

# Chapter 15

## Patents, Intellectual Property, and Licenses

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Patents  
Other Forms Of Intellectual Property

Ownership and Licensing

Got a great idea? The field of health care is driven by innovation, and the source of most of that innovation is from health care professionals themselves. It seems like each week a remarkable advance in medical progress hits the market in the form of a new medical device, drug, or biopharmaceutical. The physicians, researchers, nurses, and technicians who work daily to improve patient health are in the best position to evaluate inefficiencies in the system and develop novel solutions. Intellectual property refers to the legal rights that apply to the tangible manifestations of human creativity, and all inventors need to be aware of what intellectual property rights they are eligible for and how best to protect those rights.

This chapter surveys options for health care professionals who want to develop their research or ideas into new inventions. The first section describes patents, a powerful form of protection for inventions. The second section examines other types of intellectual property, including trade secrets, copyrights, and trademarks. Finally, the third section looks at how to take these intellectual property rights to the market through licensing and other development options.

### PATENTS

Health care professionals, medical research companies, and universities have used patented innovations to change the practice of medicine. The process of giving anesthesia, for example, was patented in 1844 and the Bayer Company patented aspirin in 1900.<sup>1</sup> Getting a patent, however, is not simple. The multistep process takes an average of 2 years to complete and can cost up to \$10,000.<sup>2</sup> Medical practitioners interested in patenting their innovations must understand what a patent is and the basics of applying for patents before they begin the arduous process of pursuing this form of intellectual property protection.

#### What Is a Patent?

A patent is a legal monopoly over a particular invention, granted by the federal government through the Patent and Trademark Office (PTO). The Patent Act was promulgated under constitutional authority to “promote the progress of

science and the useful arts”<sup>3</sup> and dates back to 1790. Notably, patents do not give inventors any affirmative rights; rather, they give patent owners the right to “exclude others from making, using, offering to sell, or selling in the United States” the invention claimed in the patent.<sup>4</sup> The monopoly lasts for 20 years from the date the inventor officially applies for the patent.

A patent is classically thought of as a *quid pro quo*.<sup>5</sup> On the one hand, the government provides a monopoly—which might otherwise be illegal—for a limited time. The patent encourages inventors to risk the cost and time to develop their ideas, because it gives them a competition-free period in which to market a successful invention. On the other hand, the patent document becomes part of the public domain and can help inspire other inventions.

Why apply for a patent? Patents are not required to market inventions, but once a nonpatented item is put on public display, any rival company can copy and sell it with impunity. Thus, patents can defend against encroachment on an inventor’s idea. Patents can also be used as an offensive strategy to grab a segment of a market and force others to execute agreements, such as licenses, with the inventor.

Three types of patents exist. Utility patents cover any “process, machine, manufacture, or composition of matter”<sup>6</sup> and can therefore be used for new medical equipment, drugs, or computer programs. Design patents shield the aesthetic qualities of items such as lamps, clothing, and furniture. The third kind of patent is reserved for plants.

#### Requirements for Patentability

##### Subject Matter and Usefulness Limitations

To qualify for a utility patent, inventors must be able to classify their inventions under one of the four statutory subcategories listed in the Act—that is, a process, machine, manufacture, or composition of matter. In reality, the threshold for meeting this statutory requirement is very low. In *Diamond v. Chakrabarty*, the Supreme Court ruled that a bacterial plasmid was patentable because it was man-made, noting that “anything under the sun made by man” falls under one of the categories.<sup>7</sup> Examples of impermissible subject matter include laws of nature (e.g., cardiac

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output = heart rate × stroke volume), material found unadulterated in nature (e.g., the bark of a tree), and physical phenomena (e.g., lightning). Obviously, this leaves a great deal of subject matter available for the potential inventor.

Another low-threshold statutory limitation is that of usefulness. Inventions, to be patentable, must be useful,<sup>8</sup> but just so long as the applicant postulates any reasonable use, it will be taken as presumptively correct<sup>9</sup> and the requirement will be satisfied. Usefulness remains an issue mostly when attempting to patent so-called “incredible” inventions, like perpetual motion machines, and new chemical compounds where utility might not be immediately apparent.

### Novelty and Anticipation

Another requirement for patentability is that the invention be “novel,” which is akin to saying that one cannot get a patent for reinventing the wheel. If the invention is substantially the same as a previous invention that is either in existence or described in a patent application or other publication (which, together, is called the “prior art”), it is ineligible for patenting.<sup>10</sup> Detailed regulations in the Patent Act define “prior art.”<sup>11</sup> Practically speaking, to ensure compliance with the novelty limitation, inventors should look for any devices, publications, or patent applications that anticipate their proposed inventions and thus make the patent application unworkable. As with the subject matter limitation, “novelty” is interpreted broadly; to be excluded, every single aspect of the new invention must also be found in a piece of prior art.

Notably, pending patent applications anticipate proposed inventions. The United States, however, grants patents to the first inventor to conceive of an idea, even if that person files the patent application second. Inventors, therefore, should take rigorous steps to document the conception dates of their ideas by writing down brainstorming, having a witness attest to the date, and keeping all further development work in a signed and dated log book. As long as the inventor does not “abandon, suppress, or conceal”<sup>12</sup> his or her invention after this point on the way to developing a prototype or getting a patent, the evidence can prove the date of conception and defeat an earlier-filed patent application that otherwise would anticipate the invention.

### Nonobviousness

The final major statutory requirement for patentability is that the proposed invention must be nonobvious in light of the prior art. If “novelty” was the only standard, then any small change to a prior invention would render it patentable. Obviousness ensures that small changes are not accorded patents, so that each patent adds to the progress of science and the useful arts. According to the Patent Act, the proper way to evaluate what is obvious is from the point of view of a “person of ordinary skill in the art,”<sup>13</sup> that is, the field to which the invention relates.

Obviousness is one of the least predictable aspects of patent law, so patent cases often turn on this issue. Courts are supposed to place themselves in the era when the invention was made, but one problem is that what may seem

obvious in hindsight was not obvious at that time. Another issue is how broadly or narrowly to define the field in which the “person of ordinary skill in the art” is deemed to encompass. A third issue is how much to weigh so-called “objective indicia of non-obviousness,”<sup>14</sup> such as commercial success of the invention and long-felt need for the particular invention in the field.

For example, in *Cardiac Pacemakers v. St. Jude Medical*, the court had to decide whether the invention of an externally programmable implantable cardiac defibrillator was obvious.<sup>15</sup> In the “prior art” were programmable external defibrillators and the existence of implantable pacemakers that could be externally modulated. Was it obvious to a person of ordinary skill in the art to apply the technology from pacemakers to the defibrillators? The court thought not, finding no evidence in the record of any suggestion to combine those pieces of prior art.

The basic principle behind nonobviousness is that trivial variations in known inventions will not support a patent. Rather, some level of ingenuity is needed.

## Applying for a Patent

### The Patent Document

Putting together a patent application and submitting it to the PTO for approval is the next step. Applicants can proceed by themselves (“pro se”) or can hire a patent attorney or agent, a legal representative (who may or may not be a lawyer) with a technical background and a special certification from the PTO. The process can be lengthy and expensive, involving much back-and-forth communication with the PTO and multiple processing fees. Moreover, deadlines emerge at each step that, if missed, can render a patent application void. Given these pitfalls, inventors with the means to do so are strongly encouraged to seek out a patent attorney or agent.

The patent document traditionally includes a number of different sections, such as an abstract, a summary, and drawings, but the most important part of the application is the claim. The claim is the meat of the patent and defines the limits of the patent holder’s intellectual property right. Despite what may be written elsewhere in the patent document, inventors must officially “claim” a particular feature to get patent protection over it.

The Patent Act requires four other significant formalities to complete the patent document.<sup>16</sup> The first is a written description of the invention, telling readers what the invention is and notifying people that the inventor understands what he or she is trying to patent. The second is an enablement requirement, which means that the patent document must “[e]nable any person skilled in the art. . . to make and use invention.”<sup>17</sup> This helps fulfill the inventor’s contribution to the patent quid pro quo—in exchange for a limited-term monopoly, the inventor must fully reveal to the public how to make and use the invention.

The third requirement is that inventors disclose the “best mode” (if they have contemplated one) available for making their inventions work. For example, a patent for an ultrasonic-assisted liposuction device was invalidated in

part because a jury found that the patentees had determined, but did not disclose in the patent document, the device's "preferred frequency stabilizing circuit."<sup>18</sup> Fourth, patent claims must be definite, meaning that inventors must "particularly point out and distinctly claim"<sup>19</sup> their invention. Using comparative terms like "substantially" or "approximately" jeopardizes a patent's validity if they make the claims too vague for a person of ordinary skill in the art to understand the nature of the invention.

### The Examination Process

Completed patent documents go to the PTO for evaluation, along with a fee and an oath attesting to the fact that the inventor is correctly named and that the inventor has disclosed any knowledge of prior art that may impact its patentability. The PTO classifies the invention based on the subject matter of its claims and sends it to an examination group, or "art unit." These groups are composed of patent examiners, PTO employees who have expertise in the general subject matter of their unit. One particular examiner assumes responsibility for the patent.

The examiner then checks the application for technical accuracy and examines the claims by comparing them to the prior art. This begins what can be a long process of communications and responses between the patent examiner and the applicant in which the examiner may require multiple alterations or rewording of claims to make them patentable. Applicants can invoke appeals and resubmissions to argue their cases further. The process can take months to years, depending on how back-logged the particular art unit is and how many changes are needed.

### Special Patenting Issues for Health Care Professionals

Though the patenting process is the same for a new mechanical heart or a skateboard, there remain a few special considerations for health care professionals who pursue patents, including a special exception to the patent law, the desire of many medical practitioners to seek publication of new results, and the ethics of medical patenting in general.

#### Medical Process Patents

In 1993, controversy arose when an Arizona ophthalmologist patented a "no-stitch" incision process for cataract surgery, and then sued a Vermont ophthalmologist for infringing the patent by using the procedure on his patients.<sup>20</sup> This was the first known occurrence of a lawsuit being used to enforce a patent for a medical process.<sup>21</sup> Commentators worried that such process patents would threaten patient access to new procedures, increase health care costs through licensing prices, and hinder the advance of medical knowledge.<sup>22</sup>

In 1996, Congress amended the Patent Act, depriving patentees of remedies for patents on surgical or medical procedures not involving a new drug or device.<sup>23</sup> While medical and surgical methods are patentable, the patent cannot be enforced against a health care practitioner utilizing the procedure. If any step of a medical process involves using a patented device, however, the health care professional

still infringes the device patent. As a result, pure medical or surgical methods, such as the Heimlich maneuver or carotid artery massage to lower heart rate, are not worth patenting, no matter how novel or nonobvious they might be.

#### Publication and Use of Patentable Inventions

Many health care professionals look to publish their research results and new ideas in the medical literature in order to disseminate the information among colleagues and gain professional respect. They also seek to put their inventions into practice as soon as possible, to advance patient care or test their effectiveness. There is no reason to restrain these practices, but if the health care professional also wants to seek a patent, a few principles should be understood.

First, according to the Patent Act, an inventor's own dissemination or publication will not serve as prior art to impact patentability unless it occurred more than a year before the patent application, or a less formal and less expensive version, called a "provisional" patent application, was filed.<sup>24</sup> This so-called "statutory bar" is inflexible and can result in complete surrender of patent rights. According to the Federal Circuit, in determining what acts will invoke the bar, "the touchstone is public accessibility."<sup>25</sup> Submission to a journal for consideration of publication does not start the clock, but placing a single copy in a remote public depository in Alaska does. Health care professionals, therefore, should not necessarily feel constrained in publishing their inventive ideas. Rather, they should mark all prepublication copies as "classified" to restrict dissemination, and ultimately be cognizant of the publication date.

Any public use of an invention begins the one-year grace period for patent application submission as well. Experimental uses intended to perfect an invention, however, are not considered public uses. Thus, if health care professionals want to test their inventions before determining whether to pursue patents, they should take extra care to receive no payments, sign confidentiality agreements with all users, maintain written research progress notes, and ensure that they have complete control over the parameters of the test. These and other factors will help show that the use was experimental and does not invoke the statutory bar.

#### The Ethics of Medical Patenting

Some have argued against pursuing health care patents because of the potential barriers it places to the dissemination of ideas and innovations. The AMA Code of Ethics in the 1950s claimed patenting medical devices was unethical.<sup>26</sup> Concerns include an increase in health care costs due to higher research costs from the legal and administrative expenditures in the patenting process, and a drive away from basic science research toward more profit-seeking motives.<sup>27</sup> Some argue that competing patents can slow scientific research because of all the licensing arrangements and permissions that would be needed to undertake meaningful research projects.<sup>28</sup>

Currently, however, while the AMA considers medical process patents unethical, it permits the patenting of drugs and devices.<sup>29</sup> Other commentators note that patenting

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ideas can help bring more advances into the public arena by providing future economic incentives for initial research and development costs.<sup>30</sup> Also, they provide for full disclosures of discoveries in the patent document, whereas otherwise inventors might keep them secret. It is an ethical decision for health care practitioners to make for themselves.

### OTHER FORMS OF INTELLECTUAL PROPERTY

Patents are not the only form of intellectual property protection available; trade secrets, copyrights, and trademarks provide different kinds of protections. Health care professionals can utilize these legal creations in many aspects of their practices as well.

#### Trade Secrets

A trade secret is a piece of information whose economic value derives from it being kept confidential. Many corporations have trade secrets, including, for example, the ingredients in Coca-Cola syrup. The classified information is protected by state law—unlike the act of Congress that created patents—so the definition of a trade secret varies from state to state. Most states agree, however, that the company must have invested time and money in developing the information, the information must be valuable to the conduct of the business, and the company must make a constant, vigilant effort to keep the information secret.<sup>31</sup>

Trade secrets also differ from patents in that statutory requirements like “novelty” and “non-obviousness” are not required. Any confidential, economically valuable piece of information can be considered a trade secret. Moreover, there is no 20-year time limit—a trade secret stays enforceable as long as the information remains a secret.

On the other hand, in many ways, patent protection is more secure than trade secret protection. The vitality of the trade secret depends on the vigilance used in guarding it, and any public pronouncements make the secret moot. If an enterprising customer deduces the secret information on his or her own, then the intellectual property protection is lost as well. A patented item is protected no matter how simple it may be for other people to construct.

Trade secrets are perfect for discrete pieces of knowledge that can easily be kept confidential or, like a recipe for Coca-Cola syrup, are unpatentable. Yet it is important to keep in mind that some trade secrets may be eligible for patenting, which can provide more substantive intellectual property protection.

#### Copyright

A copyright, like a patent, is a statutory entity. According to the Copyright Act, a copyright attaches to an “original work of authorship fixed in any tangible medium of expression.”<sup>32</sup> Copyrights give the authors “exclusive rights” to profit from their work by copying, performing, publicly displaying, or producing derivative works from it.<sup>33</sup>

The two key aspects for copyright eligibility are originality and fixation in tangible form.<sup>34</sup> The Supreme Court ruled that to be original, a work must be independently created and possess “some minimal degree of creativity.”<sup>35</sup> Copyrights and patents, which have their own requirement of novelty, therefore serve the similar purpose of helping encourage the production of original, creative works by attaching government-sponsored monopoly rights to them.

The primary difference between copyrights and patents is in what they protect. Utility patents cover technological innovations in their entirety, such that any item that matches the claims of a particular patent (or is an obvious variation thereof), no matter what it looks like, infringes the patent. A copyright, on the other hand, protects a specific individual expression of an idea.<sup>36</sup> Moreover, only true copying of the expression is protected, so two parties who, for example, separately draw similar maps of the same region can both copyright their own maps.<sup>37</sup>

Other differences are also important. Whereas patents last for 20 years, copyrights (for works created on or after January 1, 1978) last for the life of the author plus 70 years.<sup>38</sup> Unlike patents, a copyright immediately affixes to any tangible expression, so one need not engage in an application process. In fact, since March 1989, official notice does not even have to be placed on the item as a condition of copyrighting.<sup>39</sup>

Health care professionals who write textbooks, develop patient education videos, or publish journal articles should be aware that copyright protection vests in those works. Copyrights, like patents, can be exploited by licensing, assigning, or selling them. Moreover, health care professionals should be careful that they do not unintentionally infringe others’ copyrights. For example, in *American Geophysical Union v. Texaco*, the Second Circuit found that the “institutional, systematic, archival multiplication of copies” of articles from scientific journals for its researchers violated the journals’ copyrights.<sup>40</sup>

#### Trademark

A third important form of intellectual property is the trademark, a distinctive entity used to identify goods that a person or business intends “to use in commerce... to identify and distinguish his or her goods... from those manufactured or sold by others.”<sup>41</sup> Trademarks can attach to anything distinctive—a word or phrase, a symbol, packaging, or any combination thereof. Trademarks protect the name of the business and prevent unscrupulous businessmen from deceiving customers by attempting to capitalize on someone else’s success.

Trademark protection occurs on the federal level,<sup>42</sup> but like trade secrets, state laws and common law also protect trademarks.<sup>43</sup> As a result, one can either register a trademark through the official process with the PTO, or can acquire common law trademark protection over time simply by employing his or her mark in commerce. Trademarks can last indefinitely, as long as the mark remains in commercial use.

As with patents and copyrights, trademarks protect the business-related activities of health care professionals. For example, pharmaceutical companies register trademarks in their medication names, and Blue Cross/Blue Shield has a well-known health care services trademark. So, in developing a business to sell a patented item, be sure to register your trademark to protect your distinctive line from copycat products in the future.

## OWNERSHIP AND LICENSING

Issuing a patent is just the beginning. This section examines patents as pieces of intellectual property, first by discussing the issue of who owns the patent and then by examining what can be done with it, including basic principles of patent licensing and marketing.

### Ownership of the Invention

According to the Patent Act, patents have “the attributes of personal property”<sup>44</sup> and so can be transferred, assigned in wills, and even mortgaged. The inventor named in the patent application becomes the original owner. If two or more inventors are listed, each is a joint owner of the patent, and each can make, use, or sell the patented invention without the consent of the other coinventors.<sup>45</sup> Such “freedom to exploit” the patent includes the ability to “license to others to exploit the patent”<sup>46</sup> as well, so a manufacturer can receive an exclusive license to produce a patented item from any of the joint owners, and the contract will bind them all.

Inventor/owners have three major options regarding what they can do with their patents. They can assign their patent rights to third parties, they can grant licenses under their patents, or they can pursue the development and marketing of their inventions by themselves.

### Assigning Patent Rights

Patents are freely assignable, so inventors can directly convey their entire patent rights to a third party. The assignment is legally binding only if the assignment is in writing and then recorded in the PTO within 3 months.<sup>47</sup> In the case of joint inventors, each can assign his or her own patent rights, but all joint owners must agree to assign the full patent to a third party.

Under certain circumstances, inventors have a legal duty to assign their ownership rights in a patent. Courts will uphold premade express agreements to assign patent rights, as long as the agreements meet the standard requirements of any basic contract. In addition, there is a long-standing common law principle that people hired to perform specific inventive tasks must assign any forthcoming patent rights to their employer, even in the absence of an agreement.<sup>48</sup>

Outside of this one narrow case, however, dividing up patent assignment rights in the employer/employee context is more complicated. The default rule is that employees own the rights to their inventions, even if it is made on

an employer’s facility, during working hours, or with an employer’s materials.<sup>49</sup> No generalized obligation to assign patent rights exists for employees. Rather, under these circumstances, the employer automatically receives a “shop right,” a nonexclusive and nontransferable license to use the particular invention for free during the lifetime of the patent.

Savvy employers should therefore include an invention assignment clause in their employees’ contracts, because courts are reluctant to imply such an agreement. For example, such a clause might require employees to disclose all inventive activity and to assign their inventions’ “right, title, and interest.”<sup>50</sup> This requirement ensures that employees do not steal employers’ time, materials, or ideas for individual profit.

Yet limits on employee assignment provisions prevent employers from laying claim too broadly on employee inventive activity. Courts often insist that employee obligatory assignment clauses be reasonable in breadth and time, restricted to inventions relevant to the employer’s business and made during the term of employment (or some reasonable duration of time thereafter). Some states have codified these principles into invention assignment statutes. California law states that employers cannot require employees to “assign that which is solely the product of the employee’s time and effort outside of the employment assignment.”<sup>51</sup>

Health care employers should establish a reasonable and predefined patent rights assignment policy—and health care employees should analyze the particulars of their employment contract. For example, Cedars-Sinai Hospital in Los Angeles requires all employees to sign an invention disclosure statement giving the hospital the rights to all employee inventions, but the clause specifically excludes intellectual property developed on employees’ own time without the use of hospital equipment, unless it relates to hospital business or results from work performed by hospital researchers.<sup>52</sup> Employees, for their part, should define their job responsibilities and expectations, segregate their inventive activity, using their own supplies and time, and always act in good faith regarding their employers’ intellectual property.<sup>53</sup>

### Licensing Patent Rights

The entity that gains control of the patent rights must then decide what to do with them. One option is to develop, perfect, and sell the item individually. This alternative can maximize profits and control. The entrepreneur should contact designers to commission prototypes, contract with factories to engage in mass production, and work with retailers to move the product to the public. This approach, however, also has the most risk. Some estimate the average cost of perfecting a product and marketing it to be \$250,000.<sup>54</sup> Moreover, busy health care professionals often cannot commit the requisite free time and leg work this strategy entails.

A more feasible means for health professionals to develop their inventions, then, is to work with an established

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production company that can provide the start-up capital and other resources. The patent holder can establish this relationship by signing a license with the company, a contract agreeing that the patent holder will not sue the company for infringing its patent rights when it subsequently develops the invention. Licenses can be exclusive, so that the licensee is guaranteed that no other company will be granted the same rights, or nonexclusive.

Determining when to pursue a licensing agreement is an important issue. A basic principle of licensing transactions is that the further established the intellectual property, the better one's bargaining position is with potential licensees.<sup>55</sup> Some entrepreneurs go further and develop a working prototype of their idea that they can use in pitch meetings with potential licensing partners.<sup>56</sup> The goal of improving bargaining position, however, must be weighed in each entrepreneur's mind against the incremental cost of taking each step along the way.

The first phase for patent holders interested in licensing their patent rights is to find a suitable licensing partner. For health care professionals, this can involve soliciting representatives from companies presenting similar products at national meetings or direct contact via phone or mail with companies' marketing directors or vice-presidents of research and development. Do not reveal too much information at this early stage, or else the company can use the idea to develop a similar item that does not infringe the patent; only the product specifically outlined in the patent, not the general idea behind it, is protected. It is more prudent to sign a nondisclosure agreement with licensees before meeting with them. This document should outline that any disclosures will be held confidential, in return giving the potential licensee a fixed amount of time to decide whether it wants to license the invention.

In executing the license, the patent holder must consider a number of important contractual points. The most obvious is how much the rights to develop the invention cost. This normally involves an up-front licensing fee and a royalty, either a fixed sum per unit sold or a percentage of net sales. The average royalty rate for nonexclusive licenses is less than 5%, while exclusive licenses can command up to 15%.<sup>57</sup> Royalties can also be graduated, to either increase or decrease after the licensee reaches a certain sales volume.

Yet other contractual points should not be overlooked. The inventor can use the license contract to encourage the licensee to market the product better by setting a minimum royalty payment or early termination. The license should cover who owns future intellectual property rights in the invention, such as improvements made to the technology either by the inventor or the licensee. The inventor can contract with the licensee to provide technical assistance for proper development if the invention is complicated. The inventor can even contract to review the licensee's accounting practices or advertising practices to have confidence in the royalty payments and assure the quality of the item once it is mass-produced. Some intellectual property textbooks have examples of template license agreements that cover these points and more.<sup>58</sup>

Entrepreneurs need to consider carefully every eventuality that may arise in the licensee/licensor relationship and outline a basic agreement in the license contract. Many companies will have standard licensing agreements that they have developed, but entrepreneurs can negotiate points to reflect their predilections. Health care professionals who are not skilled in contract negotiations should consider working with an intellectual property attorney to help them understand and fashion an appropriate contract in this regard.

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