Originally published by Logos Press in
Biotechnology Entrepreneurship: From Science to Solutions.

Chapter 4

Intellectual Property Protection and Strategy

Nancy W. Vensko, JD*
Partner, Fitch, Even, Tabin & Flannery

INTRODUCTION: GETTING A PATENT

Intellectual property (IP) is defined as a property right protecting products of the human intellect, constituting mainly trademarks, copyrights, and patents, but also trade secrets. Commercializing new drugs and laboratory tests often depends on the existence of patent protection. Typically, small companies in-license technologies from universities and research institutes or develop technologies in-house, with the goal to out-license technologies or partner with large companies.

What are some points to consider in the decision to get a patent? Under what my colleague, Thomas F. Lebens, calls the "patent business triangle," the invention must be patentable, a market needs to exist, and you have to be able to meet the demand. This chapter will focus on the "invention" side of the triangle.

* Disclaimer: The information and material in this chapter are provided for informational purposes only. This chapter does not provide legal advice. This chapter does not necessarily reflect the opinions of Fitch, Even, Tabin & Flannery (FETF) or Sinsheimer Juhnke Lebens & McIvor (SJLM) or their clients. Reading this chapter and/or contacting FETF or SJLM based on this chapter does not create an attorney-client relationship between you and FETF or SJLM.

Kenneth W. Dam, as well as other economists, describes the economics underlying patents.[1] These government grants reward research and development (R&D) in exchange for a "limited right" to exclude others from copying the patented invention during the term of the patent. If companies could not recover the costs of R&D because the invention could be copied by all, then we could expect a much lower level of innovation. Patents fix the copying problem so that a company can recover the costs of R&D. This is how patents stimulate innovation and incentivize new drugs and laboratory tests.

Biotechnology is an industry having a business model that is based on taking significant risks to develop new drugs. Specifically, the biotechnology business model is based on R&D of new chemicals, such as proteins and genes, which become new drugs. Joseph A. DiMasi and colleagues report that the average cost of bringing a new drug from concept all the way to FDA approval is about $800 million and that it takes about 10 years.[2]

Take, for example, the case of thyroid-stimulating hormone (TSH) of US patent no. 6,284,491. Many valuable proteins occur in nature only in minute quantities, or are difficult to purify from natural sources. The availability of substantially pure TSH made the diagnosis and treatment of human thyroid cancer a reality. Previously, the only available method to diagnose and treat human thyroid cancer involved administering cadaver-originating TSH to stimulate the uptake of radioactive iodine into the cancer. All of the diagnostic tests and treatments depended upon high levels of human TSH. However, there was not enough natural product available from human pituitaries collected at autopsies. Furthermore, even if available, the human pituitaries had been found to be contaminated with viruses. As a result, the regulatory authorities had forbidden the use of the natural product for any human diagnostic or treatment studies.

The diagnosis and treatment of thyroid cancer now involves cloning the gene for TSH and using it to make "recombinant" TSH. Recombinant TSH means making TSH by cloning the gene. TSH is now available in large quantities and is uncontaminated with viruses or other by-products of collecting human pituitaries from autopsies.

Although the exact cost of bringing this new drug from concept to FDA approval has not been disclosed, a figure anywhere near the DiMasi estimated average would represent a significant investment. By virtue of a "limited right," patents let companies recoup the high cost of R&D, thus giving companies an incentive to invest in new drugs and laboratory tests.

Yet, on the reasoning that the price for obtaining a single US patent is about $25,000 to $50,000, if you want a 10-fold return on investment then the technology needs to net $250,000 to $500,000 over the lifetime of the patent. Perhaps the invention can easily be protected as a trade secret, making patenting unnecessary; a trade secret is information that derives independent economic value from not being generally known or readily ascertainable by others, and is the subject of reasonable efforts to maintain its secrecy. Should the invention not easily be protected as a trade secret, then you need to balance the benefits of getting a patent against the costs.

If the patent covers an invention that has hefty R&D costs, getting a patent may be worthwhile. Recall that the economics underlying patents hold that patents on an invention having hefty R&D costs prevent competitors (*e.g.*, those that have no R&D costs) from undercutting the price, and thus permit the innovator to recover the costs of invention. Even a patent on an invention that does not have hefty R&D costs may be profitable by reason of increasing prices, restricting use, and securing investment.[3]

Additionally, if the patent covers an "improvement," which, although patentable, infringes a prior unexpired patent for a "pioneering" invention, the cost-benefit analysis may favor getting a patent. This is because the owner of the prior unexpired patent would need a license to make, use, or sell your improvement. While you, yourself, would need to license the prior unexpired patent to make, use, or sell your own improvement, cross-licensing could save you both from infringement liability.

Patenting an improvement which, although patentable, infringes a patent for a "pioneering" invention, does not grant you a freedom-to-operate. You should probably seek a right-to-use search, also called a freedom-to-operate search, before you manufacture, use, or sell an allegedly patented thing. As you will see, a patent grants you a right

to exclude others from trespassing on your intellectual property, but not a right to trespass on the intellectual property of others.

This chapter will examine the basics about patents, formal requirements for getting a patent, substantive conditions for getting a patent, the meaning of a "statutory bar," the meaning of a "printed publication," suggestions for preparing an invention disclosure describing a discovery sought to be patented for technologies you develop in-house, the fundamentals about provisional patent applications, the essentials about patent protection in foreign countries, tips for working with a law firm, and the tests for patent infringement.

PATENT BASICS

A patent protects an invention or discovery by giving its owner the right to exclude others from its use. In contrast, a trademark (or service mark) protects words, phrases, symbols, or designs that identify and distinguish the source of a good (or service). Copyright protects original works of authorship including literary, dramatic, musical, and artistic works, such as poetry, novels, movies, songs, computer software, and architecture.

Your invention may be marked with the notice "patent pending" once you file a patent application with the United States Patent and Trademark Office (USPTO). By comparison, any time you use a trademark or service mark, you may add the "TM" (trademark) or "SM" (service mark) designation in connection with your good or service to alert the public to your claim; you may use the federal registration symbol "®" after the USPTO actually registers the trademark or service mark. Showing a copyright notice does not require advance permission from, or registration with, the Copyright Office; the copyright notice consists of c in a circle, name of the copyright owner, and year of first publication, *e.g.*, © 2008 John Doe.

There are three types of patents. A utility patent is the most common, and it protects inventions that are functional in terms of utility, as opposed to aesthetics. A design patent protects designs that are ornamental. A plant patent protects plants that are asexually reproduced (*i.e.*, other than from seed); seeds can be protected with a certificate from the US Department of Agriculture (USDA).

Generally, the term of a new patent is 20 years from the date on which the application for the patent was filed in the United States. If the application relates to an earlier-filed application as a continuing application, the term is 20 years from the date on which the earliest such application was filed. Filing a provisional patent application before a basic, or "non-provisional," patent application effectively extends the patent term to 21 years.

The right conferred by a patent is, in the language of the statute, "the right to exclude others from making, using, offering for sale, or selling" the invention in the United States or "importing" the invention into the United States. A patent does not confer a right to make, use, or sell the invention. For example, you may need marketing approval by a regulatory authority to sell a patented drug or device. Rather, what is granted is the right to exclude; a patent is like a "no trespassing" sign. And a US patent has effect only in the US. If patent protection is required in other countries, it is necessary to file for foreign patents.

The Constitution of the United States sets forth the reasons for patenting in Article I, Section 8, by giving Congress the power "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." Under this power, Congress enacted the first patent law in 1790, with the most recent patent law being reenacted in 1952. The patent laws are now codified in Title 35 of the United States Code. The operative words from the Constitution are "limited" and "right." The Constitution authorizes these awards of a *limited right* to inventors for their discoveries in order to promote the progress of the useful arts.

What in the way of inventions and discoveries can be patented? You cannot patent a mere idea, but rather a reduction to practice of that idea. In the language of the statute, anyone who "invents or discovers" a "process, machine, manufacture, or composition of matter" or "improvement thereof" may obtain a patent. These statutory classes of subject matter taken together include, in the words of the legislative history of the 1952 Patent Act, "anything under the sun that is made by man."

The USPTO takes the position that an isolated and purified DNA

molecule that has the same sequence as a naturally occurring gene is eligible for a patent because that DNA molecule does not occur in that purified or isolated form in nature. Products of nature cannot be patented because they are not "made by man." However, natural substances may constitute patentable subject matter, provided that they are "isolated and purified," because they do not occur in that "isolated" or "purified" form in nature.

The USPTO examines applications for patents to determine if the applicants are entitled to patents under the law. It grants the patents when the applicants are so entitled. The USPTO publishes patent applications 18 months from the earliest filing date, and patents are published upon issuance.

Inventorship determines ownership. The owner of the invention is the inventor; joint inventors are joint owners. Inventors usually assign their rights in the invention to the company that employs them. The entity to which the invention is assigned (*e.g.*, the company) is known as the assignee. The assignee should ensure that the assignment is recorded in the USPTO.

FORMAL REQUIREMENTS FOR GETTING A PATENT

To get a filing date, the inventors (or the assignee) must file a patent application with the USPTO that includes a specification having a description and at least one claim, drawings where necessary, an oath or declaration, and the prescribed fees. The latter two elements may be submitted late, but you will be levied a surcharge. If the inventors (or the assignee) qualify as a small entity (independent inventor, small business concern, or non-profit organization), they may claim this status and be eligible to have the Patent Office fees discounted by 50%.

The application papers must be in the English language, or an English language translation of the non-English language papers filed. The papers must be presented in a form to permit electronic reproduction, having a certain size, margins, spacing, font, font size, etc. If foreign priority (the benefit of the filing date of a prior foreign application) is claimed, you must furnish a certified copy of the priority papers before grant of the patent.

The specification must include a written description of the invention. Under contract theory, the *quid pro quo* for the patent is full disclosure. The written description requirement promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their specifications, in exchange for the right to exclude others from copying the invention for the duration of the patent term.

The specification must enable a "hypothetical" person having ordinary skill in the art to make and use the invention. The "art" refers to the area of technology related to the invention. The invention must be enabled so that a person having ordinary skill in the art can make and use the invention without undue experimentation.

The "best mode" contemplated by the inventors of carrying out their invention must be set forth in the specification. This requirement prevents inventors from disclosing their second-best embodiment, while retaining the best for themselves. In general, to satisfy the best mode requirement, the inventors must disclose the preferred embodiments of their invention.

The specification must conclude with one or more claims. The claim or claims are required to particularly point out and distinctly claim the subject matter that the applicant regards as the invention. The claims define the scope of protection afforded by the patent, as well as the questions of patentability to be decided by the USPTO and the questions of infringement to be judged by the courts—the claims set forth the boundaries of the property being safeguarded against trespassers.

Where necessary for an understanding of the invention, drawings are required. The drawings must be presented in a form to permit electronic reproduction. The sheets of drawings must have a certain size, margins, views, etc.

Another requirement is an oath or declaration, signed by the inventors, swearing that they believe themselves to be the original and first inventors of the invention as defined by the claims. Inventorship is not the same as authorship of an academic publication. To be an inventor, the collaborator must generally contribute to the conception of the invention as claimed. Conception is "the formation in the mind of the inventor of a definite and permanent idea of

the complete and operative invention as it is thereafter to be applied in practice." An inventor is not one who, although perhaps a Nobel laureate, acts solely like an encyclopedia. Neither is a laboratory technician who serves merely as a "pair of hands" an inventor. But they are inventors if they make a contribution to the conception of the invention, defined as the idea as it is to be carried out in practice and that is present in the claims.

Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary, in a patent depository such as at the American Type Culture Collection (ATCC).

The USPTO maintains a standardized format, called a "sequence listing," for descriptions of nucleotide and amino acid sequence data, in conjunction with the required submission of that data in computer readable form.

SUBSTANTIVE CONDITIONS FOR GETTING A PATENT

For an invention to be patentable it must be novel. Novelty means the invention must be "new" (*i.e.*, original), as well as not being precluded from patenting by what is defined in the patent law as a "statutory bar." For example, an invention cannot be patented if the invention is publicly disclosed, such as by publication of a manuscript, or commercialized, such as by offer for sale. The US provides a grace period of one year before such "statutory bars" come into play. Many countries, such as those in Europe, have no grace period. In those foreign countries, absolute novelty is required; a public disclosure before the filing date destroys patent rights.

Even if the subject matter sought to be patented is novel, and involves one or more differences from the prior art, a patent may still be refused if the differences would be obvious. In other words, to be "non-obvious" the subject matter sought to be patented must be sufficiently different from what has come before to a person having ordinary skill in the art. For example, in the original obviousness case decided by the Supreme Court of the United States in 1850, the substitution of porcelain for wood to make a doorknob was deemed

to be unpatentable. The prior art was a wood doorknob. Even though the porcelain doorknob invention was novel in view of this prior art doorknob, it was nevertheless unpatentable because it would have been obvious to substitute porcelain for wood in a doorknob.

Utility, the third substantive condition, ensures that patents are granted on only those inventions that are "useful." For example, an expressed sequence tag (EST) has been held to be unpatentable for failure to be "useful" where the full length sequence of the complete gene is unknown. As another example, data from *in vitro* and animal testing are generally sufficient to support pharmacological utility in humans, if these tests would be viewed by a person having ordinary skill in the art to reasonably predict the human situation.

Under the statutory bar, patenting is precluded on an invention known or used by others in the US prior to the date of invention by the inventor; an invention patented or described in a printed publication anywhere (US or abroad) prior to the date of invention by the inventor; an invention patented or described in a printed publication anywhere (US or abroad) more than one year prior to the filing date of the patent application; an invention in public use in the US more than one year prior to the filing date of the patent application; and an invention on sale in the US more than one year prior to the filing date of the patent application.

QUIZ: WHICH OF THE FOLLOWING ARE EXAMPLES OF PUBLIC ACCESSIBILITY BY PRINTED PUBLICATION?

- The inventor presented a poster constituting 14 slides pasted on poster boards, for two and a half days, at a scientific conference.
  - Yes, the judiciary decided this is a printed publication. The moral of the story is to keep your invention secret until you file a patent application.

- The inventor presented an entirely oral presentation at a scientific conference that included neither slides nor copies of the presentation.
  - No, the judiciary decided this is not a printed

publication. Could it be a public disclosure? An oral presentation could be a public disclosure and thus be a statutory bar.

- The inventor made an oral presentation at a scientific conference that included a display of slides; a projection of the slides at the lecture was transient; and no one could be expected to remember the invention from, or take pictures of, the slides.
  - No, in 1981 the judiciary decided this is not a printed publication. How about today with cell phones? A slide show could constitute a printed publication today, due to the availability of cell phones that take pictures, and consequently be a statutory bar.

- The inventor delivered a paper orally to a scientific conference; as many as 500 attendees heard the presentation; but far less than 500 copies (approximately six copies) of the paper were distributed.
  - Yes, the judiciary decided this is a printed publication. Refer to the above moral of the story about keeping your invention secret.

- A document was posted for seven days on an Internet website and then taken down. Although the paper was accessible in a navigable directory structure, the file had a non-informative acronym name.
  - No, the judiciary decided this is not a printed publication. But the dissent argued that the paper, by being posted on the Internet on a public server for seven days, was available to anyone, and, although the file had a non-informative acronym name, was publicly accessible by virtue of a navigable directory structure. This is a close case. Refer, again, to the above moral of the story about keeping your invention secret.

SUGGESTIONS FOR PREPARING AN INVENTION DISCLOSURE

To describe a discovery sought to be patented, for technologies you develop in-house, first identify potential statutory bar dates based on past activities such as publications, abstracts, posters, talks, slide shows, manuscripts, Internet postings, grant applications, and theses and dissertations. Second, anticipate imminent statutory bar dates based on future activities. Third, describe the invention, *e.g.*, what problem(s) it solves, progressively discuss the invention in more detail, identify advantages and improvements, determine possible variations and modifications, establish competing technologies, and ascertain commercial applications. Fourth, provide data that would be required by a person having ordinary skill in the art to support the hypothesis that the invention solves the problem(s) in the prior art. Fifth, recognize who might infringe along the chain of production and among users. Sixth, determine how your competitors might design around the invention. Seventh, distinguish the relevant prior art, and discuss how it is inferior and the invention is new and improved. Eighth, indicate potential inventors. Ninth, describe the inventor's relationship with the company, *e.g.*, employee, consultant, officer. Tenth, does the government have any rights in the invention? If the invention was made with government support, (*e.g.*, a National Institutes of Health grant), the government has certain rights in the invention, including "march-in" rights. March-in rights amount to compulsory licensing, but the government has never exercised these rights.

PROVISIONAL PATENT APPLICATION FUNDAMENTALS

A provisional patent application is a "place-holder" that gives you a filing date without having to incur the cost of filing a basic or "non-provisional" patent application; by delaying the filing of a non-provisional, the inventor gets an additional year of protection and the opportunity to add data to the specification thus strengthening the patent. The provisional patent application expires 12 months after the filing date, and a non-provisional patent application claiming benefit during pendency must be filed to preserve priority. Provisional patent applications cannot themselves claim the benefit of a previously-filed

application, either foreign or domestic. A provisional patent application should preferably conform to the paper size, margins, spacing, font, font size, etc. guidelines for non-provisionals; the specification must, however, comply with the written description, enablement, and best mode requirements, and refer to drawings, where necessary, for an understanding of the invention, in order to receive the benefit claimed by a later-filed non-provisional patent application. A provisional patent application can be cheaper to file than a non-provisional, because the governmental fees are considerably lower, a provisional does not need claims, and no oath or declaration is required; additionally, no costs are incurred for prosecution (getting a patent) because a provisional patent application is not examined, published, or granted.

PATENT PROTECTION IN FOREIGN COUNTRIES

Foreign patent applications should be filed within one year of the US application (whether provisional or non-provisional) so that they can claim priority from the US filing date under an international treaty called the Paris Convention (to which most industrialized nations in the world belong). There are three principal routes for foreign filing, (a) filing directly in each country, (b) filing an EPC (European Patent Convention) application, and (c) filing a PCT (Patent Cooperation Treaty) application. In the first route, national applications are filed in each country of interest. In filing an EPC application, a single EPC application is filed in the European Patent Office. Filing a PCT application consists of an international phase and a national phase. In the PCT international phase, a single international application is filed in one office (in the US), unless a foreign filing license has already been obtained, and in one language (English). In the PCT national phase, the PCT patent application is used as a vehicle to "go national," or file national applications, in each of the designated countries in which a patent is sought 30 months after the earliest filing date. About 140 countries are members of the PCT, uniting most industrialized nations in the world. Advantages of filing a PCT patent application are lower initial costs, a delay for 30 months in which to reflect on the desirability of seeking protection in foreign countries, a chance

to evaluate patentability based on a "patentability report" prepared by the PCT authorities, an opportunity to amend the international application to obtain a positive patentability report, and an effective means of putting the world on notice of the application, which can assist in the watch for potential licensees. Factors to be considered in deciding the foreign countries in which to seek patent protection include the location of one's markets, competitors, and manufacturers.

TIPS FOR WORKING WITH A LAW FIRM

Registered "patent attorneys" and non-attorney "patent agents" are permitted by law to represent inventors before the USPTO. Registration means passing an examination on patent law and rules and USPTO practice and procedures and possessing a college degree in engineering or physical science or the equivalent. Both patent attorneys and agents are permitted to prepare an application for a patent and conduct the prosecution in the USPTO, but patent agents cannot conduct patent litigation in the courts or perform various services considered to be practicing law. In California, as well as other states, attorneys must have written fee agreements with their clients whenever the client's total expense, including fees, will foreseeably exceed $1,000, where the fee agreement states any basis for compensation including, but not limited to, hourly rates, flat fees, and other standard charges (*e.g.*, photocopying). For non-litigation, clients tend to pay by the hour at the firm's prevailing rates for all time spent on the client's matter by the firm's legal personnel, as opposed to litigation, where clients may negotiate payment by the hour or by a contingency fee. Many firms have moved to alternative billing for their services even for non-litigation, for example, by charging a "flat fee" that remains fixed regardless of the amount of time spent and attracts clients who wish to obtain predictability of cost and sharing of risk. The client may grant its attorney a lien for any sums owed to the attorney to attach to any patent the client may obtain, presumably as a result of the attorney's work.

THE ABCs ABOUT PATENT INFRINGEMENT

Briefly, patent infringement is defined as the unauthorized making, using, or selling, or offering to sell, the patented invention in the US, or importing of the invention into the US, during the term of the patent. You can sue for an injunction to stop the infringement or seek damages. To determine whether there is infringement, the claims will be interpreted, and the properly interpreted claims will be compared to the allegedly patented thing. Infringement requires that each and every element of the claim is found, either literally or as an equivalent, in the allegedly patented thing. Infringement may be direct, in which the actor that is sued is performing the unauthorized acts, or indirect, in which the actor that is sued is not itself performing the unauthorized acts but is contributing to it (*e.g.*, by supplying components of the allegedly patented thing) or inducing others to perform the unauthorized acts.

CONCLUSION

In conclusion, you have examined the basics about patents, formal requirements for getting a patent, substantive conditions for getting a patent, the meaning of a "statutory bar," the meaning of a "printed publication," suggestions for preparing an invention disclosure describing a discovery sought to be patented for technologies you develop in-house, the fundamentals about provisional patent applications, the essentials about patent protection in foreign countries, tips for working with a law firm, and the tests for patent infringement. Serious consideration of patent protection for your valuable inventions does not end upon the filing of a patent application. You need to reevaluate the value of your inventions during prosecution, issuance (when you pay the issue fee), and maintenance (when you pay the maintenance fees, which are due 3-½, 7-½, and 11-½ years after issue in the US). In this way, patent procurement will mediate the achievement of your quest to in-license technologies from universities and research institutes or develop technologies in-house, with the goal to out-license technologies or partner with large companies, and ultimately to commercialize new drugs and laboratory tests.

REFERENCES

1. Kenneth W. Dam, *The Economic Underpinnings of Patent Law,* 23 Journal of Legal Studies 247 (1994)
2. Joseph A. DiMasi, Ronald W. Hansen, & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 Journal of Health Economics 151 (2003)
3. Stuart J.H. Graham & Ted Sichelman, *Why Do Start-ups Patent?* 23 Berkeley Technology Law Journal (September 6, 2008). Available at SSRN: http://ssrn.com/abstract=1121224

About the Editor

Michael L. Salgaller, PhD, has over 20 years of business and scientific and business experience in various life science sectors. He is an experienced industry and venture capital executive with a successful background in business development, strategic planning, technology assessment, and capital formation. He has held various positions with consulting and drug discovery firms, as well as directing the development of cancer therapeutics. He began his career as a senior staff scientist at the National Institutes of Health, and has consulted for various biotech companies, economic development entities, and disease foundations. Dr. Salgaller earned his PhD in pathology from the Ohio State University, and was awarded a biotechnology fellowship at the National Cancer Institute. He is an author on over 60 articles and book chapters, and serves on the editorial boards of several journals. He was elected to the Sigma Xi Research Honorary, as well as the Pi Delta Epsilon Journalism Honorary.

Michael can be contacted at *mlsalgaller@yahoo.com*.

Related Titles from Logos Press®

http://www.logos-press.com

Building Biotechnology

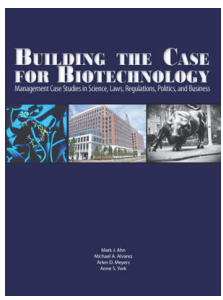
Scientists know science; businesspeople know business. This book explains both.

Hardcover ISBN: 978-09734676-5-9
Softcover ISBN: 978-09734676-6-6

Best Practices in Biotechnology Business Development

Valuation, Licensing, Cash Flow, Pharmacoeconomics, Market Selection, Communication, and Intellectual Property

ISBN: 978-09734676-0-4



Building the Case for Biotechnology

Management Case Studies in Science, Laws, Regulations, Politics, and Business

Hardcover ISBN: 978-1-934899-16-8
Softcover ISBN: 978-1-934899-15-1