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Advisory

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INTELLECTUAL PROPERTY

Medical Device Patents: An Important Business Asset

Protecting novel medical devices with patents is an essential and integral element of a company's success in marketing and selling its devices. It is an area in which both the patents and competitors are numerous, and the difference between having a strong patent position and not having one may well be the difference between success and failure. This area of patent law also possesses interesting, and often complicated peculiarities. Many of these peculiarities are due to complex regulatory requirements in a rapidly changing legal environment relating to medical devices, particularly the regulatory requirements of the Food and Drug Administration (FDA). Protecting intellectual property through effective patent prosecution, litigation and licensing efficiently and effectively should therefore be a vital concern for medical device companies.

Effective Protection for Your Medical Device

Protecting a medical device can be a complex matter, and with the number of such patents, conflicts frequently arise. Prior to manufacturing or developing a medical device, it is truly in the company's best interest to determine whether other, third party, patents are already in existence covering the device. If there are, many options arise, including: whether it is in the company's best interests to obtain a license from the patentee (if available); whether the company is free to experimentally use the device while obtaining FDA approval; and whether the company can effectively design around the claims of the patent(s), and perhaps file one or more application(s) to cover its own development. Medical device companies are among the most prolific patentees, a local well-known Boston medical device company having been granted nearly 300 patents since 1996 alone!

There is a good deal of litigation in the medical device arena, due in large part to the degree of competitiveness between medical device companies trying to sell to the same customer base. The adoption of a patent prosecution strategy which envisions careful attention to third party patents and possible litigation in the future, either in an offensive or defensive mode, goes a long way toward securing the company's position in the market.

Patent Term Restoration

A specific peculiarity in the protection of medical devices concerns the term during which such a device enjoys protection. In general, the exclusionary rights conveyed to a patent holder begin upon the filing of a patent application and continue for a term of twenty years. The term of protection for medical device patents, however, differs in that it may be extended for up to five years. Before marketing or using medical devices, it is often necessary for the company to obtain approval from the FDA, a process that can take many years. This means that the company is unable to reap any financial benefits for the patented device for the duration of the regulatory review, since the company cannot market the device until FDA approval is had. Thus, an extension may be obtained for an amount of time required for the regulatory review, so long as the patent applicant has exercised due diligence during the regulatory review period. The difference in the term of protection can have a significant impact on the successful marketing of a patented medical device. In order to harvest the full amount of financial reward, careful attention to procedural timelines incumbent on the applicant/patentee is necessary, or the term extension may be unnecessarily compromised.

Clinical Trials

In addition to a potential term extension, patent protection for medical devices is unique in that there is an exception to allow for clinical trials. Generally, a patent holder's rights in his patented product are to the exclusion of the rights of others, meaning

no other competitor can manufacture the protected product for the term of the patent. The competitor is forced to wait until the end of the patent term to develop and manufacture the product. When that product is a medical device, however, a competitor wishing to begin to produce the protected medical device after the end of the patent term must seek and obtain approval from the FDA before proceeding, which is a time consuming process. The patent holder, therefore, from a practical standpoint, may have enjoyed extended protection while the FDA determined approval for the competitor. This led to the adoption of an exception for clinical trials of medical devices that require FDA approval: manufacturers are not liable for patent infringement when they practice the patented invention during the term of the patent if they are doing so to obtain data necessary for the FDA to approve the device. Once the FDA approves the device, the competing manufacturer need only wait for the patent to expire, at which point the product can immediately be sold. Issues can arise concerning whether a competing use is entitled to the clinical trials exception, since a competitor taking advantage of this exception is essentially free to sell the experimental device, even while the patented device remains protected. The competitor may be, therefore, distorting the patent holder's market under this exception. In such a case, the patent holder, in order to protect his market share, should make certain that the competitor is using the experimental device only for the intent of acquiring FDA approval, as was the intent of the exception.

Mintz Levin Experience

Engagement of experienced patent counsel is a key factor in securing the rights of a company in the medical device field. Not only is it indispensable to obtain patent protection, but other factors become increasingly critical to the success of the company, such as negotiating licenses, protecting existing medical devices, and reducing the risk of infringing existing patents. Further, preventive counseling in the early stages of device development minimizes potential risk of future litigation. In the event that adverse legal action is a threat, which is not atypical in this complicated area of patent law, experience in protecting such devices is crucial.

We at Mintz Levin have the experience it takes to successfully develop patent portfolios to protect medical device patents, not to mention the experience necessary to defend against third parties' patents and undertake patent infringement actions against third parties when the need arises. From preventive counseling measures to litigation defense, we possess an experienced and thorough understanding of FDA regulations and the impact such regulations may have on your medical device, from the moment of initial development and throughout the full length of patent protection.