Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

510(k) In Patent Litigation: Applicants Should Be Cautious

Law360, New York (April 13, 2015, 10:57 AM ET) --

Medical device manufacturers often view their patent strategies and risk assessment as wholly separate form their regulatory approval process. But there is at least one potential intersection of these two functions with serious implications: the use of representations regarding predicate devices in 510(k) devices in subsequent patent litigation. Consequently, in crowded technical areas or markets with histories of aggressive patent assertion, medical device companies would be well advised to understand the potential implications for representation made in the course of their 510(k) submissions.

Carlos Perez-Albuerne

Before any medical device can be marketed or sold within the United States, it must first receive approval from the U.S. Food and Drug Administration. This approval takes different forms depending on how the FDA classifies the subject device. Under 21 U.S.C. § 360(k), at least 90 days prior to launch, any person proposing to begin commercial distribution of a covered device must make a "premarket notification" to, and obtain approval from, the FDA.

One mechanism to obtain approval is by utilizing the accelerated process outlined in Section 510(k) of the Food, Drug and Cosmetic Act. The 510(k) process applies predominantly to class II devices — those medical devices that pose an "intermediate level of risk" to the public and is principally focused on the applicant's ability to demonstrate to the FDA that its new device is at least as safe and effective as an existing device currently being marketed with FDA approval. More specifically, the process entails the applicant establishing that the new device is "substantially equivalent" to at least one predicate device that has been legally marketed.

As a part of the 510(k) process, and in order to establish the safety and efficacy of the new product, the applicant must furnish to the FDA a statement of intended use. The statement must identify the "diseases and conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended." To the extent that the intended use of the new product differs from that of the predicate device(s), the applicant must establish that any distinguishing factors do not render the new device less safe or less effective than the predicate device. The applicant must also describe the "technological characteristics" of the new device, establishing that elements of design, material selection, chemical composition, etc. are either the same, or not less safe and effective than the predicate device.

Intersection With Patent Allegations

Once a 510(k) notification is cleared by the FDA, the document becomes publicly available. Any person or entity, including an entity involved in a patent infringement dispute against the applicant, may then access the 510(k) filing via a Freedom of Information Act request or through discovery in a civil case. A successful 510(k) applicant may be justifiably concerned (or be blissfully unaware) that rival patent holders can easily gain access to a document comparing the technological characteristics of its device to another device that could be argued to be practicing the rival's patented technology. Likewise, the 510(k) submission could reveal that the marketer and seller of a medical device has itself taken the position that a new product that allegedly practices its own patented technology is the "substantial equivalent" of a predicate device that is in the prior art. In fact, these issues have arisen in court cases involving patent infringement and inequitable conduct.

Some Courts Have Found Aspects of 510(k) Filings Inadmissible

Generally, courts have found that claims of "substantial equivalence" in 510(k) filings may not be considered admissions of patent infringement. In 2008, the Federal Circuit stated in John's Hopkins v. Datascope Corp. 543 F.3d 1342, 1349 (Fed. Cir. 2008) that FDA equivalence was not relevant to infringement because it involves "fundamentally different inquiries." Whereas a 510(k) filing compares the new device to the predicate device, or the commercial embodiment of the patent, the inquiry in a patent infringement requires an allegedly infringing device infringes each element of a patent claim.

Other courts have likewise refused to admit 510(k) filings as evidence of infringement. For example, in Ethicon Endo-Surgery Inc. v. Hologic Inc. 689 F. Supp. 2d 929, 935-36 (S.D. Ohio 2010) the U.S. District Court for the Southern District of Ohio held that letters in support of a 510(k) notification were not competent evidence when proffered to support infringement contentions under the doctrine of equivalents. Citing Datascope, the court granted summary judgment to the alleged infringer where the patent holder had sought to introduce evidence from the defendant's 510(k) submission — in which the defendant asserted that the types of motors used in the new and predicate devices were used interchangeably in the same field of use. Id. In Abbott Point of Care Inc. v. Epocal Inc., 2012 U.S. Dist. LEXIS 54435 (N.D. Ala. Apr. 18, 2012), the court held that the admission of information contained in a 510(k) notification, though potentially relevant, must not be admitted because its relevance is substantially outweighed by the danger prejudice and jury confusion.

Other Courts Have Found Aspects of 510(k) Filings Admissible

Despite this favorable case law and the general agreement of courts that the mere claim of "substantial equivalence" cannot be viewed as an admission of infringement, 510(k) filers should be cautious about the claims they make in support of their substantial equivalence assertions. Some courts have held that information related to statements of intended use and those comparing the technological characteristics of a new device with those of a predicate device may be some evidence of infringement.

Though the Federal Circuit's "fundamentally different inquiries" language in Datascope, seems to preclude the admissibility of evidence derived from 510(k) filings, earlier district court cases considering such evidence in specific circumstances, and for specific purposes, arguably still offer guidance as to how 510(k) submissions may be considered. For example, in United States Surgical Corp. v. Hosp. Prods. Int'l Pty 701 F. Supp. 314, 347 (D. Conn. 1988, a case involving surgical stapling instruments, the district court looked to statements made in support of a 510(k) filing, finding that these statements could be

"construed as admissions of infringement."

The court in United States Surgical specifically referenced language made in support of patent defendant's 510(k) filing in which the then 510(k) applicant had stated "both devices utilize the same type of disposable cartridges ... [w]hich utilize similar staples, similar anvils, similar staple line configurations, and the same tissue joining methods." A 1998 U.S. district court case from Florida, University of Florida Research Found. Inc. v. Orthovita Inc., perhaps best demonstrates the fine line courts walk with regard to the admissibility of evidence contained in 510(k) submissions. While holding that that it may not consider the FDA 510(k) notification to determine infringement by equivalence, the court noted that a chart submitted with the 510(k) submission demonstrated a "marked difference" between the applicant's device and the predicate device that was alleged to practice the patent claims at issue.

United States Surgical also exemplifies another potential danger inherent in the intersection of patent cases and 510(k) submissions. In evaluating whether there should be an enhancement in damages due to willful infringement, the court in United States Surgical awarded enhanced damages and attorneys' fees to the patent holder whose product was a predicate device in infringer's 510(k) filing. In finding enhancement justified, the court relied on information included in an infringer's 510(k) submission related to the infringing product as part of the "totality of the circumstances" warranting enhancement of damages and fees.

The Prudent Path

Companies filing 510(k) submissions can reduce the risk of complicating their later patent litigation by choosing predicate devices (when a choice exists) that are less likely to be covered by unexpired patents. These efforts can range from the rather simple, like checking to see if the predicate device is marked, to the more complex, like performing research on the patent portfolios of the manufacturers of potential predicate devices.

If potential issues are identified, either a different predicate device can be chosen, or — if that is not a viable option — care can be taken to distance the specific representations of equivalence in the 510(k) submission from the claimed features of the identified patents. No matter what the situation is, companies have to first recognize the possible interaction and allocate appropriate resources to avoid potential pitfalls.

—By Carlos Perez-Albuerne and Gary D. Finley, Choate Hall & Stewart LLP

Carlos Perez-Albuerne is a partner and Gary Finley is an associate in the intellectual property litigation group at Choate in Boston.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.
