



Medical Device Marketing Under Substantial Equivalence—FDA Clearance and USPTO Patent Considerations

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This article focuses on medical device regulation by the US Food and Drug Administration (FDA) and medical device patent protection by the US Patent and Trademark Office (USPTO). The authors state most companies operating within the medical device space do not provide for sufficient interaction between those responsible for FDA approval and those responsible for patent protection. Because a “leak” of information about an invention during the FDA approval process before a patent application is filed can destroy any chance for meaningful patent protection, the authors suggest medical device companies should work to promote a better understanding of patent objectives and risks among those responsible for FDA approval, as well those responsible for patent protection.

Introduction

The US operates under a federal system providing uniform regulation to many industries and institutions operating across the 50 states as well as US territories. Fundamentally, this is possible due to the Commerce Clause contained in Article I, Section 8, Clause 3 of the US Constitution, which empowers the federal government to regulate all activities within the interstate commerce. This is true for healthcare-related products and new inventions marketed within the states. Accordingly, this article focuses on medical device regulation by the US Food and Drug Administration (FDA) and medical device patent protection by the US Patent and Trademark Office (USPTO).{1,2}

USPTO is the federal agency responsible for evaluating and granting patent rights for novel and non-obvious inventions meeting the requirements of Title 35 of the US Code and Title 37 of the US Code of Federal Regulations. USPTO grants patents and decides validity challenges. The US federal courts, likewise, decide validity challenges and also decide claims of patent infringement.

FDA is the agency appointed by Congress to regulate and oversee all public safety matters related to drugs, medical devices, biologics, veterinary products, food, tobacco and nutritional supplements. FDA authority extends to product development, market approvals and field compliance. FDA's mission is founded on public safety, meaning every regulated subject must meet required regulations to assure members of society are not harmed by the introduction of new healthcare-related products.

As USPTO and FDA differ in purpose, there are notable differences in regulating medical devices and protecting inventions. While the fundamental purpose of a market authorization for a medical device is public safety, the purpose of the patent grant is to reward the inventor or owner with the right to exclude anyone within the US from duplicating the patented invention. The work of those responsible for FDA approval and those responsible for patent protection does not overlap in a natural scenario. However, the purposes and objectives of FDA clearance and patent protection give rise to conflicts, and this represents a concern to protected inventions as patent infringement may reach market exposure within the US. Accordingly, the potential conflicts between the purposes and objectives of FDA and USPTO motivates the discussion in this article.

FDA Medical Device Clearance Process Under Substantial Equivalence

Medical devices are regulated by FDA.^{3} The agency defines “device” as:

“An instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, the US Pharmacopoeia or any supplement to them
- intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in man or other animals
- intended to affect the structure or any function of the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes”

There are many pathways for FDA medical device market authorization and they are defined by its device code and classification. While the code is related to the nature of the device and its intended use, there are three main classifications of devices intended for human use: Class I, Class II and Class III. The assignment of a classification, as outlined in 21 U.S.C. § 360c, depends on the risk associated with the device:

- Class I, General Controls—a device for which the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i or 360j or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is neither intended for life support nor the prevention of health impairment; and it does not represent an unreasonable risk of illness or injury. These are devices deemed to be a low risk, therefore requiring general regulatory controls.
- Class II, Special Controls—a device which cannot be classified as a Class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance.
- Class III, Premarket Approval—a device that cannot be classified as a Class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and it cannot be classified as a Class II device because insufficient information exists to determine that the special controls would provide reasonable assurance of its safety and effectiveness.

Unless it is exempted, there are two different marketing authorizations associated with the device classification. First is the Premarket Approval (PMA), a market authorization required whenever there is a device with considerable safety risk or there is a lack of safety data on file from prior submissions. In all instances, a device under a PMA

submission will require clinical trials to prove device safety and effectiveness. This is typically applicable to Class III devices.

The other option is Premarket Notification, or 510(k). This option requires demonstrating substantial equivalence to a predicate device, a device currently and previously marketed within the US, which can be proven by means of equating the new device's attributes and technology, same or new, to the predicate device's indications for use. A critical difference between the two approaches is that while FDA approves products successfully submitted under a PMA, it will provide only a "clearance" status for those submitted under a Premarket Notification. Under substantial equivalence, the device should be tested/equated to the predicate device in terms of performance testing to demonstrate it is "not worse than" (i.e., equivalent to) the predicate.

Granting USPTO Medical Device Patents

Section 101 of the *US Patent Law* allows for the patenting of "new and useful processes, machines, manufactures, compositions of matter or any new and useful improvement thereof." 35 U.S.C. § 101. This list has been held to be inclusive of practically everything made by man, including processes for making products. Essentially all medical devices regulated by FDA are eligible for patent protection under Section 101.^{4}

A patentable invention also must be novel under Section 102 and non-obvious under Section 103 of US patent law (35 U.S.C. §§ 102, 103). The novelty requirement precludes the allowance of a patent claim if a single prior art reference shows each and every element of the claim. The prior Art (art) reference can be a prior patent, a printed publication, a public use, a sale or any other piece of information that was otherwise available to the public, anywhere in the world, before the effective filing date of the application. Prior art can sometimes be created merely by an applicant's admission. The non-obvious requirement prevents the grant of a patent for a claimed invention, even though the claimed invention is novel, if the differences between the claimed invention and any combination of prior art is such that the claimed invention as a whole would have been obvious to a person having ordinary skill in the relevant art.

A patent application consists primarily of a specification with a detailed description of the invention, drawings as needed to complement the written description and claims defining the metes and bounds of the invention. The specification must describe the invention and the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person ordinarily skilled in the technological area to which the invention pertains to make and use the invention without undue experimentation. The specification concludes with patent claims that particularly point out and distinctly claim the subject matter that the applicant regards as the invention. The claims are, in a sense, the most important part of the application since they define the scope of the exclusive protection afforded by the patent. Patent applications are kept secret for 18 months after filing.

Once filed, an application is assigned for examination by a US patent examiner knowledgeable in the relevant field. The examiner reviews the application for compliance with formal and legal requirements, then searches for US and foreign prior art and decides if the claimed invention is new and non-obvious. If the legal and formal requirements are met, the examiner issues a notice of allowance and a patent is granted. More typically, however, an examiner will issue at least one rejection of an application. The examiner states the reasons for rejection and the applicant is given an opportunity to reply. If the rejection is based on prior art, the applicant may contest the rejection or narrow the claims to avoid the prior art.

If the examiner persists in rejecting any of the claims, the applicant may appeal to the USPTO's Patent Trial and Appeal Board and, if unsuccessful, to the federal courts. As an alternative to appeal, the applicant can file a continuation application to submit additional evidence of patentability or to request the examiner's consideration of amended patent claims. If the examiner has allowed claims for some but not all of the patentable subject matter, the applicant can take a patent for the allowed subject matter and file a continuation application for the remaining subject matter. A continuation application proceeds through the same examination process as the original application.

A US patent is normally valid for up to 20 years after the original application filing date, provided maintenance fees are paid. US patent law takes into account long delays in

FDA's approval process can shorten the patent term relative to marketing intent. In these cases, the patent term can be extended under 35 U.S.C. § 154(b). Sometimes a patent owner can correct defects in a patent by way of a "reissue patent." A reissue application can sometimes serve to narrow the original patent claims to avoid newly discovered prior art and thereby preserve validity. A reissue application also can broaden the scope of the original claims if the application is filed within two years of the issue date of the original patent. Broadening can be important when the patent owner included an unnecessary claim limitation in an original claim and a broader claim is needed to cover FDA-approved embodiments or successfully claim infringement.

Risk From an Organizational Perspective

The possibility of creating patent-defeating prior art through an admission or argument to FDA presents special risks for medical device companies. The problem can arise when company representatives responsible for FDA approval argue and assert facts to show that the new device is substantially equivalent to a predicate device under Section 510(k). Some patent owners have successfully convinced courts to deny a patent challenger's use of FDA-related statements to assess patent validity or scope. But patent rights are not immune from damage by FDA material, and some patent challengers have successfully used the material to avoid infringement liability. Accused patent infringers can rely on equivalency arguments and assertions to demonstrate obviousness or lack of novelty. An argument for equivalency also may help a competitor assert patent infringement against the company when the competitor owns a patent covering some of the features of the predicate device. Going in the other direction, a company's argument of distinctions over the prior art to gain patent protection can conflict with arguments for FDA equivalency.

Accordingly, it is critically important to maintain the confidentiality of an invention until a patent application is filed since, with limited exceptions, no valid patent can result from a patent application filed after the claimed invention became publicly available. Another risk for medical device companies is that information about the device becomes available to the public in the course of the FDA approval process, before a patent application is filed. FDA publishes summaries of cleared Premarket Notifications (510(k)s) on its website as a consequence of its agency policy and in keeping with the *Freedom of Information Act (FOIA)*.{5}

The *FOIA* is a federal statute requiring the disclosure by any federal agency of records in its possession when requested in writing by an individual. With few exceptions, as established in the nine exemptions contained in the Act or by one of the three special law enforcement exclusions, FDA would release information from the applicant's 510(k) that—in most cases—contains the device indication and technology. From a patent strategy perspective, the *FOIA* process as it relates to FDA medical device clearance based on substantial equivalence represents a major risk to the protection of intellectual property.

A US patent confers "the right to exclude others from making, using, offering for sale or selling the invention throughout the United States or importing the invention into the United States" and its territories and possessions during the patent term. 35 U.S.C. § 154(a)(1){6} Since the patent does not positively grant the owner the right to make, use, offer for sale, sell or import, but only to exclude others from doing so, the owner needs to ensure its practice of the invention will not infringe others' patents or violate state or federal regulations including, importantly, FDA's rules and regulations.{7}

To prove infringement by a competitor, the patent owner must show that the accused device includes each and every element of at least one of the patent claims. The patent owner can sometimes rely on the doctrine of equivalents to broaden the literal scope of a patent claim to cover a competitor's device having an element that is not the same as a corresponding element of the claim, but is substantially equivalent to the element. However, a patent owner cannot expand the meaning of a claimed element to include equivalents when, in order to avoid the prior art during prosecution of the patent, the patent owner either added the element or relied on the element (whether or not added during prosecution) to help convince the examiner of the invention's patentability.

Conclusions and Recommendations

Most companies operating within the medical device space do not provide for sufficient interaction between those responsible for FDA approval and those responsible for patent protection. For no apparent reason, organizations keep these two functions separate in the day-to-day operation, as there is a belief they represent different business interests and objectives. The only common link between these two functions is typically the company's research and development team, which provides essential input to accomplish the business goals of both patent protection and product clearance.

Medical device companies should work to promote a better understanding of patent objectives and risks among those responsible for FDA approval and a better understanding of FDA objectives and risks among those responsible for patent protection. For example, they should strive to educate employees in both groups about the nature and legal significance of establishing the substantial equivalence of a new company product and a predicate device for FDA approval, and also about the nature and legal significance of establishing the requirement novelty and non-obviousness of the new product over the prior art for obtaining a patent. Arguments for FDA approval and patent protection should be vetted and narrowed so they say no more than is necessary to achieve their purpose. Companies also should consider the use of internal procedures for communication between FDA-related personnel and patent-related personnel, defining FDA equivalency terms and patentability terms in a way that do not conflict, and filing continuation applications and managing patent prosecution timing to maintain flexibility in patent drafting. It can be helpful to conduct a search for relevant prior art before filing a patent application, and it is important that corporate employees involved in the FDA approval process disclose all known prior art to those responsible for patent protection. Early knowledge of prior publications and other relevant prior art enables the applicant to avoid the expense of patenting if the invention has already been disclosed by another, and it allows the patent attorney to distinguish the invention from close prior art upon filing the original patent application. This, in turn, increases the likelihood that the resulting patent will be defensible when asserted against an infringer. It also increases the likelihood the patent owner will be able to rely on the doctrine of equivalents to prevent an infringer from avoiding infringement by making insubstantial changes to the invention as literally claimed.

It is important for the company to ensure those responsible for FDA approval are aware of patent strategy and submissions and those responsible for patent protection are aware of FDA strategy and submissions. In this way, companies can prevent risks from potentially conflicting FDA and patent objectives. Arguments should be vetted and approved by both teams, for example, to ensure arguments for equivalency are worded in a way to limit their scope to safety and efficacy. The coordination and timing of disclosures and events can be especially critical to the achievement of competing FDA and patent goals. Otherwise, a leak of information about an invention during the FDA approval process, before a patent application is filed, can destroy the opportunity for meaningful patent protection. A premature conclusion to the prosecution of a patent application can result in patents that do not protect the FDA-approved and most commercially viable product.

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