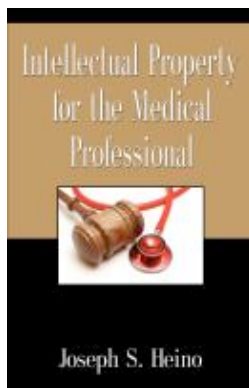


Intellectual Property for the Medical Professional



Joseph S. Heino



Intellectual Property for the Medical Professional provides a concise overview of patent, trademark, copyright and trade secret concepts protected under United States laws by using examples that are relevant to the medical profession. Collectively, these concepts are referred to as intangible "intellectual property." This book will help the medical professional recognize what intellectual property is and what mechanisms are available to protect it.

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1. INTELLECTUAL PROPERTY IN GENERAL

1.1 What is Intellectual Property?

The first thing that you need to know about intellectual property is that it is “intangible” and does not exist in the natural world. It exists only in the collective “intellect,” or minds, of humankind. Simply put, intellectual property exists because we say it does and it exists only in our minds, a product of our intellect.

This explains the “intellectual” component of the term “intellectual property,” but what about the “property” part of it? For that, we need a short history lesson. There was a time when Native Americans roamed this continent freely and without any boundaries other than those created by nature – vast oceans, wide rivers, tall mountains and deep canyons. It was their belief that the land belonged to no one and, at the same time, to everyone. It was only when Europeans “re-discovered” North America that the concept of defining land by “metes and bounds” was introduced to all inhabitants of the “New World.”

The phrase “metes and bounds” is the description given to a boundary line that circumscribes a parcel of land, as well as the land within that line. When the boundary line is “drawn,” and the land that is defined within the boundary line is “claimed,” the “owner” can assert his or her ownership and control over that parcel of land. What that land “owner” really has is not the right to use the land the way he or she sees fit. Rather, the land owner has a right to keep everyone else off that land, which is a

“negative” right. Such negative rights are the cornerstone of that body of law known as “real property” law.

While the “boundary line” mentioned above is really an “imaginary” or “man-made” line, the land defined within the boundary is quite real; hence, the name “real property.” You can bend down, grab a handful of dirt and sift it through your fingers. You can walk on it. You can even excavate and build on it. Though the owner can affirmatively do things to the real property, the owner need not do a thing to it. Without doing anything more, the owner still owns that negative right – the right to exclude others from using that land.

This concept of “real property” is closely paralleled by another form of tangible property, called “personal property.” The concept of personal property is actually an example of another negative right that substantially predates the concept of real property. I suppose even our earliest ancestors had some notion as to the ownership of personal possessions and what they could do to protect them. If one of them found a unique and beautifully colored stone, for example, placing it in the pocket of one’s garment (assuming that one had a garment and further assuming that the garment had a pocket) would have been viewed by others as a claim of possession and ownership of that stone.

Fast forward to present day. This guide is itself a piece of personal property. If you bought it at a bookstore or received it as a gift, you own it. It is yours to remove from your bookshelf as you please. It is yours to read, to the exclusion of anyone and everyone else, and no one can take it from you, at least not legally. Personal property is tangible because you can touch it and it unquestionably exists tangibly in the real world.

Now, let's go back to the concept of intellectual property. What intangible property constitutes intellectual property? Certainly, not every thought that we have and not every idea that comes to us is protected, or even protectable, piece of intellectual property. Most are not, but many are. Moreover, each form of intellectual property protection is created and functions differently. That is, each form confers a different type of property right to its owner. The next chapter will introduce the different forms of intellectual property protection that are available.

1.2 The Four Areas of Intellectual Property

It is easiest to think of intellectual property as existing within a box having four compartments. The compartments are labeled as follows:

- Trademarks;
- Copyrights;
- Patents; and
- Trade Secrets.

These are the four categories of intellectual property available under current state and federal laws. If a concept or idea cannot be put into any one or more of those compartments, it is not protectable intellectual property.

The compartment, "Trademarks," will include useful information concerning "marks in trade," or more simply, "marks." I prefer this latter term because it encompasses both trademarks and service marks – trademarks for goods and service marks for services. This is the oldest form of intellectual property

and has its origins in common law, which is non-legislative or non-statutory law, typically derived from court decisions. Common law still exists where legislation or statutes have not overridden it. However, newer statutory protections exist for marks at both the state and federal levels. For the moment, think of marks as “source identifiers” and “quality identifiers” for goods and services. They tell us where a particular product or service comes from. They also tell us that we can expect uniform quality from products or services sold or provided under the same mark.

In our second compartment, “Copyrights,” we will consider what constitutes copyrightable subject matter. While the common law of copyright has gone the way of the dinosaur, you will see how copyrights have constitutional origins and are now protected only at the federal level. You will see that copyright-protected subject matter attaches immediately to virtually any form of “expression.” For the moment, think of copyright as a type of protection for all forms of “creative expression.”

The compartment labeled “Patents” is reserved for patentable subject matter. I will sort through this compartment to help you understand the legal origin of patents, which is also constitutional, and will review the basics for protecting “patentable subject matter.” This compartment will also include information on how patent protection can be obtained, how long it lasts and what is needed to maintain its special status as patented subject matter. For the moment, think of patents as being simply technological innovations that are, or will be, introduced into the “public domain.”

Lastly, in the “Trade Secrets” compartment, you will learn that trade secrets are, as the name implies, a type of

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information that is maintained in confidence. Unlike patents, which are disclosed to the public by way of a formal document, trade secrets are best thought of as technological innovations that are kept confidential. Also unlike patents, the scope of trade secrets encompasses more than just technological innovations. That is, a trade secret need not be patentable, which means that trade secrets can cover a much broader range of protectable subject matter. For the moment, think of trade secrets as a type of protection for “undisclosed confidential information,” which information gives its owner an economic advantage over his or her competitors, provided the owner has taken steps to keep such information confidential.

4. PATENT PROTECTION

4.1 The Origin of Patent Protection

United States patent protection traces its roots to our Constitution. Specifically, Article I, Section 8, gives 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” (emphasis added).

So what does this constitutional mandate really mean for inventors? It means that, by encouraging inventors to place their innovations in the public domain, for the presumptive benefit of all, the United States will give those inventors a “monopoly” on their ideas. This monopoly is limited, however. That is, the government provides a basis for patent protection but will not do anything affirmatively to protect a patent. That is up to the patent owner.

The rationale for providing this basis for protection is that, without such protection in place, those who would invest in the research and development of innovative concepts would have no incentive to do so if others could freely copy and practice those innovations once they are made public. So, this is the trade-off – bring your invention to light, via a patent grant, and the federal government will give you the exclusive right to prevent others from making, using and selling your invention for a limited period of time. That time period is currently twenty years from the date that an application for patent is filed.

Note the use of the words “prevent others.” Here again, this is the concept of the “negative right” mentioned earlier. The disclosure of patentable inventions has nothing to do with the inventor’s ability to use the invention. Rather, it is the patent holder’s ability to prevent others from doing that. What the inventor ultimately decides to do with the invention is, for the most part, irrelevant under the patent laws.

That said, it has been recognized that there is a certain inherent “tension” that exists between what medical professionals do in caring for patients and what medical professionals do relative to protecting their innovations under the patent laws. In a 1951 federal court decision, the court observed the following:

“The professional ethics of doctors and surgeons are more consistent with the widespread use of their medical and surgical discoveries for the benefit of mankind than in obtaining a monopoly to control their discoveries for personal commercial advantage.”

A more modern analysis of this tension seems to favor patent laws when discoveries come about in the medical profession, as we will see in the coming sections.

4.2 Why Would You Want to Obtain a Patent?

As mentioned at the outset, a patent can be a valuable asset of any business, including a medical practice. It gives the patent “owner” the exclusive control over the manufacture, sale and distribution of products made in accordance with the patent. We also know that this is a “negative right,” and provides the patent holder or owner with the ability to prevent others from making, using or selling infringing products. This ability, or

patent “privilege,” can be attractive to potential investors in your business. Indeed, a keystone patent greatly enhances the value of your company and, in turn, everyone’s ownership interest in it. Potential buyers of your business will factor in the value of the patent portfolio held by your company in any due diligence that is conducted by such buyers. The bottom line is that a worthwhile patent can add to a company’s “bottom line.”

Aside from valuation issues, the real benefit of a patent is that it allows the owner to pursue infringers who may be tempted to “knock off” the product. Recall the adage, “copying is the most sincere form of flattery.” There is much truth to that statement, particularly in the business world of competing products and processes. A patent is a governmental “grant” that gives the patent owner a monopoly, albeit a time-limited one, to prevent others from practicing the invention. That grant comes with some substantial “teeth.” For example, the patent owner can avail himself or herself of the federal court system to seek damages, and even enhanced damages and attorneys’ fees if the infringement is willful. Recent federal district court decisions have enforced such rights where the patent holder appears to be playing the role of David, whereas the infringer is assuming the role of Goliath. The playing field has been made more level in situations as this and small patent owners should not be discouraged from seeking patent rights and then moving, when necessary, to enforce them.

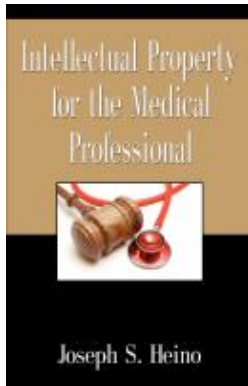
In most instances of alleged patent infringement, the realities are that it is the litigating attorneys who have the most to gain, however. Realizing this, many patent owners opt to offer a license to the infringer, which may create a “win-win” situation for all parties involved. However, every case turns on its facts and patent litigation is not a “one size fits all” proposition. But

negotiating from a position of power goes a long way in bringing the parties to the business table to reach a compromise. This situation cannot be realized without having the patent protections mentioned above in place in the first instance.

4.3 A Word on the “America Invents Act”

The America Invents Act was signed into law on September 16, 2011. The Act has been touted as the most significant change to the U.S. patent legislation since 1952. Most significantly, the Act changes the patent system from a “first-to-invent” system to a “first-to-file” system. In actuality, the Act brings U.S. practice in line with virtually every other country in the world, although there is a subtle difference in that any prior art published by the inventor within a one-year grace period immediately prior to the filing date cannot be cited against that inventor’s filed application. Inventors who do not publish their inventions prior to filing will receive no grace period. This provision will go into effect on March 16, 2013.

There are other changes that are less substantial, but important nonetheless. For example, the Act expands the definition of “prior art” to include public use, sales and publications available to the public anywhere in the world. The Act also changes certain ways that a third party can challenge the scope of a patent. For example, the Act retains *ex parte* reexamination but expands *inter partes* reexamination and renames it *inter partes* review. It also adds post-grant review and adds preissuance submissions by third parties. Some of these changes will be addressed briefly in this guide. Other changes are beyond the scope of this guide.



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