LEGAL, CLINICAL AND REGULATORY



Can I Make, Use and Sell My Patented Invention? The Answer May Surprise You.

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I had the honor of sitting on the IP panel at OMTEC[®] 2014. One question that came up during the panel discussion and then repeated subsequently was, "You mean if I get a utility patent allowed by the Patent Office, I may not be able to make or sell my invention?" The simple answer is, yes, that could occur. How can that be? The reason will be outlined in this article, along with the best practice to ensure that you are never faced with this dilemma.

What is Patentable?

The four patent requirements are: 1) It has to qualify as statutory patentable subject matter; 2) It has to be new or "novel"; 3) It has to be useful and 4) It has to be nonobvious.

What qualifies as "statutory patentable subject matter"? U.S. patent law states that only processes, machines, articles of manufacture and composition of matter, as well as "any new and useful improvement" of an existing process or product can be patented. Looking a little deeper, a "process" is generally described as a method, operation or series of actions

that are intended to achieve some end result. A "machine" is a device or apparatus that consists of fixed or moving parts that operate together to form some sort of function or create a product. An "article of manufacture" is an item to an experienced patent attorney in this field before moving forward to assess your options.

The next requirement is that the invention must be new or "novel." This essentially means that the invention has not been disclosed publically under certain circumstances. The patent law pertaining to what certain public disclosures need to be avoided or what type of disclosures make your invention unpatentable is very fact-specific and complicated. Generally, your invention would not be patentable if it was known to the public before it was conceived by the person seeking patent protection, or the invention was described in a publication more than one year prior to the inventor's patent application filing date for his/her invention; or the invention was used publically, offered for sale or otherwise available to the public more than one year prior to the effective filing date of the patent application seeking protection for that invention. The key takeaway for this requirement is that there is a one-year period after the first public disclosure or offer for sale during which a patent application must be filed. If an application is not filed

There is a one-year period after the first public disclosure or offer for sale during which a patent application must be filed. during this period, the inventor may be barred from filing and will lose his/her opportunity to gain patent protection. One must also remember that this one-year grace period really only applies

or object that is made or built by a person or by a machine (i.e., a paper clip). Finally, "composition of matter" is seen as a compound of material that is made up of two or more different substances or is a product that contains multiple substances. These substances may result from chemical unions or mechanical mixtures and may be in the form of gases, fluids, powders or solids.

Items that do not qualify as "patentable subject matter" include laws of nature (i.e., law of gravity), mathematical formulas (i.e., F=ma) and abstract ideas. Further, naturally occurring things (i.e., a leaf on a tree) or living things cannot be patented. However, one can patent genetically-engineered animals or plants. Of significant current interest is the ability to patent software. This patentability of type of invention is in a state of flux, given recent Federal court decisions. Should you desire to file an application on such an invention, please talk

in the U.S., so if one publically discloses his invention anywhere in the world, he will likely be prohibited from filing in all other countries.

The third requirement is that the invention must be useful. This is pretty self-explanatory. An invention that would fail the useful test is a machine that does not operate to perform its intended purpose.

The fourth and last requirement is the most difficult to describe, as a large degree of subjectivity is used to determine whether the invention is "obvious" or not. The patent law provides that a patent cannot be granted for an invention if the differences between invention and the prior art (i.e., patents, technical articles, etc.) disclose information such that the invention "as a whole would have been obvious" before the filing date of the patent application covering the invention, "to a person having ordinary skill in the art." Essentially, this means that the invention must be a nonobvious improvement over prior inventors (in the field) in the eyes of a like-qualified and skilled inventor. Examples of obvious design modifications that would typically not be patentable are changes in materials, sizes and shapes.

What is Freedom to Operate or Clearance to Use?

Remember, the query above was essentially, "I have a patent now; *can I make, sell or use my invention without any risk*?" The answer is *maybe*, if you do not infringe another's already issued and in effect patent. How does the inventor with the new issued patent determine whether his/her invention infringes the patent claims of another? They perform a Freedom to Operate or Clearance search.

Patent infringement falls into two categories. The first is *literal infringement*, which means that each and every element that is recited in a patent claim is also found in the allegedly infringing invention. The second category of infringement may be found under the *doctrine of equivalents*. An invention is typically only reviewed under the doctrine of equivalents in the event that literal infringement is not found. For a claim to be infringed under the doctrine of equivalents, the elements that make up the invention are found to be substantially equivalent to the elements of the patent claim. Determining whether an element is

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3

substantially equivalent is accomplished by applying the "function, way and results" test. A patent attorney will review the possibly infringing device and see if certain elements perform substantially the same "function," is substantially the same "way," to achieve substantially the same "result." Essentially, the doctrine of equivalents expands or broadens the claim coverage over what may be found literally. However, this expansion is limited and possibly eliminated by what happens during the prosecuting of that patent with the patent office. Simply, if the claims of the patent are amended during the course of prosecution, the doctrine of prosecution history estoppel and also the prior art cited by the patent office may reduce the impact of the breadth of the doctrine of equivalents. This analysis is quite complicated. If your device has to be reviewed under the doctrine of equivalents, you will need to consult with a qualified patent attorney.

Performing the actual infringement review will determine whether a claim of the patent "reads on" your invention 1) literally or 2) covers the invention under the doctrine of equivalents. The first step is to determine and construct the "scope" of the literal language of the claims. This is accomplished by looking at the words of the claims and giving them their ordinary and customary meaning and using the patent specification for guidance. If the ordinary meaning cannot be determined, extrinsic

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An Example of the Literal Infringement Analysis

The best way to show how one may get an issued patent, but then may not be able to make, use or sell is by showing a simple example of how the literal infringement analysis is performed.

Company A was issued U.S. Patent No. 1, 234, 567 on a bicycle, five years before Inventor Z's recently allowed patent on a new design for a bicycle. Claim 1 of Company A's patent reads:

1. A bicycle comprising:

- a metal frame;
- a seat and handlebars, wherein the seat and handlebars are coupled to the metal frame;
- a front sprocket and rear sprocket, where the front and rear sprocket are connected by a chain and the front sprocket has a plurality of pedals; and at least two wheels, the two wheels being rotatably connected to the metal frame.

Inventor Z also is claiming a bicycle; however, his invention has two additional elements: a basket and a light.

The U.S. Patent Office has determined during prosecution that this new bike in combination with the basket and light is a new, useful and nonobvious invention. Thus, it is patentable. Claim 1 of Inventor Z's newly allowed patent reads:

1. A commuter bicycle comprising:

 a frame having an attachable saddle and handlebars; wherein the commuter bicycle further comprises a chain connecting a front sprocket to a back sprocket that are rotatably coupled to the frame; wherein the front sprocket further comprises a pair of pedals for turning the front sprocket; two tires coupled to the frame, wherein the two tires turn upon movement of the pedals; and a basket and light coupled to at least one of the handlebars and the seat.

When performing the infringement analysis, one will construct the Claim 1 of the U.S. 1,234,567 patent and then list each element to see if Claim 1 "reads on" the commuter bicycle of Inventor Z to determine whether literal infringement exists. Below is the side by side comparison of the elements.

Company A's Claim 1	Inventor Z's Invention
(1) Metal frame	(1) Frame
(2) Seat	(2) Saddle
(3) Handlebars	(3) Handlebars
(4) Front sprocket	(4) Front sprocket
(5) Rear sprocket	(5) Rear sprocket
(6) Chain	(6) Chain
(7) Plurality of pedals	(7) Pair of Pedals
(8) At least two wheels	(8) Two tires

Clearly, the elements of Inventor Z's commuter bicycle read on the elements of Claim 1 of Company A's patent, even though Inventor Z's bicycle includes the additional basket and light elements and was found to be patentable. Because Inventor's Z's bicycle infringes claims of the 1,234,567 patent, Inventor Z would not be able to practice his commuter bicycle invention without the permission of Company A. evidence, like a dictionary, may be used to construct the meaning of a word or term. Finally, one may also look at the prosecution history for the patent and see if the applicant asserted any arguments or definitions that would assist in determining the meaning of a claim term.

The next step in the infringement analysis is to compare the now-constructed claim terms to the invention, and determine whether literal infringement exists. If not all elements in a particular patent claim are found in your invention, then literal infringement is avoided for that particular claim.

If literal infringement is not found, then the patent claim is reviewed under the doctrine of equivalents and your invention is reviewed to determine whether it includes substantially equivalent structures to the elements of the patent claim. Remember as noted above, the function, way, result test must be applied to your inventor's elements to determine whether a substantially equivalent element is present. This is typically done on an element-by-element basis. In other words, one lists all of the elements of a particular claim and then a side-by-side review of the invention elements is performed. As discussed above, the extent of the application of the doctrine of equivalents will depend upon how and why amendments to the claims were made during the prosecution process.

Best Practice

The best practice to reduce the possibility of this situation occurring would be to conduct a patentability search before you file any application. This should give you an indication of other patents and published applications that may impact your ability to obtain a patent and the possible breadth of claims that may be allowable. Not all relevant prior art may be returned in a search, because there is an 18-month delay in publication of pending applications. Thus, post-filing, an applicant may want to conduct a freedom to operate search on the final invention. This will provide the applicant with guidance on what roadblocks may be out there for his/her use of the invention, post-allowance. It may also give the applicant the opportunity to initiate designarounds and file corresponding updated continuation applications to attempt to get claims that cover the redesigned commercial product, which avoid the found blocking patents. Taking the steps to invest in these two searches at the appropriate pre-filing and post-filing time periods may avoid downstream invention use and practice issues and lost revenue because of the need to enter into third party license agreements.

Please remember that this article was written for informational functional purposes only and should not be interpreted as legal advice.

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