

## 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.”<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> 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 Kogoyokabushiki 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.<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup>

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.<sup>10</sup> 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.<sup>11</sup>

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.<sup>12</sup>

### 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.<sup>13</sup> 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.<sup>14</sup>

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.<sup>15</sup> 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.<sup>16</sup> 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).

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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).