Special Patent Considerations for Medical Device Manufacturers

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Intellectual property has become an increasingly hot topic recently in the medical and biotechnology field. Recently, the Supreme Court upheld non-naturally occurring DNA as being patent eligible in Association for Molecular Pathology v. Myriad Genetics. Additionally, patent litigation rates have increased at an annual growth rate of 5%. Patents regarding medical devices are governed by the same laws as all other patents, but special exceptions require particular consideration by companies that work in this area.

The Medical Practitioner Exception

United States Law provides that “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title” (35 U.S.C. § 101). Unlike the European Patent Office (EPO), which does not grant patents regarding “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods,” the United States recognizes medical devices and procedures as patent-eligible subject matter (European Patent Convention, Article 53, section (c)).

In 1996, Congress enacted a provision, codified as 35 U.S.C. § 287(c), which creates an exemption for medical practitioners and healthcare entities, wherein they are not liable for patent infringement regarding medical activities. This Congressional

action was the result of lobbying from medical personnel following an infringement lawsuit initiated by Dr. Samuel Pallin regarding his patented cataract surgery method. There are a number of exceptions to this immunity, including “the use of a patented machine…in violation of such patent” (35 U.S.C. § 287(c)(2)(A)(i)). However, the fact that the exemption exists at all shifts the focus of infringement suits in the medical field away from the direct infringers. Typically, device manufacturers are highly targeted, as well as distributors, rather than doctors and hospitals. While the exemption and its policy implications have been the topic of debate, the law remains unchanged.

Two Strategies

Broadly speaking, there are two general tactics medical device manufacturers and distributors can use as protection in litigation.

Cultivate a Patent Portfolio

First, a company can file patent applications to pursue patents covering their products in development of their own patent portfolio. The information a company discloses in a patent application can prevent competitors from obtaining patents on that subject matter in later filed applications. Acquiring patents also has the added benefit of all the rights afforded to a patent owner, such as the right to exclude others from selling patented products, as well as the ability to create additional revenue streams for a company by licensing the invention. Under the threat of litigation, a defendant manufacturer can potentially use their patents in a countersuit as a defensive measure, and cross licensing can be used to avoid litigation. There are cases, however, when a product may be well-known in the prior art and a patent cannot be obtained. Patents in and of themselves do not guarantee non-infringement however; a company can have a patent covering an aspect of a product, and that product or its use, in its entirety, can still infringe other existing patents.

Obtain Clearance Opinions

The second general tactic, a clearance (or freedom-to-operate) opinion fills many of the previously mentioned deficiencies. A clearance opinion is a legal opinion provided by a patent attorney explaining that a given product or process does not infringe one or more patents. During litigation, the opinion provides preliminary support for a defendant’s case of non-infringement. Further, the fact that a company acquired a clearance opinion is evidence against a finding of willfulness of infringement. This translates to a savings on the order of millions of dollars in many cases. Clearance opinions can be especially helpful in markets where similar products exist and the manufacturer is unsure of the patent landscape. This information is also useful for targeting companies for licensing or acquisition.

In creating a clearance opinion, a search is performed to identify issued patents and pending patent applications which contain claims relevant to a company’s product. A patent attorney then performs a legal analysis to determine if the product infringes the discovered patents and subsequently authors a legal opinion providing their explanation and rationale. Expertise in performing the search is as important as that in the legal analysis itself, because opinion can be less valuable if critical patents are not discovered for consideration in the opinion. The database of issued

patents is extremely large, which makes it cumbersome to navigate, and the classification scheme is notoriously difficult to navigate, further in support of seeking specialized searchers.

Specific to the medical field, it is also important to consider the literature accompanying a product when authoring a clearance opinion. Due to the fact that medical practitioners may be exempt from infringement of medical process patents, as discussed above, patent owners find device manufacturers as more lucrative targets as inducing patent infringement. Material evidence to prove infringement by inducement typically includes marketing materials, instructions, and best practices guides that accompany a product.

For example, a patent may claim a surgical process for setting a fractured femur, and a manufacturer may make a bone plate and screws. The manufacturer itself does not perform the patented method and accordingly does not directly infringe the patented method. However, if the hardware sold by the manufacturer includes recommended instructions directing the physician to perform a surgical procedure that would infringe the patented method, then the company could be held liable for induced infringement because they provide the necessary components and suggest they be used in a process that infringes an issued patent. To provide a defense in this case, the literature accompanying a medical product can also be part of the scope of the clearance search and opinion. In this way, the entire product package can be cleared for market.

Conclusion

Medical devices encounter special circumstances in the realm of intellectual property. While the same general rules apply, specific exceptions congressionally granted to medical practitioners shift the focus of litigation away from the entity directly infringing patented medical procedures. This puts a heavier burden on the companies providing the tools to make the operation possible, and the patent strategies and scope of defensive opinions must adapt accordingly. Taking these concerns into account, manufacturers can be prepared with commensurate measures.

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