

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].