing through a master licensee is determined to be appropriate and desirable, the next step is to determine how to equitably share royalties with that party. One solution is to simply share the royalty collected between the university and the mas-

ter licensee according to a predefined formula. The master licensee can be made responsible for the costs of any plant variety protection, commercial registration, or other steps associated with establishing the variety. If these costs are substantial, the agreement may have to consider some form of temporary relief or allow the master licensee to defer payment to induce participation.

A concern about a straight royalty split is that such a term does not prevent the master licensee from setting an unreasonably low royalty. One approach is to set a floor royalty to be paid to the university and share royalties over and above a predetermined amount. Alternatively, the university can set the amount it wishes to receive, and leave the local royalty structure to the master licensee's discretion.

As noted earlier, any international strategy must take into account the views of and impact on the domestic industry. If a strategy, for sound business reasons, appears to treat foreign producers more favorably, then the backlash from the domestic industry could create more damage to the university than the financial benefit from any royalty received from the licensing program.

Notwithstanding the potential for such negative reactions, international licensing may indeed serve the greater goals of a university by making valuable varieties available to farmers in developing countries to enhance the local food supply or support regional agricultural economies. Accordingly, all such elements should be evaluated before choosing this path.

Enforcement

Enforcing plant variety rights, whether they be U.S. plant patents, U.S. PVPCs, or foreign plant variety rights, is an area with very little judicial precedent, and so any decision to pursue an infringement action must be carefully considered. Even in countries with well-established judicial systems such as the U.S., infringement suits are rare.

For both U.S. plant patents and U.S. PVPCs, as well as other UPOV-compliant rights, the basis for awarding the right is the physical description of the variety as provided in the

application. Thus, the decision as to whether the alleged plant infringes is based on comparing the physical characteristics, which by its very nature can be subjective and dependent on the conditions under which the plants were grown.

Despite the ability to characterize plants using DNA-based markers, and the widespread and accepted use of microsatellite markers for human identification in judicial processes, such markers are not the basis by which a court will determine infringement in plant cases. One reason for this is that human identification is made using a standard set of polymorphic alleles and the statistical probability inclusion/exclusion is very well-documented. In comparison, in plant species, no such standards or statistical information exists.

Notwithstanding the uncertainty of enforcement, plant variety licensing programs for universities can be very successful. The University of California strawberry variety program brings in annual royalties in the order of \$5 million from its global licensing program, so it is clear that the deterrent effect of litigation is sufficient to ensure acceptance and compliance with licensing agreements.

Conclusion

University-developed plant varieties have played and will continue to play an important role in advancing agricultural production. Protecting and licensing these varieties effectively helps establish value for the university and its industry partners. The laws and practices in this area have some fundamental differences from those related to licensing other technologies created through university research, so understanding these differences is essential to capturing the value created.

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Protection of New Plants and New Plant Technologies in Canada and the United States

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In Canada, the protection and commercialization of intellectual property associated with new plant varieties and cultivars are governed federally under one or both of the Canadian Seeds Act¹ and the Canadian Plant Breeders' Rights Act,² while protection of new plant-related inventions is generally governed under the Canadian Patent Act.³ In addition, the Canadian Seeds Act specifies rules and regulations for the importation, labeling, and distribution of seeds and propagules of novel plants.

In the United States, new asexually propagated plant varieties can be protected under the U.S. Plant Patent Act,⁴ while novel sexually propagated plant varieties can be protected under the U.S. Plant Variety Protection Act.⁵ Novel plant-related technologies, as well as new plant varieties produced with novel technologies, can be protected under the U.S. Patent Act.⁶ The U.S. Federal Seed Act⁷ provides federal governance for the importation of novel agricultural and vegetable seeds and their interstate commerce.

This chapter will compare relevant acts and regulations and discuss the similarities and differences between the options for protecting new plants and new plant technologies in Canada and the United States.

Plant Breeders' Rights

Canada

Canada is a member of the International Union for the Protection of New Varieties of Plants (UPOV). UPOV is an intergovernmental organization with headquarters in Geneva, Switzerland, established by a diplomatic convention in 1961 with the objectives of provid-

ing an internationally recognized and adhered-to system for plant variety protection and encouraging the development of new varieties of plants for the benefit of society.

The International Convention for the Protection of New Varieties of Plants came into force on August 10, 1968, after ratification by the United Kingdom, the Netherlands, and Germany. The UPOV convention⁸ was subsequently revised three times⁹ to reflect technological developments in plant breeding and experience acquired with the application of the UPOV convention. As of June 2007, there are sixty-four member countries of UPOV. Canada formally joined UPOV in 1990 and promulgated the UPOV Convention of 1978 as the Canadian Plant Breeders' Rights Act (PBRA) in August 1990. The Canadian Food Inspection Agency operates the Plant Breeders' Rights Office (PBRO) on the behalf of the Canadian federal government. The PBRO receives and assesses plant breeders' rights (PBR) applications and grants rights for individual plant varieties that meet the specified criteria in the form of PBR certificates.

PBR Certification Criteria and Stipulations

All categories of the plant kingdom qualify for a PBR certificate except for algae, bacteria, and fungi. The new variety must be clearly distinguishable from all other known varieties by one or more identifiable characteristics. The new variety must be stable in its essential characteristics so that, after repeated reproduction or propagation, the progeny remain true to type. The new variety must be sufficiently homogenous so that during the course of its sexual reproduction or vegetative propagation in large, i.e., commercial quantities, any variations in the commercial crops are predictable and commercially acceptable.

The primary method for determining if an application for a PBR certificate will be granted is the assessment of the novel plant variety's distinctness, uniformity, and stability (DUS) in comparative tests and trials with suitable reference varieties. The selection of the reference varieties and the organization of the trial designs must be done in accordance with test guidelines published by UPOV, and the PBR application must contain photographs of the new and reference varieties as specified in the Canadian PBRA and guidelines.

While many UPOV countries have state-run testing systems for assessing PBR candidates, Canada has a breeder-run testing system in which the trials are conducted by the breeder and/or applicant, its agent, or by someone contracted by the applicant. The PBRO conducts a review of the applicant's data as well as one or more independent onsite trial examination(s) to verify the DUS results. It is important to note that the Canadian PBRA requires the submission of one year of testing data for asexually propagated plant varieties, and two years of testing data and independent site examination for sexually propagated (i.e., seed-sown) plant varieties. Another important component of the Canadian system is the publication, in the PBRO's *Plant Varieties Journal*, of trial designs, data, and photographs of the novel variety in comparison to the reference varieties, for public and/or peer information and opportunity for input regarding the new variety's DUS prior to the granting of a PBR certificate.

It should also be noted that a registration under the Canadian Seeds Act is a requirement for the newly certified PBR plant variety before it can be commercially sold and distributed within Canada and before it can be exported from Canada.

After a PBR certificate has been issued, the PBRO may grant compulsory licenses to third parties upon their application to ensure that the PBR-certified variety is made available to the public at reasonable prices, is widely distributed, and maintained in quality. In such circumstances, the holder of the PBR certificate is required to make propagating material available to the third-party holders of the compulsory licenses for which they will receive remuneration. In addition, the holder of the PBR certificate is required to maintain propagating material of the PBR-certified variety for the eighteen-year term of the certificate.

PBR Applicant Criteria and Application Stipulations

A breeder, its employer, or an entitled person (e.g., a licensee) may apply for a PBR certificate. The applicant must be a Canadian citizen or a resident or alternatively have a registered office in Canada. Citizens or residents of UPOV member countries may also apply for Canadian PBR certificates but must use a Canadian agent to file the application and correspond with the PBRO regarding prosecution of the PBR application, its granting, and maintenance.

Sales of the new variety in Canada are not permitted before filing a PBR application. In the case of an international filing for PBR protection in Canada, such applications must be filed within twelve months of the first filing in a UPOV member country. In such cases, the Canadian application will be given the foreign priority date with the effect being that sales in Canada are permissible as of the foreign filing date.

PBR-Related Costs

The PBRO fee to (a) file and examine a PBR application is Can\$1,000, (b) issue a PBR certificate is Can\$500, and (c) maintain a PBR certificate is Can\$300 annually for the eighteen-year term of the PBR certificate from the date of its issue. Accordingly, the cost to file, issue, and maintain a PBR certificate in Canada for a novel variety will be at least Can\$6,600 for the PBRO fees plus the agent's costs to file and prosecute the application through to issuance of the certificate and pay annual maintenance fees.

PBR-Infringing Acts

The following acts by a third party will infringe a Canadian PBR certificate:

1. unauthorized selling or offering to sell, exchanging, or transferring possession of propagating material of a PBR-certified variety;
2. unauthorized production of a PBR-certified variety for sale as planting seed or propagation material; or
3. unauthorized importation of a PBR-certified variety into Canada.¹⁰

The holder of a PBR certificate is entitled to undertake legal actions against the infringing parties and receive compensation and relief against the infringing acts.

Exemptions and Limitations for PBR Monopolies in Canada

Canada's PBRA is based on the 1978 UPOV convention that contained the following exemptions to PBR certificate holders' monopoly over their novel plant varieties. A first exemption is referred to as the *farmer's rights*¹¹ to retain and carry-over portions of the crop seed produced from a PBR-certified variety for planting the following year with the proviso that the farmer purchased the PBR-certified variety from the PBR certificate holder.

A second exemption is referred to as *brown bagging*,¹² which occurs when a farmer who is legally entitled to carryover a portion of his production of a PBR-certified variety for his or her own use provides excess leftover seed to his neighbors. While such brown bagging is considered to be an unauthorized practice, the terminology regarding farmer's rights in the 1978 UPOV convention and as promulgated in the Canadian PBRA is unclear.

A third exemption is referred to as an *innocent bystander*¹³ exemption, which occurs when the pollen from a PBR-certified variety growing in an authorized grower's field is carried by wind into adjacent third-party fields where it crosspollinates with another variety, thereby transferring one or more of PBR-protected novel traits to a third party's crop. The answers to questions regarding compensation, if any, due to the PBR certificate holder in such situations are not readily apparent under the 1978 UPOV convention or in the Canadian PBRA.

The fourth exemption is referred to as the *breeder's exemption*¹⁴ and allows a plant breeder to use a PBR-certified variety once, and once only, in a new breeding program. The use of a PBR-certified variety a second time in a breeding program (e.g., in second generation, third generation, or further generation crosses) is considered a repeated use and not allowable under the current Canadian PBRA.

UPOV recognized the deficiencies in the 1978 convention regarding the above exemptions and significantly clarified the language and eliminated or limited the scope of the above-noted exemptions in the 1991 convention. The Canadian government conducted an extensive plant breeders' rights consultation¹⁵ with Canadian stakeholders in mid-2004 through early-2005 to determine if the UPOV 1991 convention should be adopted and promulgated in Canada.

However, no action has yet been taken by the Canadian government toward this end as of July 2008 and, at this time, there are no clear indications if and when the 1991 UPOV convention will be promulgated in Canada.

The United States

In comparison to Canada, intellectual property (IP) protection for novel plants produced by plant breeders can be secured via (a) a plant patent for an asexually reproducible variety under the U.S. Plant Patent Act¹⁶ or (b) a plant variety protection certificate (PVP certificate) under the U.S. Plant Variety Protection Act (PVPA).

The U.S. Plant Patent Act (1930)

The statutes governing the content and format of plant patent applications, their submission, prosecution, allowance, and issue are outlined in (a) the U.S. Consolidated Patent Laws¹⁷ and (b) the U.S. Consolidated Patent Rules¹⁸ and are under the purview of the United States Patent and Trademark Office (USPTO). A U.S. plant patent is issued with one claim only that describes the distinguishing characteristics of the novel plant being claimed.

In general terms, U.S. plant patents provide breeders with protection for the exclusive reproduction, use, and sale of the novel whole plant, produced through breeding or naturally occurring, for a period of twenty years from the filing date of the U.S. patent application. U.S. plant patents, however, do not provide protection for plant parts (e.g., propagules or cuttings, genes, or traits) and, furthermore, do not provide protection against sexual reproduction by third parties (i.e., via seed production) of the novel plants. Consequently, the scope of legal protection provided by U.S. plant patents is rather narrow and cannot be extended to germplasm or the products of biotechnology.

The USPTO fee to (a) file a U.S. Patent is US\$80 for a small-entity applicant (i.e., a non-profit organization or a small business with less than 500 employees) and US\$160 for a large-entity applicant, (b) issue a U.S. plant patent is US\$550 for a small-entity applicant and US\$1,100 for a large-entity applicant, and (c) maintain the plant patent through the end of its term is US\$3,500 for a small-entity applicant and US\$7,000 for a large-entity applicant, payable at three, four-year intervals. Accordingly, the USPTO fees to file, issue, and maintain a plant patent in the U.S. will be at least US\$4,130 for a small-entity applicant and US\$8,260 for a large-entity applicant, plus the agent's costs to file and prosecute the application through to issuance of the patent and for attending to the three maintenance fee payments.

The U.S. Plant Variety Protection Act (1970)

The PVPA was drafted and enacted in the U.S. in 1970 to provide plant breeders with similar scope and quality of IP protection for novel plants that reproduced sexually as provided by the UPOV conventions. The United States became a member of UPOV in 1981 and became party to the 1991 UPOV convention in 1999. Consequently the granting and protection of plant breeders' rights according to the UPOV convention are governed under the PVPA by the Plant Variety Protection Office (PVPO), which is an agency of the United States Department of Agriculture (USDA).

PVPA Features and Stipulations

Although the PVPA is generally modeled after the other U.S. patent laws, it is consistent with the UPOV conventions and includes the UPOV criteria for registration of new varieties such as that new varieties have a distinctive appearance from all other varieties of the species, uniformity among all individuals of the new variety, and generational stability. As under the Canadian PBRA, all categories of the plant kingdom qualify for a plant variety protection (PVP) certificate except for algae, bacteria, and fungi.

PVP certificates are granted on a first-to-file basis as compared to the first-to-invent basis currently in use at the U.S. patent office. The granting of a PVP certificate is based on the PVPO's examination and evaluation of merits of the application contents as filed. Onsite examination of trials comparing the new variety with reference varieties is not a PVPA requirement, but will be done if so requested by the applicant.

Another key difference from the Canadian PBRA is that PVPA applicants must deposit at least 3,000 seeds of the new variety with a USDA-approved depository within three month of the PVPA application filing date.

PVP applications must be filed within twelve months of the first commercial sales of the new variety in the United States and/or within four years of commercial sales in any foreign jurisdiction. A PVP certificate provides the holder the legal right to exclude others from selling or offering for sale; from reproducing, importing, or exporting the novel variety for a period of twenty years from the date of the certificate's issue; and for a twenty-five-year period in the case of a novel tree or vine variety.

Most significant with respect to the Canadian PBRA is that the current form of the PVPA corresponds to the 1991 UPOV convention, which clarified and restricted the scope of the farmer's exemption and the breeder's exemption. Under the current PVPA, U.S. farmers are entitled to carryover PVPA-certified seed for their planting use only during the next growing season but are prevented from brown bagging excess seed. As in Canada, the PVPA allows a plant breeder to use a PBR-certified variety once, and once only, in a new breeding program. The use of a PBR-certified variety a second time in a breeding program (e.g., in second generation, third generation, or further generation crosses) is considered a repeated use and not allowable under the current PVPA. However, the PVPA explicitly prevents the use of a protected variety in the production of a hybrid (as opposed to developing a hybrid in a breeding program).

The PVPA fee (a) to file an application is US\$5¹⁸, (b) for searching and examining the application is US\$3,864, and (c) for allowance and issue of the PVP certificate is US\$786, for a total of US\$5,168 plus the agent's costs to file and prosecute the application to grant the certificate. The PVPA does not require the payment of post-issue annual maintenance fees.

The key differences and similarities between the Canadian Plant Breeders' Rights Act, the U.S. Plant Patent Act, and the U.S. Plant Variety Protection Act are summarized in Table 1.

Utility Patents

Although similar language is used to define the word *invention* in the Canadian and United States patent acts, legal interpretations of the definitions by the supreme courts in the two countries are very different and significantly impact the scope of IP protection available for novel plant technologies and novel plants that may be produced.

The Canadian Patent Act states that an invention, "means any new and useful art, process, machine, manufacture or compositions of matter, or any new and useful improvement in any art, process, machine manufacture or composition of matter."¹⁹

Table 1: Comparison of the Canadian Plant Breeders' Rights Act, the U.S. Plant Patent Act, and the U.S. Plant Variety Protection Act.

	Canada	USA	
	PBRA	PVPA	PPA
Protects			
All plant species except algae, bacteria, and fungi	Yes	Yes	Yes
Asexually propagated varieties	Yes	Yes	No
Sexually propagated varieties	Yes	No	Yes
Whole plants	Yes	Yes	Yes
Seeds	Yes	No	Yes
Propagules (e.g., cuttings, tissue culture, somatic embryos)	Yes	Yes	No
Application Bars			
Domestic applications	No sales prior to filing	Sales more than 12 mos. prior to filing	Sales more than 12 mos. prior to filing
Foreign applications	Sales more than 12 mos. prior to filing	Sales more than 12 mos. prior to filing	Sales more than 48 mos. prior to filing
Key Features			
On-site trial examination	Yes	No	No
Deposit of the novel variety with an approved depository	No (holder must maintain the variety)	No	Yes, at least 3,000 seeds
Term of protection	18 yrs from certificate issue	20 yrs from application filing date	(1) 25 yrs from certificate issue for trees and vines (2) 20 yrs from certificate issue for all other species
Minimum office fees (agents' and prosecution fees are additional)	Can\$6,600	(1) US\$3,500 for a small entity (2) US\$7,000 for a large entity	US\$5,168
Exemptions			
Farmer's exemption	Yes	No	Yes
Breeder's exemption	Yes	No	Yes
Research exemption	Yes	Yes	No
Brown bagging	Yes	No	Yes
Innocent bystander	Yes	No	No

The U.S. Patent Act reads, “whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirement of this title.”²⁰

The question of whether or not utility patents are available in the U.S. for living biological materials was addressed by the U.S. Supreme Court in *Diamond v. Chakrabarty*.²¹ Chakrabarty filed a patent application, assigned to his employer General Electric Co. (GE), for his invention of a genetically engineered bacterium capable of breaking down crude oil, the process of making the genetically engineered bacterium, and inoculum compositions comprising a carrier and the genetically engineered bacterium. Chakrabarty’s patent application was rejected by the USPTO. GE appealed the rejection to the USPTO Board of Appeals. The appeal was denied and the Board of Appeals upheld rejection of the patent application on the ground that living things are not patentable subject matter under definition of *invention* as written in 35 C.F.R. 101. GE appealed the Board of Appeals decision to the Court of Customs and Patent Appeals, which reversed the rejections while concluding that the fact that microorganisms are alive is without legal significance for purposes of the patent law.

The U.S. Supreme Court upheld the Court of Customs and Patent Appeals decision and provided the following statements in the written decision, which set the foundation for a broad and wide scope of patent protection available in the United States for living organisms and the products of biotechnology:

HELD: A live, human-made micro-organism is patentable subject matter under 35 C.F.R. 101. Respondent’s microorganism constitutes a “manufacture” or “composition of matter” within that statute.²²

(a) In choosing such expansive terms as “manufacture” and “composition of matter,” modified by the comprehensive “any,” Congress contemplated that the patent laws should be given wide scope, and the relevant legislative history also supports a broad construction. While laws of nature, physical phenomena, and abstract ideas

are not patentable, respondent's claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter a product of human ingenuity "having a distinctive name, character [and] use."

(b) The passage of the 1930 Plant Patent Act, which afforded patent protection to certain asexually reproduced plants, and the 1970 Plant Variety Protection Act, which authorized protection for certain sexually reproduced plants but excluded bacteria from its protection, does not evidence congressional understanding that the terms "manufacture" or "composition of matter" in 35 C.F.R. 101. do not include living things.²³

In summary, the consequence of the *Diamond v. Chakrabarty* (1980) U.S. Supreme Court decision is that it made it possible to successfully obtain in the United States patent claims protecting novel gene constructs for insertion into plant genomes for the purpose of creating novel plants; processes for creation of novel plants; processes for production of novel plants, novel plants, plant parts, and propagules; novel traits expressed by plants produced by such processes; novel metabolites and compounds produced by novel plants; novel compositions containing novel metabolites and/or compounds produced by novel plants, and novel uses and methods of use of novel plants, plant parts, propagules, their compounds, and/or metabolites; and compositions containing their compounds and/or metabolites. The criteria that will be used by the USPTO during its assessments of the patentability of such claims will be strictly based on the novelty, nonobviousness, and utility of the subject matter being claimed.

The situation in Canada is not as clear and straightforward. There have been three significant Canadian Supreme Court decisions during the past twenty years that served to confuse and then slightly clarify the options available for patenting life forms and the products of biotechnology in Canada. These decisions are:

1. *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*²⁴
2. *Harvard College v. Canada (Commissioner of Patents)*²⁵
3. *Monsanto Canada Inc. v. Schmeiser*²⁶

The *Pioneer Hi-Bred v. Canada* case was the first legal test in Canada regarding the patenting of life forms and products of biotechnology under the Canadian Patent Act. Pioneer Hi-Bred filed a Canadian patent application for a novel genetically engineered soybean variety (variety 0877) in 1983. The application was rejected by the Canadian patent office on the grounds that a new variety developed from an artificial crossbreeding program did not constitute an invention as defined by the patent act, and its decision was subsequently affirmed on appeal by the Canadian Commissioner of Patents.

Pioneer Hi-Bred appealed the rejections to the Federal Court of Appeal, which affirmed the examiner's and commissioner's rejections. Pioneer Hi-Bred then appealed the rejections to the Supreme Court of Canada. The Supreme Court recognized that the real issue in this case was the patentability of life forms.²⁷

However, the Supreme Court chose to avoid dealing with this issue at that time by finding that, while the patent disclosure described the basic materials used for the crossbreeding component of the invention, there was no indication of the genetic engineering steps undertaken to develop soybean variety 0877 and, therefore, the application did not meet the disclosure requirement of the patent act.

Furthermore, the Supreme Court stated that a deposit of soybean variety 0877 did not constitute an adequate disclosure, and for those reasons, denied Pioneer Hi-Bred's appeal. As such, a clear answer was not provided in that decision to the question of whether human intervention in the reproduction of a life form constituted a patentable invention.

The *Harvard v. Canada* case was a landmark case in which the Canadian Supreme Court considered whether life forms were patentable in Canada. The Canadian patent office decided that, while process claims for producing and manufacturing a genetically engineered mouse were patentable, product claims for the genetically engineered mouse were not.

Its decision was upheld by the Commissioner of Patents. Harvard College appealed to the Federal Court Trial Division, the Federal Court of Appeals, and, finally the Supreme Court. The Supreme Court wrote in its decision denying the Harvard appeal, that the main question it considered was whether the words *manufacture* and *composition of matter*, within the context of the patent act, are sufficiently broad to include higher life forms. In answer to that question, they wrote that:

while the definition of “invention” is broad, Parliament did not define “invention” as “anything new and useful made by man.”²⁸

The word “manufacture” (“fabrication”), in the context of the Act, is commonly understood to denote a non-living mechanistic product or process, not a higher life form.”²⁹

The words “composition of matter” (“composition de matières”) as they are used in the Act do not include a higher life form such as the oncomouse.³⁰

Just as “machine” and “manufacture” do not imply a living creature, the words “composition of matter” are best read as not including higher life forms.³¹

Higher life forms can not be conceptualized as mere “compositions of matter” within the context of the Patent Act.³²

The current Patent Act does not clearly indicate that higher life forms are patentable. (page 5)

The immediate consequence of the Supreme Court decision in the *Harvard v. Canada* case was that the Canadian Intellectual Property Office began applying this decision to reject all patent claims to all higher life forms including animals, plants, and fungi.

Monsanto v. Schmeiser was making its way through the Canadian courts at about the same time as *Harvard v. Canada*. The issue in *Monsanto v. Schmeiser* was whether a

farmer, i.e., Schmeiser, infringed Monsanto's Canadian Patent No. 1,313,830 by growing genetically engineered Round-Up resistant canola from seed that he did not purchase from Monsanto. The claims of CA 1,313,830 protected among other things (1) a unique chimeric plant gene and (2) a glyphosate-resistant plant cell comprising the chimeric plant gene.

The lower Canadian courts previously ruled and affirmed that Schmeiser infringed Monsanto's CA 1,313,830 patent. Schmeiser appealed to the Supreme Court on the ground that Monsanto's patent was invalid because the *Harvard v. Canada* decision made it clear that higher life forms such as plants were not patentable. However, the Supreme Court ruled that Monsanto's CA 1,313,830 patent was valid because no claims were issued for "a plant" but instead, for "genes" and "plant cells."

In its decision, the Supreme Court wrote that:

The patent is valid. The respondents did not claim protection for the genetically modified plant itself, but rather for the genes and modified cells that make up the plant.³³

A purposive construction of the patent claim recognizes that the invention will be practiced in plants regenerated from the patented cells, whether the plants are located inside or outside a laboratory.³⁴

Whether or not patent protection for the gene and cell extends to activities involving the plant is not relevant to the patent's validity.³⁵

The consequence of *Monsanto v. Schmeiser* is that the door is open for patent protection of higher life forms and the biotechnology products in Canada and provides at least some assurance that genetically engineered plants can be protected in Canada. However, great care will have to be taken in drafting the specification and claims in Canadian patent applications with awareness of the guidelines put forward by the three Supreme Court decisions referred to.

First, in reference to the *Pioneer Hi-Bred v. Canada* case, the steps required to produce a novel plant or plant component part must be described in explicit detail. Second, in reference to *Harvard v. Canada*, claims for genetically engineered higher life forms such as whole plants and whole reproductive units such as seeds, bulbs, tubers, and such, will likely be rejected by the patent examiners.

However, it should be possible, in reference to *Monsanto v. Schmeiser*, to secure claim allowance for novel plant genes and plant cells thereby gaining protection for plants wherein they are resident and expressed. However, another strategy worth considering for Canada, is to file:

1. patent applications with (a) process claims to protect methods for developing and producing novel plants, (b) product claims to protect novel genes and gene constructs produce novel plants, and (c) product claims to protect plant cells containing novel genes and/or gene constructs; and
2. PBRA applications to protect reproductive material (e.g., seeds, tubers, bulbs, corms, and somatic embryos) produced from the products of biotechnology.

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The Uniform Biological Material Transfer Agreement: Origin and Evolution

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The Origin

In the late 1980s, there was a rising tide of concern about the impact of material transfer agreements (MTAs) on the research enterprise. A number of articles were written about the problem, faculty members were complaining, and technology transfer offices were feeling the heat. The National Institutes of Health (NIH) Office of Technology Transfer was receiving so many complaints that it convened a meeting in 1990 to discuss possible solutions. That meeting was held on the NIH campus and drew a considerable number of concerned technology transfer professionals and Association of University Technology Managers (AUTM) leaders. That was the beginning of the effort that resulted in the uniform biological material transfer agreement (UBMTA).

The goals of the participants in the effort were lofty—to develop an agreement or agreements that would simplify exchanges of biological materials among nonprofit institutions and, perhaps, even transfers from the for-profit sector to nonprofits. Unfortunately, the latter goal was not achieved, but the first was. On March 8, 1995, the NIH and Public Health Services published in the Federal Register (page 12771 et seq., see http://www.autm.net/aboutTT/aboutTT_fedReg.cfm) the UBMTA and its implementing letter (see Appendix 1).

The Issues

The first challenge for the working group was agreeing upon a set of definitions. While this may seem trivial, it turned out to be surprisingly difficult. First, you had the stuff that one scientist transferred to another—the original material. The recipient scientist might (a) grow up more of the *original material* without introducing changes (*progeny*); (b) divide that original material or its progeny into its component parts

(*unmodified derivatives*); (c) alter the original material, progeny, or unmodified derivatives or combine any of them with other substances to create *modifications*; or (d) use the original material, progeny, unmodified derivatives, or modifications in some way to create substances that are not themselves progeny, unmodified derivatives, or modifications of the original material.

Once having agreed upon these definitions, it was important to agree which of the above the provider or recipient scientist owned and/or controlled. It was easy to agree that the provider owned and/or controlled the original material, progeny, and unmodified derivatives (taken together, the *material*). It was also fairly easy to reach agreement that the recipient scientist owned and/or controlled substances created through the use of the original material, progeny, or unmodified derivatives so long as the substance created was not itself progeny, unmodified derivatives, or modifications of the original material.

The big issue was ownership and/or control of modifications. These clearly included some portion (or even all) of the original material or its progeny, but they also included something contributed by the recipient scientist. The solution was to treat modifications much as a book written by one person (the recipient scientist) that contains a chapter written by another person (the provider scientist); the book is owned and/or controlled by its author, but he or she is constrained regarding what he or she can do with the book by an agreement with the author of the chapter.

The UBMTA stipulates that the recipient scientist owns the modification, but the provider scientist still owns the part of the modification that is the original material, progeny, or an unmodified derivative. The provider scientist agrees that the creator of the modification can distribute the modification to other scientists at nonprofit organizations (under agreements equivalent to the UBMTA) but cannot provide them to for-profit entities or for any commercial purpose.

The next major issue was how to handle any resulting patents. It was agreed that the provider should not restrict the recipient from filing patent applications on inventions made through the use of the material, but if a patent application claims modifications or methods of manufacture or use of the material, the provider must be notified.

Finally, there was the issue of potential liability for the provider or the recipient. The solution was essentially that neither party made any warranties and each assumed any liability for damages resulting from its actions.

Implementation

When the UBMTA and its implementing letter were published in the Federal Register in 1995, AUTM committed itself to maintaining a list of those institutions that agreed to be bound by the terms of the UBMTA when the providing and receiving institutions both signed an implementing letter. To date, more than 300 institutions have signed on to the UBMTA (see http://www.autm.net/aboutTT/aboutTT_umbtaSigs.cfm).

Unfortunately, many nonprofits often failed to use the UBMTA, even though they had signed on, and nonprofit-to-nonprofit transfers continued to require negotiation on a case-by-case basis. This, coupled with the more difficult problems experienced by scientists at nonprofits who wished to obtain materials from the for-profit sector, led NIH to establish a blue-ribbon Working Group on Research Tools. The working group deliberated for more than a year and issued its report in June 1998 (see <http://www.nih.gov/news/researchtools>).

Based on this report, NIH published a final notice in the Federal Register (see http://grants1.nih.gov/grants/intell-property_64FR72090.pdf) entitled *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice*—commonly referred to as NIH's research tools guidelines.

These guidelines endorsed the use of the UBMTA but went further by strongly recommending the use of the simple letter agreement for the transfer of materials (see Appendix 2) when transferring unpatented research tools unless the tools are licensed to an exclusive distributor.

Next Steps: Addressing Continuing Problems

So where are we today? Technology transfer offices still feel overburdened by the increasing flow of MTAs, and scientists at nonprofit institutions still complain about the length of time it takes to negotiate MTAs. While many nonprofits do base their MTAs largely on the principles and even the text of the UBMTA, they invariably include some changes, and the MTAs are presented as separate documents rather than using the implementing letter approach.

As a result, the potential to streamline MTA review is largely lost, with nonprofit-to-nonprofit transfers continuing to require detailed document review and some negotiation on a case-by-case basis. Admittedly, the longest negotiating delays occur when the supplier of the material is a for-profit. That's understandable since the company is concerned about protecting its investment in the material in question. Still, many of these company-supplied materials are of limited value and should be able to be distributed with few or no restrictions.

But, aside from materials coming from the for-profit sector, why are nonprofit to nonprofit transfers still the subject of so much negotiation? Increased use of the UBMTA and the simple letter agreement (as recommended by NIH) would go a long way toward making life a lot easier, as would Web-based systems utilizing these agreements. The following are several examples of recent initiatives seeking to improve the transfer of materials.

Science Commons has under way the Biological Materials Transfer Agreement Project, which is working to develop and make available standard, modular contracts for the exchange of a variety of types of biological materials. These will include existing standard agreements (UBMTA and simple letter agreement), along with a suite of alternative clauses in a Web-based library.

Addgene is a nonprofit depository for plasmids that uses the UBMTA for almost all of its materials, although special MTAs are required for some materials when proprietary technology is included, e.g., Cre-Lox. Addgene offers its materials via the Web, and most transactions are handled electronically.

AUTM's MTA Special Interest Group is developing an eMTA Commons, which it hopes will become a global Web-based MTA system that will provide efficient work-flow management and tracking as well as materials search capability to both principal investigators and technology transfer offices. The eMTA Commons is being designed to afford institutions the ability to establish their own review and approval processes and will handle standardized, dual-party-specific as well as custom agreements. The lead institution is City of Hope, with the assistance of approximately two dozen individuals from institutions around the country. Both Science Commons and Addgene are participating in this effort.

So there is hope, and, perhaps, these efforts and others like them will one day create agreements and systems that will make complaints about MTAs a thing of the past. And best of all, science will be able to move forward without the frustration of long negotiations to obtain essential research materials.

In the meantime, I encourage you to make use of the existing UBMTA and simple letter agreement formats for as many of your materials exchanges as possible.

Appendix 1:

UBMTA and Implementing Letter

Upon execution of an Implementing Letter in the form attached which specifies the materials to be transferred, this organization agrees to be bound by the terms of the attached Uniform Biological Material Transfer Agreement (“UBMTA”) published in the Federal Register on March 8, 1995.

Attachments:

UBMTA

Implementing Letter

Organization:

Address:

Authorized Official:

Title:

Signature:

Date:

Please return an executed copy of this Master Agreement to: The UBMTA Project, Association of University Technology Managers (AUTM), 111 Deer Lake Road, Suite 100, Deerfield, IL 60015. AUTM will be maintaining signed originals and the official list of signatory organizations.

The Uniform Biological Material Transfer Agreement

March 8, 1995

I. Definitions:

1. PROVIDER: Organization providing the ORIGINAL MATERIAL. The name and address of this party will be specified in an implementing letter.

2. PROVIDER SCIENTIST: The name and address of this party will be specified in an implementing letter.
3. RECIPIENT: Organization receiving the ORIGINAL MATERIAL. The name and address of this party will be specified in an implementing letter.
4. RECIPIENT SCIENTIST: The name and address of this party will be specified in an implementing letter.
5. ORIGINAL MATERIAL: The description of the material being transferred will be specified in an implementing letter.
6. MATERIAL: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL shall not include: (a) MODIFICATIONS, or (b) other substances created by the RECIPIENT through the use of the MATERIAL which are not MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES.
7. PROGENY: Unmodified descendant from the MATERIAL, such as virus from virus, cell from cell, or organism from organism.
8. UNMODIFIED DERIVATIVES: Substances created by the RECIPIENT which constitute an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by the PROVIDER, or monoclonal antibodies secreted by a hybridoma cell line.
9. MODIFICATIONS: Substances created by the RECIPIENT which contain/incorporate the MATERIAL.
10. COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. COMMERCIAL PURPOSES shall also include uses of the MATERIAL or MODIFICATIONS by any organization, including RECIPIENT, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met.
11. NONPROFIT ORGANIZATION(S): A university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal

Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government agencies.

II. Terms and Conditions of this Agreement:

1. The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.
2. The RECIPIENT retains ownership of: (a) MODIFICATIONS (except that, the PROVIDER retains ownership rights to the MATERIAL included therein), and (b) those substances created through the use of the MATERIAL or MODIFICATIONS, but which are not PROGENY, UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e., do not contain the ORIGINAL MATERIAL, PROGENY, UNMODIFIED DERIVATIVES). If either 2(a) or 2(b) results from the collaborative efforts of the PROVIDER and the RECIPIENT, joint ownership may be negotiated.
3. The RECIPIENT and the RECIPIENT SCIENTIST agree that the MATERIAL:
 - (a) is to be used solely for teaching and academic research purposes;
 - (b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the PROVIDER;
 - (c) is to be used only at the RECIPIENT organization and only in the RECIPIENT SCIENTIST's laboratory under the direction of the RECIPIENT SCIENTIST or others working under his/her direct supervision; and
 - (d) will not be transferred to anyone else within the RECIPIENT organization without the prior written consent of the PROVIDER.
4. The RECIPIENT and the RECIPIENT SCIENTIST agree to refer to the PROVIDER any request for the MATERIAL from anyone other than those persons working under the RECIPIENT SCIENTIST's direct supervision. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agrees to make the MATERIAL available, under a separate implementing letter to this Agreement or other agreement having terms consistent with the terms of this Agreement, to other scientists (at least

those at NONPROFIT ORGANIZATION(S)) who wish to replicate the RECIPIENT SCIENTIST's research; provided that such other scientists reimburse the PROVIDER for any costs relating to the preparation and distribution of the MATERIAL.

5. (a) The RECIPIENT and/or the RECIPIENT SCIENTIST shall have the right, without restriction, to distribute substances created by the RECIPIENT through the use of the ORIGINAL MATERIAL only if those substances are not PROGENY, UNMODIFIED DERIVATIVES, or MODIFICATIONS.
 - (b) Under a separate implementing letter to this Agreement (or an agreement at least as protective of the PROVIDER's rights), the RECIPIENT may distribute MODIFICATIONS to NONPROFIT ORGANIZATION(S) for research and teaching purposes only.
 - (c) Without written consent from the PROVIDER, the RECIPIENT and/or the RECIPIENT SCIENTIST may NOT provide MODIFICATIONS for COMMERCIAL PURPOSES. It is recognized by the RECIPIENT that such COMMERCIAL PURPOSES may require a commercial license from the PROVIDER and the PROVIDER has no obligation to grant a commercial license to its ownership interest in the MATERIAL incorporated in the MODIFICATIONS. Nothing in this paragraph, however, shall prevent the RECIPIENT from granting commercial licenses under the RECIPIENT's intellectual property rights claiming such MODIFICATIONS, or methods of their manufacture or their use.
6. The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of the PROVIDER, including any altered forms of the MATERIAL made by the PROVIDER. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS, or any related patents of the PROVIDER for COMMERCIAL PURPOSES.
 7. If the RECIPIENT desires to use or license the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with the PROVIDER to establish the terms of a commercial license. It is understood by the RECIPIENT that the PROVIDER shall have no obligation to grant such a license to the RECIPIENT, and may grant exclusive or non-exclusive commer-

cial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.

8. The RECIPIENT is free to file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL but agrees to notify the PROVIDER upon filing a patent application claiming MODIFICATIONS or method(s) of manufacture or use(s) of the MATERIAL.
9. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.
10. Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL. The PROVIDER will not be liable to the RECIPIENT for any loss, claim or demand made by the RECIPIENT, or made against the RECIPIENT by any other party, due to or arising from the use of the MATERIAL by the RECIPIENT, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the PROVIDER.
11. This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or the MODIFICATIONS. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications.
12. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.
13. This Agreement will terminate on the earliest of the following dates: (a) when the MATERIAL becomes generally available from third parties, for example, through reagent catalogs or public depositories or (b) on completion of the RECIPIENT's cur-

rent research with the MATERIAL, or (c) on thirty (30) days written notice by either party to the other, or (d) on the date specified in an implementing letter, provided that:

- (i) if termination should occur under 13(a), the RECIPIENT shall be bound to the PROVIDER by the least restrictive terms applicable to the MATERIAL obtained from the then-available resources; and
 - (ii) if termination should occur under 13(b) or (d) above, the RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS; and
 - (iii) in the event the PROVIDER terminates this Agreement under 13(c) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the PROVIDER will defer the effective date of termination for a period of up to one year, upon request from the RECIPIENT, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS.
14. Paragraphs 6, 9, and 10 shall survive termination.
15. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested by the PROVIDER, the amount will be indicated in an implementing letter.

UBMTA Implementing Letter

The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the PROVIDER SCIENTIST (identified below) and the RECIPIENT SCIENTIST (identified below) to abide by all terms and conditions of the Uniform Biological Material Transfer Agreement (“UBMTA”) March 8, 1995, and to certify that the RECIPIENT (identified below) organization has accepted and signed an unmodified copy of the UBMTA. The RECIPIENT organization’s Authorized Official also will sign this letter if the RECIPIENT SCIENTIST is not authorized to certify on behalf of the RECIPIENT organization. The RECIPIENT SCIENTIST (and the Authorized Official of RECIPIENT, if necessary) should sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER SCIENTIST will forward the material to the RECIPIENT SCIENTIST upon receipt of the signed copy from the RECIPIENT organization.

Please fill in all of the blank lines below:

1. PROVIDER: Organization providing the ORIGINAL MATERIAL:

Organization: _____

Address: _____

2. RECIPIENT: Organization receiving the ORIGINAL MATERIAL:

Organization: _____

Address: _____

3. ORIGINAL MATERIAL (Enter description):

4. Termination date for this letter (optional):

5. Transmittal Fee to reimburse the PROVIDER for preparation and distribution costs (optional). Amount: _____.

This Implementing Letter is effective when signed by all parties. The parties executing this Implementing Letter certify that their respective organizations have accepted and signed an unmodified copy of the UBMTA, and further agree to be bound by its terms, for the transfer specified above.

PROVIDER SCIENTIST

Name: _____

Title: _____

Address: _____

Signature: _____

Date: _____

RECIPIENT SCIENTIST

Name: _____

Title: _____

Address: _____

Signature: _____

Date: _____

RECIPIENT ORGANIZATION CERTIFICATION

Certification: I hereby certify that the RECIPIENT organization has accepted and signed an unmodified copy of the UBMTA (May be the RECIPIENT SCIENTIST if authorized by the RECIPIENT organization):

Authorized

Official: _____

Title: _____

Address: _____

Signature: _____

Date: _____

Appendix 2:

Simple Letter Agreement

PHS Simple Letter Agreement Rev. 12/1999

Simple Letter Agreement for the Transfer of Materials

In response to the RECIPIENT's request for the MATERIAL [insert description]

to be used for the purpose of _____

the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community.
2. THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.
3. The MATERIAL will be used for teaching or not-for-profit research purposes only.
4. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement, to other scientists for teaching or not-for-profit research purposes only.
5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.
6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, Recipient assumes all liability for claims for damages against it by third parties which

Name of Authorized Official: _____
Title of Authorized Official: _____
Signature of Authorized Official: _____
Date: _____

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

Signature of Recipient Scientist

Date

The Effects of Patent Agreements on Small-Entity Status

Paul C. Craane, JD

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If you are an independent inventor, are associated with a startup, or work in a nonprofit technology transfer office, the attorney that prepared your patent application probably discussed with you whether you should pay the filing fees at the small-entity rate. Given the expense of the application, you undoubtedly were pleased to hear that the U.S. government reduces the filing fees by half for persons and companies entitled to small-entity status.

Unfortunately, qualification for small-entity status can be lost for any of a great number of reasons, the details of which may not have been explained by the attorney. For example, your efforts in finding a commercialization partner to develop, finance, or make and sell your invention could cause you to lose your right to the reduced fees. While proper planning can ameliorate the effect of the increased fees, failure to appreciate the consequences of your actions in the technology transfer process can lead to complete loss of rights in the patent or application.

During the process of filing, processing, and maintaining a patent, the applicant/patentee will have to pay significant fees to the United States Patent and Trademark Office (USPTO). There are application fees due for filing, search, and examination. During the process, other fees may come due depending on the timing and nature of actions taken. There are also issue fees, payable if the applicant is fortunate enough to convince the USPTO that the invention disclosed and claimed in the application is patentable. After the patent issues, maintenance fees (taxes) are required to prevent the patent from expiring.

In recognition of the fact that there is a governmental interest in making the patent process less expensive for certain groups, Congress authorized the USPTO to establish and maintain a qualification referred to as *small-entity status*.¹ If an applicant/patentee

is eligible for small-entity status, many fees payable to the USPTO are reduced by 50 percent. Given the sizable maintenance fees (taxes) due after grant, small-entity status may end up being worth in excess of \$5,000 in savings over the life of a single patent.

There is a downside: Paying a fee at the small-entity rate when the party is not eligible to qualify for small-entity status may render the patent unenforceable.² According to the courts, it is not merely sufficient that the fee be paid incorrectly, there must be an intent to deceive the USPTO as well.³ The intent may be inferred from circumstances, and at least one court has inferred the intent, at least in part, from an attorney's failure to abide by the USPTO's guidance as provided in the Manual of Patent Examining Procedure (MPEP).⁴

So why not just pay the normal fees, regardless of actual eligibility for small-entity status? Canadian patent practitioners routinely advise their clients to pay at the normal entity rate under the Canadian system, which also provides for a small-entity fee reduction. However, for even a small portfolio of patents, the fee reductions attributable in the United States to small-entity status may run into tens of thousands of dollars.

For institutions such as universities, which routinely qualify for small entity-status and have sizable portfolios, the fee savings may run into the hundreds of thousands, if not millions, of dollars. Given the size of the savings, it is not unreasonable for a client to expect that his or her attorney would be willing to perform the analyses necessary to advise whether the client qualifies.

At the outset, it is important to recognize that small-entity status is determined at three times during the life of the patent: when the filing fees are paid, when the issue fees are paid, and when the maintenance fees are paid.⁵ Consequently, it is possible for fees to be paid at the small-entity rate at one point in time and at the normal rate at another point in time. For example, the filing and issue fees for an application may be paid at the small-entity rate, but the maintenance fees may be paid at the normal rate because of an intervening change in circumstances.

In the first instance, small-entity status is determined according to the identity of the patent owner. To obtain small-entity status, the patent owner must fall within one of

three classes: (1) person(s), (2) small-business concerns with fewer than 500 employees, or (3) nonprofit organizations.⁶

Persons refers to the inventors or individuals to whom the inventor has transferred rights in the invention.⁷ Small-business concerns must meet the size standards set by the Small Business Administration, with reference to 13 C.F.R. §§ 121.801 through 121.805.

Nonprofit organizations include universities or other institutions of higher education, 501(c)(3) organizations, and nonprofit scientific or educational organizations. Further guidance is provided in the MPEP as to all three categories, although the USPTO will defer to the Small Business Administration on issues relating to small-business concerns.

While the inclusion of the patent owner within one of these three classes is necessary to small-entity status, it is not sufficient. Of particular interest for the purposes of this article, it is possible for a small entity to retain ownership of a patent and still lose small-entity status. As explained in the USPTO rules, a patentee may lose small-entity status if the patentee has *assigned, granted, conveyed, or licensed any rights in the invention* to any person, concern, or organization that would not qualify for small-entity status.⁸

It is important to note that the assignment, grant, conveyance, or license is only of interest to the analysis if it transfers rights to a U.S. patent or application. For example, if an agreement only addresses rights to a foreign patent or application, it is not of interest to the analysis.⁹ Consequently, if the rights to a U.S. patent are transferred to a party that qualifies for small-entity status, but the rights to a foreign counterpart patent are transferred to a non-small-entity, the patent owner would still qualify for small-entity status. If both U.S. and foreign rights were transferred to a non-small-entity, the patent owner would be disqualified.

Given that licenses are included in the same list as assignments, grants, and conveyances, the reader may form the impression that the rule only extends to *exclusive licenses*, i.e., licenses that may be considered tantamount to assignments such that suit may be brought by the exclusive licensee in its own name, for example. Such an assumption is unwarranted. Both the courts and the USPTO have determined that even *nonexclusive*

licenses to non-small-entities are sufficient to disqualify a patentee from small-entity status.¹⁰

In fact, not only is a nonexclusive license sufficient to disqualify a patentee from small-entity status, an *unwritten* license may also cause disqualification. In support of this position, the MPEP explicitly states that a shop right may cause disqualification.¹¹ A *shop right* is a right that permits an employer to use without charge certain inventions of his or her employees without liability for infringement, a right that is nontransferable and extends only to the manufacture and use of the invention.¹²

Rather than being based on a written agreement between the employer and employee, shop rights are grounded in principles of estoppel or in the form of an implied license. Thus, according to the USPTO guidance, even such an unwritten, limited, implied license may result in disqualification.¹³

While certain implied licenses may cause issues, other limited implied licenses do not appear to disqualify the patentee. In particular, the USPTO has explicitly recognized that implied licenses of use and resale that are attendant to an authorized sale of a product embodying the invention, for example, would not result in disqualification.

Based on the latter guidance, an argument may be made that so-called shrink-wrap or click-wrap licenses, to the extent that they implicate patent rights, also should not cause disqualification of the patentee. Shrink-wrap or click-wrap licenses are licenses that accompany software, typically involving permissions to use the copyrights and patents that cover the installation and use of the software. Where the terms of such a license extend only to the customer's use of the software, it would appear that this is not the type of license that would cause disqualification.

As further explained in the USPTO rules, a small entity may also lose small-entity status if the small entity has an *obligation* to assign, grant, convey, or license any rights in the invention to any person, concern, or organization that would not qualify for small-entity status.¹⁴ Unfortunately, the USPTO provides little guidance as to what obligations may fall within the scope of the rule.

The single example given in regard to agreements that create obligations of assignment, grant, conveyance, or license is the security agreement. As explained in the MPEP¹⁵ and the rules,¹⁶ a security interest does not involve an obligation to transfer rights except in case of default on the underlying debt. The obligation created by a security interest is, thus, not currently enforceable. As such, granting a security interest to a non-small-entity does not disqualify the small entity.

With this guidance, what is the likely effect of a patent license option agreement? Option agreements are frequently used to reserve an exclusive opportunity for a prospective licensee to negotiate with a prospective licensor. In this regard, the wording of the option agreement may be critical, given that there is no single document universally recognized as an option agreement.

For example, in *Nilssen*,¹⁷ the patent owner argued that an agreement was not a license agreement, but an option agreement wherein the obligation to license had not yet vested. In the agreement, the parties stated that the patent owner *will offer* and the prospective licensee *will take* a license agreement in the future, with no royalties accruing until a condition had been satisfied. The Court of Appeals for the Federal Circuit agreed that this language in the agreement was sufficient to disqualify the patent owner from small-entity status.

Unfortunately, it is unclear whether the Federal Circuit reached this outcome because the agreement was considered to be a de facto license with a right to future royalties or because the patent owner "reasonably expected to receive a revenue stream" such that an obligation (but no license) existed, having mentioned both in its analysis.

The reader may speculate as to the result if a modified agreement was reached by the parties. For example, the parties might agree to negotiate exclusively for a limited time period, with no mention that the parties will offer and accept anything. Does such an agreement protect the qualification for small-entity status?

Case law suggests that the answer is no. That is, the law of certain jurisdictions may imply an obligation to complete the negotiations based on the terms of the option agree-

ment. For example, if the parties have already agreed to key provisions, the parties may be under an implied obligation to complete the negotiations, which obligation may be enforceable in court. In such circumstances, the parties' statement that they will merely exclusively negotiate may not be enough to avoid conflicting with the requirement for maintaining small-entity status.

What is the patent owner to do? Certainly, where the USPTO is clear that small-entity status is lost, such as in the case of nonexclusive licenses or certain implied licenses, the patent owner disregards the USPTO guidance at its own peril. Where the USPTO is equally clear that small-entity status is preserved, as in the case of security interests, the patent owner may take comfort.

As for the large gray area, concerning option agreements and implied licenses, it is important to recognize that there is potential for disqualification and the need for further advice. Given the lack of clarity on these issues and the consequence of unenforceability, it may be prudent to pay at the undiscounted normal rate and address the fee differential in the agreement causing the potential disqualification. In any event, the patent owner is well-served in recognizing the perils that such relationships and negotiations may present to its entitlement to maintain its small-entity status.

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Notes

1. 35 U.S.C. § 41(h) (2009).
2. See, e.g., *Ulead Sys. Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139 (Fed. Cir. 2003); *Nilssen v. Osram Sylvania*, 440 F. Supp. 2d 884 (N.D. Ill. 2006), *aff'd* 504 F.3d 1223 (Fed. Cir. 2007).
3. *Ulead*, 351 F.3d at 1146.
4. *Outside the Box Innovations LLC v. Travel Caddy Inc.*, No. 05-2482, slip op. at 40 (D. Ga. Dec. 19, 2008).

5. 37 C.F.R. § 1.27(g) (2009).
6. 37 C.F.R. § 1.27(a)(1)-(3) (2009).
7. Under U.S. law, inventors are presumed to be the original owners. *See Teets v. Chromalloy Gas Turbine Corp.*, 83 F.3d 403 (Fed. Cir. 1996).
8. See 37 C.F.R. § 1.27(a)(1)-(3) (2009).
9. *Manual of Patent Examining Procedure* (MPEP) 509.02 V, at 500-46.
10. See, e.g., *Outside the Box Innovations LLC v. Travel Caddy Inc.*, No. 05-2482, slip op. at 40 (D. Ga. Dec. 19, 2008); MPEP 509.02, at 500-46.
11. MPEP 509.02 V, at 500-45.
12. See *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576 (Fed. Cir. 1993).
13. MPEP 509.02, at 500-46.
14. 37 C.F.R. § 1.27(a)(1)-(3) (2009).
15. MPEP 509.02, at 500-46.
16. 37 C.F.R. § 1.27(a)(5) (2009).
17. *Nilssen v. Osram Sylvania*, 440 F. Supp. 2d 884 (N.D. Ill. 2006), *aff'd* 504 F.3d 1223 (Fed. Cir. 2007).

Intellectual Property and Related Rights: Issues when a Researcher Moves to another Organization

Gail Norris, JD

Gail M. Norris, JD, is director of the University Technology Transfer Office and senior counsel at the University of Rochester in New York.

Introduction

Intellectual property (IP) policies of most academic research institutions provide that IP developed by researchers using the institution's resources shall be owned by the institution.¹ As the concept of IP continues to develop and expand, myriad issues arise around ownership and use of that property when a researcher leaves.

What can be taken by the researcher when he or she leaves one university for another? What should stay at the university? Are there areas where the rights of the researcher and the university in research material overlap? If the researcher's departure is the result of a failure to receive tenure or perceived disputes, the ability to address and agree on the appropriate allocation of rights may be more difficult, but also more important.

Because of the ever-increasing emphasis on technology creation at academic research institutions and the mobility of researchers, research institutions should closely examine their policies and practices relating to the documentation and ownership of research material and intellectual property. There have been two recent and high-profile court cases that have highlighted this need to stop and think when a researcher moves to another organization.

The first case, *Madey v. Duke University*,² involved a dispute between Duke and John Madey, PhD, a former faculty member. Madey brought several patents with him when he came to Duke, and he proceeded to use them in his research facilities at Duke during the decade or so that he worked there. He left Duke after being removed as lab director, and

then sued the university claiming that Duke continued to use his inventions in the lab after he left and, thus, infringed his patents.

Duke argued that Madey's patents were used at Duke purely for noncommercial research and, as such, were subject to the experimental-use defense to patent infringement.³ The court rejected Duke's argument and ruled that the experimental-use defense is not determined by the commercial nature of the research. Rather, it is determined by whether the use is in further of the institution's legitimate business objectives, "including educating and enlightening students and faculty."⁴ Therefore, Duke was unable to continue to use Madey's patents without his permission.

The second case, *Catalona v. Washington University*,⁵ involved a dispute between Washington University of St. Louis and William Catalona, MD, a renowned prostate cancer specialist who had been on Washington University's faculty. While there, Catalona and others established a tissue repository for prostate cancer cells. When Catalona left the university, he attempted to transfer some of the samples to his new employer.

The university refused, and a civil action was filed by Catalona and a handful of donors. Both Catalona and the donors insisted that the tissue samples were donated to him, not the university, and that they should be able to follow him to his new place of employment. The court disagreed and ruled that, based on (1) the language in the consent forms used and (2) the fact that the tissue samples were donated to Washington University and maintained at the university's expense in its biorepository, the samples were owned by the university.

These two cases are examples of ways the IP rights of a researcher and a university can be tested when the researcher and the university separate. To avoid expensive and high-profile litigation, researchers and universities should understand their relative rights and obligations and discuss the ownership issues before a dispute arises. Resolution of these issues necessarily depends on the facts and circumstances of the particular situation as well as the IP and other policies of the university.

This chapter outlines the IP issues that frequently arise when a researcher leaves an institution. They can serve as the basis for a checklist of considerations that should be addressed prior to the researcher's departure so that there is no ambiguity or misunderstanding between the parties regarding the use and ownership of research property.

Intellectual Property Issues when Researchers Move

Intellectual Property that Is Covered by a Patent Application or an Issued Patent

Under most university IP policies, an inventor using substantial university resources or federal research funds must assign ownership of resulting invention to the university. In exchange, the inventor shares any royalties that come from the commercial licensing of the invention. When an inventor leaves the university, therefore, the university still owns the invention. If the inventor wishes to continue to use the invention after he or she leaves, the old and new employers should arrange for a license. In the spirit of encouraging open academic research, this would typically be done through the grant of a royalty-free, nonexclusive license to use the invention for research or educational purposes.

As a practical matter, most universities are so committed to the mission of open dissemination of knowledge that it may seem like unnecessary work to put in place a formal license just for permission for one university to use another's patent for its academic purposes. If you work in the research or technology transfer office of the inventor's new institution, however, you may want to insist on the license to preserve the right to use the inventor's work into the future.

For instance, if the inventor's former institution licenses the patent to a commercial entity, sometimes the license does not reserve to the licensor broad enough rights to allow the inventor to use the patent at the new institution. Trouble could be created down the road if the inventor comes up with a new invention that is derived from its use of the first patent.

If the inventor leaves to go into a business instead of academia, or if the license will not be restricted to noncommercial uses the license may have different terms negotiated on

the potential commercial use of the patent. For example, if the inventor is leaving the university to work in a startup company that will commercialize the invention, conventional licensing terms will be negotiated.

For patents that have not yet issued, the university should discuss pending patent applications with the departing inventor to ensure that the inventor will be available to cooperate if help is needed in responding to office actions or other aspects of the patent's prosecution. Inventors should be reminded that there is good incentive to cooperate since, under most university IP policies, the inventor will share in any royalties received from the license of the patent even after he or she has left the university. The inventor and his or her new employer should consider licensing the patent application in the same manner as discussed above for an issued patent.

In cases where patent ownership lies with the inventor, the university that is losing the inventor must negotiate a license if it would like to use the patent after the inventor leaves. This may be especially important if the invention is the subject of externally funded research work that will be ongoing at the university.

Inventions that Are Partially Developed at both Institutions

Most scientific work of a researcher will continue after he or she leaves one institution and moves to another. The ongoing, fluid nature of this research work can create some interesting ownership issues. To be able to unravel them, it is important that the parties have some idea of the status of the researcher's work at the time he or she changed jobs. Under current patent law and university policies, inventive claims in a patent that were first reduced to practice at one university will result in ownership of the patent by that university.⁷ If claims in a patent were first reduced to practice at two different institutions, then joint ownership of a patent will result.

For IP that is jointly owned by both institutions, an interinstitutional agreement may be entered into to define the relative rights and responsibilities among the parties. Similarly, interinstitutional agreements can be used if the researcher develops follow-on intellectual property at his or new institution that can be filed as a continuation or a continuation in

part to the original patent. It may also be beneficial to the parties to use an interinstitutional agreement to bundle patents with common inventor(s) that are separately owned by each institution but most effectively marketed by packaging them together into one portfolio.

Research Material and other Forms of Intellectual Property

Research institutions should be aware of any material from the researcher's laboratory that moves with him or her to the new employer. Research material that was developed at a researcher's prior institution should be moved to his or her new institution under a material transfer agreement (MTA). This can easily be done through the uniform biological material transfer agreement (UBMTA) or a standard MTA used between academic institutions. Different terms may be required in the agreement if the research material will be used for commercial purposes instead of exclusively for research or educational purposes, as may be the case if the researcher moves into an industry job.

If a scientist has research material that was previously received under a MTA from a third party and that he or she wishes to continue to use at his or her new institution, best practices dictate that the research materials should not be transported to the researcher's new laboratory. Rather, the new institution should request new materials directly from the original third-party source under a new MTA. Occasionally, the MTA may be able to be assigned to the new institution, but careful attention should be paid to the terms of the agreement and to any differences in the intended use of the materials at the researcher's new employer.

If the departing researcher has developed know-how or other technical information that can be captured as an IP asset of the research institution, the ownership and rights to this property should be considered as well. This would be particularly true in cases where the specific know-how of the researcher was licensed along with a patented invention.

Copyrighted Material

As a general rule, the 1976 Copyright Act⁸ gives copyright ownership to the employer for any work prepared by one of its employee's within the scope of his or her employment.

This is based on the premise that the employee was paid by his or employer to prepare the copyrighted material and so it was work for hire and owned by the employer.

Traditionally under many university policies, however, professors have owned the copyright to their scholarly books and articles. But what about other types of copyrighted materials that are not textbooks or articles? With the advent of distance learning, Web-based software, and other types of digital media, old copyright policies are often not sufficient to clarify ownership of these types of works. New policies are being developed at many institutions that attempt to re-define copyright ownership between the university and the employee-author to encompass the many new forms of digital or electronic authorship.

The first step in addressing copyright ownership issues is to identify any copyrighted material that the researcher is taking. This would include computer software programs or written, audio, or visual works of authorship. To determine copyright ownership, the facts surrounding how and when the work was created as well as existing university policies should be examined. Special attention should be given to educational or research materials that the university intends to continue to use after the author leaves (e.g., analytical or computational software used in a laboratory, course curriculum materials, teaching modules, etc.) since the right to use that material should be clear between the parties.

Once ownership of the copyrighted material is determined, the issues created when the author leaves can be analyzed in much the same way as discussed above for patents. Copyrighted works owned by the first university can be licensed to the second university so that the author can continue to use them for his or her research or teaching. Copyrighted material that is first developed at, and owned by, one institution, and then improved at the next, will be jointly owned by both, and an interinstitutional agreement can be entered into. Copyrighted works owned by the author can be licensed to his or her former employer if the university wishes to continue to use them after the author leaves, as may be the case with teaching material that will continue to be used in a course or analytical software tools that are used in a laboratory.

Other Non-Intellectual Property Interests to Consider

External Research Awards

Research grants and contracts with federal or state agencies or with industry do not often address the issue of what should happen if the principal investigator (PI) should leave the university. Research personnel should talk with any PI who is leaving the university to discuss the status of the research project. There should be mutual agreement on what is needed for the finalization of the research project and who is responsible for its completion.

Issues relating to whether the extramural funding can or should move with the PI to the new institution, how the remainder of the research project should be carried out, what is required under the funding documents for changing PIs or notifying the funding source of personnel changes, etc., are beyond the scope of this chapter but should be considered by the university's research personnel and department chairs.

Research Data

When researchers leave an institution, they will usually believe it is necessary to take all of their research records with them. Conversely, OMB Circular A-1109 specifies that financial records, supporting documents, statistical records, and all other records pertinent to a federally funded award shall be retained by the institution. This requirement has resulted in the adoption by many universities of a policy that requires the university to own and retain all data created using federal funds. Some university policies are even broader and seek to retain data for all extramurally funded research projects or which was used to support patent applications so that the university has access to the data if necessary to support the patent during prosecution or litigation.

While the researcher works at the university, the original data generated from research is typically kept in his or her personal files or laboratory notebooks and conveyed as needed for reports or publication. Typically, there is no requirement that the data be stored in a place that is readily identifiable and accessible to university officers.

When a researcher leaves, however, the researcher and the university must provide for the university's access to the data. Sometimes this will require that two copies of the data be made for each party. Sometimes it may be easiest for the university to hold the data and make it available for the researcher on an as-needed basis. Or it may be that the researcher is allowed to take the data with him or her and make it available to the university on an as-needed basis. If the latter is the case, the university must ensure that the data be retained for the record-retention period required by its policy (taking into account any license obligations or requirements of the funding sponsor).

Research Animals

If the researcher would like to ship research animals from one university to the other, there may be procedures or approvals required by the university's animal research review body. In addition, the transfer of animals may be subject to laws and regulations such as the federal Animal Welfare Act and the U.S. Public Health Service's policies on the care and use of laboratory animals. Animals being transferred may need to undergo quarantine required by the university accepting the animals to ensure that there is no risk of pathogens entering its vivaria.

Equipment

Transfer of equipment among institutions often depends on the source of funds used to purchase it. An institution will usually prohibit the transfer of equipment purchased with its own funds. Most institutions will permit the transfer of equipment purchased using federal funds to the PI's new employer, particularly if the project will continue at the new institution. As is the case with the transfer of extramurally funded research grants, a review of the documentation and the requirements of the sponsor should be undertaken to see if the sponsor has imposed constraints on the ownership or transfer of equipment funded by it.

Personnel

When a senior researcher announces he or she is leaving, university officials should anticipate the possibility that other personnel will follow the researcher to his or her new

employer. Ideally, the departing scientist and university personnel should have open discussions regarding the scientist's staffing needs at his or her new institution. This discussion should include which existing colleagues he or she has identified as potential candidates at his or her new institution. The better the university can anticipate staffing shortages due to the researcher's migration, the easier it will be to proactively address them.

Conflicts of Interest, including Legal Representation

A researcher's departure from the university may create institutional conflicts of interest or other relationship issues with outside professionals. This is especially likely when the inventor leaves for a position in a for-profit company. A typical example arises when the researcher leaves to form a startup to commercialize technology. While the researcher was employed at the university, the researcher and the university's patent lawyers have likely been in contact as claims in the patent have been drafted and prosecuted. Then, the researcher leaves to form a startup. The company usually is looking for equity investors and legal representatives, as well as a license of the technology.

Institutional conflicts of interest arise if the university is an equity investor in the startup and the licensor of the technology. Institutional conflicts of interest may also exist if the startup also enters into a sponsored research agreement with the university so that some of the research can be continued in the researcher's former laboratory.

It may also be natural for the researcher to approach the law firm prosecuting the patent with a request to represent the company in general corporate matters. Under the ethics rules of most states, the law firm has a conflict of interest and cannot represent both parties without a written waiver from each of them.

In each of these situations, the university should carefully consider the advantages and disadvantages of permitting the conflicts to continue. If it is more advantageous for the university to allow the conflict to continue, a clear idea of how the conflict will be managed in the future should be developed. With institutional conflicts of interest, this may be done through a conflict-management plan. With law firm representation, the waiver letter may contain certain stipulations for future events. For instance, the law firm may

be required to agree not to represent either party in the event of litigation between the two in the future.

Best Practices: Exit Interviews

This chapter provides an overview of the questions that can arise when a researcher leaves a university. These questions should be used to create a framework for the policies and procedures that should be in place to govern how they should be answered. At a minimum, technology transfer personnel should understand where there may be gray areas in university policies so that issues can be identified and addressed with the departing researcher.

Ideally, an exit interview should be conducted with the departing scientist. In the exit interview, the appropriate university official should review any pending or issued patents, the status of inventive work done under research projects; the use by the parties of any copyrighted materials authored by the departing researcher; the status of all extramurally funded research projects and the plans for the project's completion; whether the researcher wants any research materials, animals, or equipment transferred; and how research data will be available to the parties.

The exit interview will afford the parties the opportunity to work through any ambiguities or differences in expectations that exist and ensure that the university maintains rights it has to its IP and research assets. At a minimum, the university must be able to contact the researcher following termination of employment.

Advice for the Researcher's New Employer: Reverse Engineer these Issues

Since IP or other rights may be lost to a university if a researcher leaves, much of the focus of this chapter has been on the identification and clarification of issues between the researcher and his former institution. Nevertheless, the researcher's new institution also has an interest in identifying potential issues so it doesn't find itself in the middle of a dispute between its new employee and institutional colleague. When a researcher comes to your university, it may be helpful to take the considerations addressed in this chapter and reverse engineer them to apply them to your institution.

The new employer should have a good idea at the outset of the employment relationship (1) what IP rights the researcher has and which rights are retained by his or her former employer and/or otherwise granted to third parties and what obligations followed the researcher, (2) what extramurally funded research projects may be following the researcher, and (3) what research materials he or she is bringing from his former institution. This initial review should serve to identify issues that may present themselves in the future or which were not adequately resolved between the researcher and his or her old employer. Early identification of issues or concerns means that the parties have a better chance to proactively resolve them before a serious dispute arises.

Notes

1. See, e.g., University of Rochester intellectual property policy stating, “ownership of a discovery of invention will vest in the university if it results from the significant use of university resources, is an institutional work, or arises out of an externally sponsored research project, consistent with the agreement(s) governing such research.” Stanford University intellectual property policy stating, “All potentially patentable inventions conceived or first reduced to practice in whole or in part by members of the faculty or staff (including student employees) of the university in the course of their university responsibilities or with more than incidental use of university resources, shall be disclosed on a timely basis to the university. Title to such inventions shall be assigned to the university, regardless of the funding source, if any.”
2. *Madey v. Duke University* (307 F.3d 1351, 2002).
3. For an explanation of the experimental-use exception in patent law, see Jennifer Miller, “Sealing the Coffin on the Experimental Use Exception,” *Duke Law and Technology Review* 0012 (2003).
4. *Madey v. Duke University*, *supra*, endnote 2, p. 1362
5. *Catalona v. Washington University* in St. Louis⁵, Memorandum Opinion, 3/31/2006 US District Court, ED Missouri, Affirmed, US Court of Appeals, 8th Circuit, June, 2007.
6. Under the Bayh Dole Act (35 USC §§ 200-212), the research university is given the legal right to elect title to inventions arising out of its federally funded research projects.

7. Although patent ownership is governed by the laws of each country, laws generally provide that, barring contrary policy or contractual obligations, the inventor(s) is (are) the owner of the patent. Most university intellectual property policies require inventors to assign ownership of patents developed using university resources to the university. See, *supra*, endnote 1.
8. Pub. L. 94-553, 17 U.S.C. §§ 101 - 810.
9. OMB Circular A-110 (Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations) Section __.45(a).