

## Patent Law Strategies for Protecting Your Intellectual Property

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### Why Is Patent Protection Important?

If you or your employees spend substantial amounts of time on new scientific developments, you can protect those inventions and make them more profitable by obtaining patent protection. An issued patent gives the patent owner the right to exclude others from practicing the claimed invention. Even if you never intend to enforce your patent rights in patent litigation, patents and patent applications have a variety of uses. For example, if you have a strong and diverse patent portfolio, you will have more bargaining power in seeking cross-licensing should you be sued for patent infringement. Also, patent protection can help you win the attention and confidence of potential investors, and thus “jump-start” a new business. Further, a well-managed patent licensing program can generate significant revenues. This article addresses some of the basics of patent protection in the United States.

### What Is a Patentable Invention?

Patent protection is available for “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”<sup>1</sup> Generally, patent protection is limited to technology and to new ways of achieving a useful result. This can include new products and materials, new processes for making existing products, new uses for existing products, and improvements over existing products. Some abstract inventions, like theories, ideas, and mathematical formulas are not patentable.<sup>2</sup>

In order to be patentable, an invention must satisfy the three basic requirements of novelty, nonobviousness, and utility. Novelty means the invention must not have been known, used or published by others, for example in a prior patent application.<sup>3</sup> Nonobviousness means that even if the exact invention was not previously used or published by others, it is not patentable if it would have been “obvious” to those knowledgeable in the relevant technical field at the time of the application.<sup>4</sup> Also, an invention must meet the utility requirement. This means a patent will not be granted “unless substantial or practical utility for the invention has been discovered and disclosed.”<sup>5</sup>

### How is Patent Protection Obtained in the U.S.?

An application for a U.S. Patent is filed with the Patent and Trademark Office (PTO). The application must be filed within one year of the first publication or public disclosure of the invention, and within one year of the first sale of the invention for commercial use. The length of time to obtain a U.S. Patent varies, depending on the industry and other factors. It can typically take from 2 to 4 years to obtain a patent in the pharmaceutical and biotech fields. The cost to obtain a patent

also varies. The simplest of patents might be obtained for as little as \$5,000, but it is not unusual for high-quality patent prosecution to cost \$25,000 or more. The PTO is currently considering rule changes that would significantly increase the cost of patent prosecution, because detailed descriptions of the prior art would often be necessary.<sup>6</sup> You should seek out experienced patent prosecution counsel with knowledge in the specific technical field of your invention.

Once you are ready to seek patent protection, depending on the business objectives, either a U.S. provisional application or a utility application can be filed.

### A. Provisional Application

The requirements for a provisional application are much less formal than for a utility application.<sup>7</sup> For example, no claims are required in a provisional application. The sole purpose for filing a provisional application is to obtain a priority date. A provisional application will not be examined and no patent will issue from the provisional application. However, in order for a later application to validly claim the priority date of a provisional application, the provisional application must still satisfy certain disclosure requirements.<sup>8</sup> The application must satisfy the written description, enablement, and best mode disclosure requirements of 35 U.S.C. § 112. These requirements are discussed in more detail below.

### B. Utility application

A U.S. utility application and an international, i.e., PCT, or foreign application must be filed within one year from the earliest provisional application filing date to obtain the priority benefit of that provisional application.<sup>9</sup> During prosecution of a utility application, various papers will be exchanged between the applicant and the PTO. Some of these are procedural, and others are more substantive.

The procedural papers that an applicant must submit may include: 1) the inventors' declaration; 2) assignment; 3) small entity status statement if applicable; 4) information disclosure statement(s); 5) sequence listings if applicable and 5) formal drawings. The patent office may issue responses relating to the above issues. Another document from the patent office that is also considered a formal requirement is a restriction requirement. In a restriction requirement, an examiner, acting on behalf of the patent office, divides claims into various groups as directed to separate and distinct inventions.<sup>10</sup> In response to the restriction requirement, the applicant must choose a particular group to prosecute. The applicant may also object to the examiner's division of claims and request that certain or all of the groups be rejoined. If the restriction

requirement is maintained, an applicant can pursue the non-elected claims in divisional applications while still preserving the priority date of the original application.<sup>11</sup>

Once the procedural or formal requirements are satisfied, the PTO will examine the substance of the patent application. In addition to the novelty, nonobviousness, and utility requirements discussed above, the application must satisfy the disclosure requirements of 35 U.S.C. § 112. Section 112, first paragraph, requires the application to satisfy the written description, enablement and best mode criteria.<sup>12</sup> Under the "written description" requirement, the applicant must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention."<sup>13</sup> Enablement means that the patent application must "provide sufficient teaching such that one skilled in the art could make and use the full scope of the invention without undue experimentation."<sup>14</sup> The "best mode" analysis requires that the inventor disclose the best way known to him or her as of the filing date for carrying out the invention.<sup>15</sup> The second paragraph of Section 112 requires that the patent conclude with "claims particularly pointing out and distinctly claiming the subject matter which the application regards as his invention."<sup>16</sup> In other words, the claim language must be clear and definite so the public has fair notice of what is being claimed.<sup>17</sup>

Although not impossible, it is rare that an application is allowed as filed. Usually, the patent office will object to the specification and reject claims for a number of reasons, either statutory and/or non-statutory. These objections and rejections are communicated to the applicant in a document called an office action. Normally, the first office action is non-final. The applicant may amend the claims and make arguments to overcome the objections or rejections. At this stage, the applicant's amendment must be entered by the examiner provided that such amendment does not introduce any new matter into the application. If an applicant's amendments and arguments successfully overcome the objections and rejections, a notice of allowance will be mailed to the applicant and the patent will issue after the issue fee is paid and formal drawings are submitted.

If an applicant's amendments and arguments do not successfully overcome the objections and rejections, a subsequent office action, which may be either non-final or final, will be issued. Once a final office action is issued, the applicant may still try to overcome the objections and rejections by making amendments and arguments. The amendments, however, will only be entered if the amendments will place the claims into form of allowance or can reduce the issues in an appeal. If an applicant's amendments and

arguments do not successfully overcome the objections and rejections of the final office action, the applicant generally has two options. One option is to appeal the final rejection to the Board of Patent Appeals and Interferences at the PTO. If the appeal is successful, a patent will issue. If the Board maintains the objections and rejections, or makes new objections and rejections, the applicant may seek judicial review of the Board's decision. The other option is to file a request for continued examination (RCE) to continue prosecution in front of the patent examiner.

After the claims are allowed but before the issue fee is paid, the applicant may still make amendments to the application. Such amendments are acceptable if the amendments do not require additional searches or substantive examination.

### C. Post-issuance proceedings and interference

Even after a patent is issued, the patent may still be amended or invalidated by the patentee or a third party. Certain trivial errors, e.g., typographical errors, can be corrected in a certificate of correction upon petition by a patentee. More serious errors, e.g., claim scope changes, may also be corrected by the patentee via a reissue proceeding. However, a reissue application broadening claim scope must be filed within two years from the patent issuance date.<sup>18</sup>

A patentee or a third party may request reexamination of an issued patent based on a prior art patent or printed publication.<sup>19</sup> The reexamination can be *ex parte* or *inter partes*. In the *ex parte* reexamination, a third party's involvement is limited to the submission of the reexamination request. In contrast, a third party can more actively participate in an *inter partes* reexamination. Pending the outcome of the reexamination, the issued claims can be maintained, partially altered, replaced by new claims, or rejected altogether. In the U.S., in contrast to Europe, a party who first invents the claimed invention is entitled to a patent. The invention date between or among different parties is determined in an interference proceeding in the patent office. The invention date is determined based on the conception date, the reduction to practice date and the reasonable diligence of the parties.

### Getting Ready to Launch Your Product

Even after you have obtained patent protection, you are still not quite ready to commercialize the invention. The patent gives you the right to prevent others from practicing the claimed invention, but it does not give you the right to practice the invention. This means you are still subject to an

infringement action for infringement of a "blocking patent." This might occur if your invention is an improvement over someone else's earlier invention. The earlier patent might "block" you from practicing your improvement unless you obtain a license. So, before you launch your product, it is crucial to conduct a freedom to operate study to find out if there are blocking patents. To avoid infringement of those patents, one option is to design around the patents of concern. Conducting a freedom to operate study can provide guidance on such designing around. Another option is to seek counsel's non-infringement and/or invalidity opinions regarding the blocking patents. A competent opinion from counsel can be helpful in defending against future claims of willful infringement.

### Enforcing Your Patents – Filing an Infringement Action

For both plaintiffs and defendants, patent litigation is a complex, and often expensive, endeavor. Patent cases can last for many years, and some cases involve multiple rounds of trial court and appellate court proceedings. Given the multiple millions of dollars at stake, you will want to engage counsel who will develop a long-term strategy that takes into account not just winning in court, but the best approach for the success of your business and the commercialization of your product. Also, while many patent cases do go to trial, you will want to consider strategies that will put you in a position to negotiate the best possible settlement.

Two steps you need to take before filing a patent infringement action are providing notice to the alleged infringer, and conducting a good faith study to determine whether the defendant's products infringe your patent. Providing notice is important because a patent infringer is only responsible for damages after the date they receive notice of the patent. The notice can be "constructive" notice. This means that the infringer should have been aware of the patent. Therefore, you should mark your products with your patent number in order to give constructive notice to all potential infringers.<sup>20</sup> Before commencing a patent infringement action against an infringer, you must also conduct a pre-filing investigation to ensure that you are making a good faith claim that the infringer's products or activities infringe the asserted patents. If you fail to do so, there is the risk that a court will find your infringement action "baseless." In that case, you may be sanctioned and may be required to pay the defendant's litigation costs and attorneys' fees.<sup>21</sup>

A patent infringement action must be filed in federal district court located in a place to which the defendant has certain connections.<sup>22</sup> Whenever possible, a patentee will usually

try to file the action in its “home court” to make the alleged infringer’s defense more difficult. In addition, if the alleged infringing products are imported from outside the U.S. (or the products are made by an alleged infringing process outside the U.S.), a patentee may choose to file the patent infringement action in the International Trade Commission in Washington D.C. If the patentee prevails, U.S. Customs will stop the importation of the infringing products. Another advantage of an ITC action is that it is much speedier than a court action.

## Defending Against Patent Infringement Claims

As discussed above, even if you have obtained patent protection for your inventions, you can still be sued for infringement of another’s patents. Your patent does not protect you against a patent infringement lawsuit. And just like if you are the plaintiff, you will want to hire counsel experienced in patent litigation who will work with you to develop an overall strategy. Especially when you are the defendant, this means keeping in mind the long-term commercial success of your product and avoiding having an injunction entered against you.

When you are sued for patent infringement, there are many defenses to consider based on the facts of your case. Noninfringement and invalidity are the two main areas of defense, although there are others. The plaintiff will have the burden of proving infringement by a “preponderance of the evidence.” You as the defendant, however, will have the burden of proving patent invalidity by “clear and convincing” evidence. This is because patents issued by the PTO are presumed to be valid. Clear and convincing evidence is a higher burden of proof than a preponderance of the evidence, so in general non-infringement is easier to prove than patent invalidity.

Invalidity defenses include lack of utility, lack of novelty, obviousness over prior art, lack of adequate written description, nonenablement, nondisclosure of the best mode and indefinite claims. Another ground for an invalidity attack is incorrect inventorship. An innocent mistake of inventorship can be corrected. However, intentionally deceiving the patent office regarding the correct inventorship may prevent correction and thus render the patent invalid. Also, an applicant and anyone who is substantially involved in prosecution of a patent has a duty of candor to disclose material information to the patent office.<sup>23</sup> Intentional breach of the duty of candor may amount to inequitable conduct and render the entire patent unenforceable.

Aside from injunctive relief, patentee often seeks a significant

amount of monetary damages. Therefore, another way to soften the impact of the infringement liability is to minimize past damages. Other ways you can consider for dealing with the uncertainty of patent litigation is to purchase patent infringement insurance or seek indemnification from business partners.

In sum, the U.S. patent laws are complex, and obtaining and enforcing a patent can be a time-consuming endeavor. However, doing so allows you to protect your investment in new inventions, and make them more profitable for your business.

## Endnotes

- 1 35 U.S.C. § 101.
- 2 See, e.g., *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); Manual of Patent Examining Procedure (“MPEP”), § 706.03(a).
- 3 See 35 U.S.C. § 102.
- 4 See 35 U.S.C. § 103.
- 5 *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563 (Fed. Cir. 1996).
- 6 The PTO’s summary of these proposed rule changes is available at <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/idsexecsummary.pdf>.
- 7 See 35 U.S.C. § 111(b).
- 8 See 35 U.S.C. § 119(b).
- 9 *Id.*
- 10 See 35 U.S.C. § 121.
- 11 *Id.*
- 12 35 U.S.C. § 112.
- 13 *Noelle v. Lederman*, 335 F.3d 1342, 1348 (Fed. Cir. 2004) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991)).
- 14 *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1337 (Fed. Cir. 2005).
- 15 See, e.g., *U.S. Gypsum Co. v. Nat’l Gypsum Co.*, 74 F.3d 1209, 1212 (Fed. Cir. 1996).
- 16 35 U.S.C. § 112.
- 17 See, e.g., *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 n.2 (Fed. Cir. 1999).
- 18 35 U.S.C. § 251.
- 19 See 35 U.S.C. §§ 301-307.
- 20 35 U.S.C. § 287.
- 21 See, e.g., *Judin v. U.S.*, 110 F.3d 780 (Fed. Cir. 1970).
- 22 28 U.S.C. § 1400(b).
- 23 See 37 C.F.R. § 1.56.

# 国家生物医药国际创新园

China International Innovation Zone of Biotechnology and Medicine



## Construction Contents

## 建设内容

国家生物医药国际创新园建设内容主要包括研发区（虚拟研究院和一批研发机构）、孵化区和产业区，并在此基础上建设国家工程实验室。近期建设目标是：引进海外高水平生物医药研发人才100-150名，吸引国内研究人才2000-3000名进入园区，建立高水平、门类全、创新能力强的研究开发队伍；至少取得10个国家一类新药证书，40-50个新药进入临床研究；引进海内外大型企业在国家生物医药国际创新园建立研发中心，形成年产值超100亿元的生物医药产业群。



The construction contents of BioMed Zone mainly involve the research & development area ( research institutions and some research & development facilities ), the incubating area and the industrial area, as well as constructing national engineering laboratory on that basis. The short-term construction goals are to introduce 100~150 senior R&D bio-pharmaceutical talented from overseas, to establish an advanced, comprehensive and highly-creative research and development team, to achieve at least 10 national A-class new medicine certificates and to put 40~50 new medicines into medical practice, along with to attract both domestic and foreign large-scaled enterprises to establish their research and development centres in the park so as to form a bio-pharmaceutical industrial group with an annual production value of ¥10 billion.