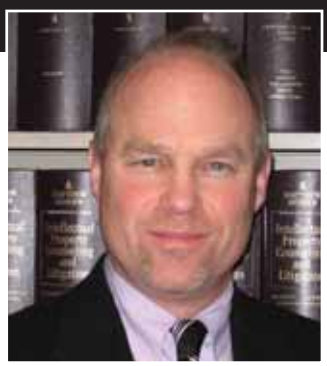
An Introduction to Patent Opinions



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Whenever a medical device company develops a new product, process or technology, the topic of getting an "opinion" inevitably arises. Many different types of patent or Intellectual Property (IP) opinions exist, each one with a specific purpose.

If one were to follow the typical product development pathway, a patentability opinion would usually be the first type of patent opinion that is obtained. This kind of opinion is based on the results of a prior art search that are used to evaluate the likelihood of obtaining a patent on a specific invention. Moving further down the product development pathway, the next type of patent opinion a company will typically seek is a freedom to operate or clearance opinion. This looks broadly at the proposed technology/product/process and focuses on whether such invention may infringe on any in effect patents.

Strategic use of opinions can provide a significant return on investment, especially when these are obtained early in the product/process/technology development timeline.

In the event a company has identified a specific patent or patents that they feel may impact their products/technology/process, a slightly different patent opinion may be obtained. This is called a non-infringement opinion and focuses upon the identified patent. The purpose is to closely examine it to see if the company's invention "reads" on the identified patent or patents. Finally, if a company determines that their product/technology/process may actually infringe, then a fourth type of opinion, a validity opinion, may be obtained. The validity opinion will focus on whether the target patent is actually valid and enforceable.

Many legal and business reasons exist for obtaining one of these four patent opinions. Typical business reasons may include: whether to spend money on filing a patent application; evaluating the infringement risks of offering a new product for sale; determining the need to license technology before releasing a product and calculating the strength and corresponding value of the patent.

The chief legal reason for obtaining a clearance and/or a non-infringement opinion is to avoid infringing another party's patent and the possible allegation of willful infringement. Remember, if a party is found to have willfully infringed another's patent, the amount of damages awarded may be tripled!

Patentability Opinions

Before a company decides to invest money in filing a patent application on a product/technology/process, it may be advisable to obtain a patentability opinion from a registered patent attorney. The process begins with a comprehensive search of public records (e.g., USPTO patent/published application database, Google, etc.) for any public disclosures that may relate to the invention to determine whether it is new, useful and not obvious. One must understand that in addition to patent and published patent applications, non-patent references (e.g., scientific articles, journals, etc.) need to be searched, as these too may be used by the patent examiner to show that someone else has thought of the invention.

Once the prior art search is completed and the results reviewed, the patent attorney should be able to provide the company with an opinion on whether it will be able to obtain a patent or not. The opinion should evaluate the relevant references that may show that the invention is not new. Further, the opinion should discuss references that could be combined to render the invention as being obvious, and therefore unpatentable. One must be cautioned that some pertinent references may not be discovered during the search because of the 18-month lag in publication of filed applications. Obtaining a patentability opinion before filing an application will often save a company money, because the opinion will provide them with important information on the likelihood of success for actually getting a patent issued. In addition, patentability opinions can provide insight as to the existence of similar inventions (either patented and/or described in a pending application) which may impact their product's continuing development.

Freedom to Operate (or Clearance) Opinions

Freedom to Operate Opinions (FTO) are a must to obtain ***before*** a company moves forward with commercializing a product, process or technology. The timing for obtaining an FTO is important, as it should occur before a significant investment is made in any project so as to allow the company the

opportunity to consider the risk of moving forward without infringing on others' IP. The hope is that the FTO will show that no relevant patents will impact or block the development of the invention, and that the company is "free to operate" in the searched field.

The first step when obtaining an FTO is to provide to the searcher and patent attorney a clear and complete description of the product/technology/process. Omissions or incomplete disclosures can significantly affect the search quality and legal analysis that is performed. The second step is to develop a comprehensive search criteria and strategy and then perform the search. The clearance search will mine for all relevant patents and published patent applications. Depending upon the company's filing/distribution strategy, the search may be limited to only the U.S. or alternatively, expanded to include worldwide filings.

Following the completion of the search, the next step is for the patent attorney to review the results and identify patents and/or published patent applications that may be infringed by the company's described technology/product/process. The identified patents, specifically the independent claims, are looked at more closely. Such closer examination would include a review of the corresponding patent(s) prosecution file history and the cited prior art.

The final step for creating an FTO is the actual drafting of the written opinion. Oral opinions may be useful for certain limited reasons (e.g., lack of time), however, it is a best practice for any oral opinion to be memorized as soon as possible with a formal written opinion to evidence the non-infringement conclusion. It is very important that the written opinion be complete, because in the event that a company is involved in an infringement law suit and holds an exculpatory FTO, the presiding judge will want to review the FTO to determine whether it is "competent" or not. A competent opinion must be drafted by a registered patent attorney and should include the following information: a description of the technology/product/process; a description of the clearance search methodologies; a detailed description of the applicable law (i.e., infringement standards); an analysis of the relevant patents and a conclusion. The analysis of the relevant patents is the most important part of the FTO and focuses on the independent claims of the identified patents. The attorney will "construct" the claims (i.e., define the terms and overall meaning of the claims) and then compare these "constructed" claims to the company's invention.

When comparing the constructed claims, the patent attorney will determine whether there is literal infringement (i.e., the technology/product/process "reads" on the claims),

FDA and Industry Reach Agreement in Principle on Medical Device User Fees

FDA and representatives from the medical device industry reached an agreement in principle on proposed recommendations for the 3rd reauthorization of a Medical Device User Fee program. Recommendations would authorize FDA to collect $595 million in user fees over 5 years, plus adjustments for inflation. Additional funding will support the addition of >200 full-time equivalent staff by the end of the 5-year program to reduce average total review times.

FDA and industry expect that the agreement in principle would result in a reduction in average total review times.

Under a user fee program, industry agrees to pay fees to help fund a portion of the FDA's device review activities while the FDA agrees to overall performance goals such as reviewing a certain percentage of applications within a particular time frame.

Once final details of the agreement with industry are completed, FDA will develop a package of proposed recommendations open to public commentary before they are submitted to Congress. The date of the public meeting has yet to be determined.

REFERENCE

FDA and industry reach agreement in principle on medical device user fees, FDA.gov, February 1, 2012.

infringement under the Doctrine of Equivalents or any limitations on the claim coverage because of prosecution history estoppel, cited prior art or a surrender to the public.

The goal is for a positive outcome of the FTO that shows that the company's technology/products/process does not infringe any identified patent references. However, if an infringement issue is found, the company will likely be required to move in the direction of either redesigning the offending invention or just abandoning it. Alternatively, the company may want to review the problem patent further to determine if it may be invalidated.

Non-Infringement Opinion

The non-infringement opinion is closely related to the FTO except the analysis is directed to a specific patent(s) that the company has identified or has been made aware of by a third party. The intent of the non-infringement opinion is the same as an FTO, which is to provide assurances to the company that their product/technology/process does not infringe the identified art.

Non-infringement opinions should be obtained anytime a company has developed a specific new product/process/technology that is similar to an existing patented product/process/technology. Other times that this type of opinion should be procured is during the course of due diligence for an acquisition or a license transaction, or when preparing the company's defense in an infringement lawsuit.

The process for preparing a non-infringement opinion is the same as for a FTO, except the search is not performed because the relevant patent(s) have already been identified. Therefore, the typical process will include having the patent attorney gain full understanding of the company's invention and then making the comparison to the independent claims of the identified patent(s). As with an FTO, the non-infringement opinion will involve constructing the claims to evaluate the exact meaning and coverage breadth of the language and then determining whether the company's invention literally or under the Doctrine of Equivalents will infringe the identified patent(s). Again, in the event a company has identified a patent that is problematic to producing or using their product/process/technology, pursuing a validity opinion may be an option to consider.

Validity Opinions

For certain situations, a company may want to obtain a validity opinion to determine whether an identified patent is valid or enforceable. This may be when the identified patent may be infringed by the company's product/process/technology. A company may also want to obtain this type of opinion before buying or licensing certain patent(s). Many times, a buyer/licensee has found that the target patent is invalid and therefore no license is needed to be able use the sought-after invention. Validity opinions are also quite useful when performing due diligence during a merger or acquisition to determine accurate IP portfolio valuation. The selling price can fluctuate significantly both up or down as a result of the validity analysis of key patents.

The goal for obtaining a validity opinion is different from the other discussed patent opinions, in that one wants to neutralize the patent claims that cannot be avoided by design-arounds or other actions. The process for formulating this type of opinion starts with a search of all prior art that may or may not have been cited by the inventor and/or the USPTO examiner during the prosecution of the patent. When reviewing the search results, the patent attorney will try to determine whether each and every claim (independent and dependent) is new and/or non-obvious in light of the found prior art. Generally, the validity opinion will include a claim chart that constructs and interprets each and every claim of the target patent and then lists any prior art that may show that the claimed invention is not valid because it is not new or is obvious. The key aspect of validity opinions is that ***each*** claim must be reviewed (for FTO's and infringement

opinions, usually only the independent claims are reviewed because they are the broadest).

The conclusion reached in a validity opinion is that all, some or none of the allowed claims are invalid in light of the found prior art references. If the claims of the target patent are found to be invalid, then depending on the reason why opinion was obtained, the company may move forward with producing/using the invention without concern of an infringement lawsuit, or to not license or purchase that patent. Alternatively, if the claims are found to be valid, then the company may attempt to license the blocking patent, or proceed with the IP acquisition/merger transaction. Validity opinions are unique from the other patent opinions, as they can be used very effectively either offensively or defensively, depending upon the business circumstances.

Patent opinions can have a high upfront cost, but given the potential time savings and mitigation of legal risk that will result, such investments are prudent.

Conclusion

These four patent opinions all have different purposes and value to a company. Strategic use of opinions can provide a significant return on investment, especially when these are obtained early in the product/process/technology development timeline. Patent opinions can have a high upfront cost, sometimes extending into five figures, but given the potential time savings and mitigation of legal risk that will result, such investments are prudent. An important closing note to remember is that any patent opinion generated by a patent attorney will be covered by the attorney/client privilege; therefore, sharing of the contents/conclusions of these opinions with non-company personnel will likely waive the privilege. So, even though a company typically wants to boast about the results of their respective patent opinions, they should be careful not to, because they may risk losing the shield of the attorney/client privilege.

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