

2013

A Survey of the Legal Landscape Facing Entities with Patents Reciting a Method of Using a Medical Device

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A SURVEY OF THE LEGAL LANDSCAPE FACING ENTITIES WITH
PATENTS RECITING A METHOD OF USING A MEDICAL DEVICE

RIGEL MENARD[†]

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I. INTRODUCTION

This article is a summary of the legal landscape faced by those holding patents that recite a method of using a medical device in the United States. The analysis is limited to medical devices and does not pertain to pharmaceutical drugs.

According to the Food and Drug Administration (FDA), a medical device is:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article, including any component, part, or accessory which is . . . (2)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, or (3)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 . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes.¹

Medical devices are regulated by the FDA, and can also be patentable subject matter.² The FDA rules regarding medical devices include restrictions and requirements on labeling, instructions for using the medical device, and requests for permission to market the medical device, among others.³ A company looking to market a medical device that falls into certain categories defined by the FDA⁴ must get FDA approval before marketing the device.⁵ The idea is that the FDA is a sort of screen that filters out possibly harmful medical devices and insures that the medical devices that are ultimately used will not cause unwanted harm.

Doctors and hospitals are typically the customers of the entities that pursue patents reciting methods of using a medical device, thus making the calculation of whether or not to sue more difficult for the patent holder. One alternative is to try

¹ 21 U.S.C. § 321(h) (2006). It is noteworthy that under the FDA's definition a placebo is considered a medical device.

² 21 C.F.R. § 807 (2006) (“Manufacturers . . . of medical devices must register their establishments with the FDA.”); *see also Device Advice: Comprehensive Regulatory Assistance*, U.S. FOOD AND DRUG ADMINISTRATION (FDA), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm> (last visited Feb. 16, 2013).

³ *See* 21 C.F.R. § 807.87.E (2012).

⁴ *Overview of Device Regulation*, FDA, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm> (last visited Feb. 16, 2013).

⁵ *See* 21 C.F.R. § 807 (2012).

and recover damages for induced or contributory infringement.⁶ With these considerations in mind, investors and inventors of patents reciting methods of using a medical device should exercise more caution than those looking to invest in or pursue other patented methods. This is especially true when the medical device required to carry out the steps in the method of use patent is in the public domain or patented by a different party. The reasons for this are fleshed out in this article. The article utilizes a simple hypothetical situation throughout to help illuminate the issues faced by the “method of using a medical device” patent holder. The simple hypothetical revolves around two entities (Edison and Morse),⁷ a medical device (catheter), and a patented method of using the catheter assigned to one of the entities (Edison).

First, the article begins by reviewing FDA approval procedures,⁸ labeling requirements,⁹ and instructions for use requirements.¹⁰ Second, the article discusses a history of induced infringement¹¹ and a review of induced infringement before and after the recent Supreme Court decision in *Global-Tech Appliances, Inc. v. SEB S.A.* and the Federal Circuit decision in *Akamai Technologies, Inc. v. Limelight Networks, Inc.*¹² Third, the article reviews the scope of immunity from infringement under 35 U.S.C. § 271(e)(1).¹³ Fourth, the article continues with a discussion of off-label use generally,¹⁴ liability for off-label use with promotion,¹⁵ and liability for off-label use without promotion, including a discussion of preemption of state tort claims related to FDA approved devices and the FDA approval process.¹⁶ Fifth, the article addresses the issue of whether applying for and obtaining FDA approval is considered an act of infringement.¹⁷ Interspersed throughout the article is an analysis of what the substantive conclusions mean for the hypothetical situation involving Morse, Edison, the catheter, and Edison’s method of using the catheter.¹⁸ The article

⁶ See 35 U.S.C. § 271(b)–(c) (2006) (defining induced infringement and contributory infringement, respectively); see also *infra* Part III (discussing induced infringement in detail).

⁷ All characters and events in this article, even those based on real people, are entirely fictional.

⁸ See *infra* Part II.

⁹ See *infra* Part II.A–B.

¹⁰ See *infra* Part II.C.

¹¹ See *infra* Part III.

¹² See *infra* Part III.A.

¹³ See *infra* Part III.B.

¹⁴ See *infra* Part IV.

¹⁵ See *infra* Part IV.A.

¹⁶ See *infra* Part IV.B.

¹⁷ See *infra* Part V.

¹⁸ See *infra* Part II.A (“Approval to Market Edison’s Method of Using a Catheter”); see also *infra* Part. II.D (“Edison Files His 510(k) Application”); see also *infra* Part. III.D (“What Inducement to Infringe and 35 U.S.C. § 271(e)(1) Mean to Morse and Edison”); see also *infra* Part

concludes with a summary of the substantive conclusions reached,¹⁹ and some ways the effects of the problems uncovered might be curbed.²⁰

Edison is now on his way to get FDA approval for a method of using the catheter. Let us briefly review what Edison must do to get approval and what Edison will gain if he gets FDA approval for a method of using the catheter.

II. BRIEF REVIEW OF FDA APPROVAL PROCEDURES FOR MEDICAL DEVICES

The FDA utilizes general controls, special controls, pre-marketing controls, and post-marketing regulatory controls to regulate medical devices.²¹ The FDA groups medical devices into three classes based on the risk the device presents to a patient.²² The level of risk determines the level of regulatory control the FDA deems necessary.²³ Thus, the class of device (Class I, II, or III) is a dominant factor in determining what regulations must be adhered to by the entity seeking approval to market the device.²⁴ In the case of a new medical device, the regulatory standards to be used can be decided by comparing the device to other similar, previously legally marketed, medical device classifications and devices with the same technological characteristics.²⁵

The FDA classifies medical devices into three categories: 1) Class I, lowest risk to the patient and lowest regulation; 2) Class III, high risk to the patient and highest amount of regulation; and 3) Class II which falls somewhere between Class I and Class III in both risk and level of regulation.²⁶

Class I devices are typically simple in design and are “not intended for use in supporting or sustaining life or to be of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable

IV.C (“What Off-Label Use Means for Morse”); *see also infra* Part V.A (“Enjoining Morse Through a Declaratory Judgment Suit”).

¹⁹ *See infra* Part V.

²⁰ *See infra* Part VI.

²¹ *See Device Advice, supra* note 2; *see also FD&C Act Chapter V: Drugs and Devices*, FDA, <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/FDCAActChapterVDrugsandDevices/default.htm> (last visited Feb. 16, 2013).

²² *PMA Approvals*, FDA, <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm> (last visited Feb. 16, 2013).

²³ *See id.*

²⁴ *See Classifying Your Medical Device*, FDA, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> (last visited Nov. 19, 2012).

²⁵ *Overview of Device Regulation, supra* note 4.

²⁶ *Id.*

risk of illness or injury.”²⁷ A majority of Class I devices are “exempt from pre-market notification and/or good manufacturing practices regulation.”²⁸

Class II devices are usually subject to special controls like special labeling requirements, mandatory performance standards, post-market surveillance, and FDA medical device specific guidance.²⁹ Class II devices are also typically required to satisfy the pre-market notification requirement with a submission of a 21 C.F.R. § 510(k) (510(k)) clearance to market submission.³⁰

The FDA typically requires those desiring to market a Class III medical device to submit Pre-Market Approval³¹ documentation.³²

A. Approval to Market Edison’s Method of Using a Catheter

To receive approval to market a method of using a medical device, the requisite medical device determines the type of submission that is required. In Edison’s case, a catheter fits the FDA’s definition of a medical device³³ that does not emit radiation.³⁴ The method of using the device is assumed to reside in Class

²⁷ *General Controls For Medical Devices*, FDA, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm> (last visited Feb. 16, 2013).

²⁸ *General and Special Controls: Class I — General Controls*, FDA, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm> (last visited Feb. 16, 2013).

²⁹ *General and Special Controls: Class II — Special Controls*, FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm#class_2 (last visited Feb. 16, 2013).

³⁰ *See id.* Some Class II devices are exempt from this submission. See 21 C.F.R. § 862–92 (2006), for a list of exempt devices.

³¹ The details of Pre-Market Approval (PMA) are outside the scope of this paper. For more details of PMA, see *General and Special Controls: Class III — Premarket Approval*, FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm#class_3 (last visited Feb. 16, 2013).

³² *See id.* Some Class III devices are only required to submit a 510(k) for clearance to market. *Id.*

³³ *See supra* note 1 and accompanying text; *see also* 21 U.S.C. § 321(h) (2006) (“The term “device” . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) 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, or (3) 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 its primary intended purposes.”).

³⁴ 21 U.S.C. § 360(hh) (2006) (defining radiation as: “(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or (B) any sonic, infrasonic, or ultrasonic wave, which is

II. Edison's method of using a catheter happens to require a 510(k) submission (since his patent is a method of using an already existing catheter he can "piggy-back" off the approval of the catheter),³⁵ including submitting satisfactory proposed labels with sufficient directions for use.³⁶ The FDA also requires a statement comparing the device to other comparable devices.³⁷

B. FDA Labeling Requirements

Under the FDA's labeling requirements,³⁸ Edison will need to adhere to the requirements relating to in vivo diagnostic product labeling.³⁹ Among the requirements that Edison must satisfy are the labeling requirements for the immediate container, inserts, and outer packaging.⁴⁰

Another requirement pertinent to patent law includes an adequate statement of the directions for use.⁴¹ If anyone in the chain of distribution intends the device for uses different from those uses intended by those "up-stream" in the chain of distribution, then these parties must furnish adequate labeling for the new

emitted from an electronic product as the result of the operation of an electronic circuit in such product.").

³⁵ *How to determine whether YOUR medical device requires 510(k) submission*, EMERGO GROUP INC., http://www.fda510k.com/file/fda_510k_steps_1_thru_7.pdf (last visited Feb. 16, 2013).

³⁶ See 21 C.F.R. § 807.87(e) (2012) (listing information required in a premarket notification submission). There is no standard application form for a 510(k) submission, but instructions are provided at 21 C.F.R. §§ 807.87–807.95 (2012).

³⁷ *Labeling: Regulatory Requirements for Medical Devices*, FDA, at 16 (Aug. 1989), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf>.

³⁸ 21 C.F.R. § 801 (2012).

³⁹ *Id.*

⁴⁰ *Id.*; see also *Labeling: Regulatory Requirements for Medical Devices*, *supra* note 37, at 12–13. Example requirements for labeling on the immediate container include the name of the product; the intended use; warnings or precautions for users listed in 16 C.F.R. § 1500; name and place of business of the manufacturer, packer, or distributor; and lot or control number traceable to product history. *Id.* Labeling requirements for inserts and outer packaging must include the product name; intended use of the product and whether it is a qualitative or quantitative type of procedure; a summary of the test including methodology, special merits, and limitations of the test; and the scientific principles of the procedure. *Id.* In the case of an instrument, the outer packaging must also include the use or function, installation procedures and requirements, principles of operation, performance characteristics and specifications, operating instructions, calibration procedure, operational precautions and limitations, hazards, and service and maintenance information, among others. *Id.* at 13.

⁴¹ Food, Drug, and Cosmetic Act § 502(f)(1)–(2), 21 U.S.C. § 352(f) (2006); 21 C.F.R. § 801.5 (2012) ("Adequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended."); see also *infra* Part II.C.

intended use.⁴² Also, in the case of a manufacturer that knows, or has information indicating that the device is to be used in ways other than that which the manufacturer is seeking approval, the manufacturer is required to provide adequate labeling in accordance with such other uses.⁴³ On its face, the rule seems to require one who becomes aware of off-label uses of his product to provide instructions or warnings regarding the newly discovered use of the product; however, at least one court has not found this to be the case.⁴⁴ In *Riley v. Cordis Corp.*, the District Court of Minnesota held that 21 C.F.R. § 801.4 does not require a manufacturer to provide instructions for use or warnings for uses that the manufacturer became aware of after FDA approval was granted for a different use.⁴⁵ The court reasoned that the FDA did not intend 21 C.F.R. § 801.4 to preempt their stringent restrictions on altering labels.⁴⁶ In other words, the *Riley* court concluded that in order to harmonize the FDA's rules, 21 C.F.R. § 801.4 cannot be viewed as creating an affirmative duty to change labeling in accordance with uses that the manufacturer becomes aware of after getting FDA clearance.⁴⁷

C. Directions for Use, Indications and Usage, and Intended Use Requirements

The FDA requires most applicants to submit materials regarding “adequate directions for use,” “indications for use,” and “intended use.”⁴⁸ Edison will have to include all of these requirements in his submission to satisfy his 510(k) labeling submission requirement.⁴⁹ Directions for use include statements of all purposes for which the device is intended, and route or method of applying the device,

⁴² 21 C.F.R. § 801.4 (2012) (stating that if the intended use changes after introduction into “interstate commerce,” then “such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses”).

⁴³ *Id.* (“But if a manufacturer knows . . . that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.”).

⁴⁴ *See Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 782 (D. Minn. 2009).

⁴⁵ *See id.* (“It seems highly unlikely that . . . § 801.4 was forcing manufacturers who knew of off-label uses of their devices but did not promote those off-label uses to provide instructions or warnings.”).

⁴⁶ *See id.*

⁴⁷ *See id.* (“It would make no sense to impose on manufacturers who were *not* promoting off-label uses of their devices a duty to instruct or warn, but to impose no such duty on manufacturers who *were* promoting off-label uses. The existence of this statutory scheme at the time relevant to this action strongly suggests that § 801.4 did not impose additional labeling requirements on manufacturers of Class III devices when those manufacturers become aware of off-label uses of their products.”) (emphasis in original).

⁴⁸ *See* 21 C.F.R. § 801.4–5 (2012).

⁴⁹ *See* Food, Drug, and Cosmetic Act § 502(f), 21 U.S.C. § 352(f) (2006).

among others.⁵⁰ The indications and usage submission, while not explicitly required in the 510(k) submission, has been a requirement under a substantial equivalence submission, and requires an accurate statement of the intended actions of the device.⁵¹

D. Edison Files His 510(k) Application

Edison diligently and accurately begins preparing his 510(k) device submission; this requires more than a nominal amount of time, money, and effort.⁵² It turns out that Edison does not have the capital required to fully prepare the 510(k) submission or perform all of the tests necessary to attain the data needed for FDA submission. To this end, he creates a sales pitch that he presents to investors to try and get the investors to invest in his method of using the catheter. As the backbone of his pitch, Edison uses the fact that he attained exclusionary rights through his method of use patent. He also states that he has the ability to sue for direct infringement if the entity infringing is not exempt from suit for infringement. Finally, he pitches that he may have a case for indirect infringement if the direct infringer is exempt from suit. His pitch is successful and he acquires an investor to invest sufficient, and substantial,⁵³ capital to fund the FDA submission. With sufficient capital in hand Edison works with FDA medical device regulation specialists, label manufacturers, and packaging specialists, just to name a few, in perfecting his 510(k) submission. Edison files the FDA report and is surprised to find that his submission goes through without a hitch and he is cleared to market his patented *in vivo* method of using a catheter. Now Edison is granted the ability to legally market and distribute his product to the general public.

It turns out that Edison's method of using the catheter is a huge success. In fact, Edison's method is so much of a success that Morse decides that trying to piggyback on Edison's success in the catheter market could be quite lucrative for him too. If Morse could just get one method of using a catheter approved for marketing and distribution, he could sell the catheter to hospitals, which could

⁵⁰ 21 C.F.R. § 801.5 (2012) ("Adequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended.").

⁵¹ *Id.* § 801.4.

⁵² JOSH MAKOWER ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION: A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES 6–8 (Nov. 2010). In a report prepared by Stanford University researchers, with support from the Medical Device Manufacturers Association, National Venture Capital Association, and multiple state medical industry organizations, it was reported that it took about ten months from filing to clearance and about \$24 million on FDA dependent and related activities. *Id.*

⁵³ *Id.*

then use the catheter for any use,⁵⁴ including the incredibly popular method of using the catheter that is patented and FDA approved by Edison. Further, Morse knows that he could even use Edison's 510(k) application submission to help him gain FDA approval. Morse would find it ideal if he could submit a 510(k) essentially identical to Edison's submission and be granted the ability to distribute the catheter in virtually the same way as Edison, including the same instructions for use and labeling. However, in Morse's quest to determine if he is able to piggyback on Edison's FDA approval for Edison's patented method of using a catheter without liability, which would definitely be possible if Edison did not have his method of use patent, Morse discovered a form of legal liability known as induced infringement.

III. BRIEF HISTORY OF INDUCED INFRINGEMENT

Prior to the 1952 Patent Act, no statute defined infringement.⁵⁵ In addition, Congress wanted to replace some of the existing patent case law that attempted to define infringement.⁵⁶ To this end, Congress took the opportunity to provide a statutory definition of indirect infringement.⁵⁷ Prior to 1952 there existed direct infringement and contributory infringement. The former was the unauthorized making, using, or selling of a patented invention. The latter was anything that was not technically direct infringement, but where a defendant displayed sufficient culpability to be held liable as an infringer (typically joint and several liability as a tortfeasor with a primary infringer).⁵⁸ Pre-1952 contributory infringement concerned mostly components that were built with no other use but an infringing one, where the component had no use outside of a use with an infringing product or process.⁵⁹ The Patent Act of 1952 split contributory infringement into

⁵⁴ See *infra* Part IV.

⁵⁵ Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. DAVIS L. REV. 225, 227 (2005) ("Indeed, it was not until the Patent Act of 1952 that the idea of active inducement was separated from the offense of contributory infringement. That statute codified a prohibition against contributory infringement in section 271(c) and against inducement in section 271(b).") (footnotes omitted).

⁵⁶ See 5 R. CARL MOY, *MOY'S WALKER ON PATENTS* § 15:2 (4th ed. 2012).

⁵⁷ See *id.* § 15:10; see also 35 U.S.C. § 271(b)–(c) (2006) ("(b) Whoever actively induces infringement of a patent shall be liable as an infringer. (c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.").

⁵⁸ See 5 MOY, *supra* note 56, §§ 15:1, 15:10.

⁵⁹ See Soonbok Lee, *Induced Infringement as a Strict Liability Claim: Abolishment of the Specific Intent Requirement*, 4 HASTINGS SCI. & TECH. L.J. 381, 399 (2012) ("It must be noted that

contributory infringement and active inducement of infringement, and these methods of infringing became what are now known as indirect infringement.⁶⁰

Post 1952 infringement has been governed generally by 35 U.S.C. § 271(a) which states that the United States will impose liability on one who makes, uses, sells, or offers to sell an invention set out in a patent.⁶¹ 35 U.S.C. § 271 continues by providing two other ways that one can be held liable for infringement: (1) by inducing another to infringe and (2) by contributing to the infringement of another by providing articles that are not staples of commerce.⁶² Thus, a cause of action for induced infringement is provided under 35 U.S.C. § 271(b), which states simply, when one “actively induces infringement of a patent [they] shall be liable as an infringer.”⁶³ As 35 U.S.C. § 271(b) is short and not detailed, there has been a significant body of case law on the topic of what exactly § 271(b) encompasses.⁶⁴

*A. Induced Infringement Before and After Global-Tech Appliances v SEB S.A.*⁶⁵

The induced infringement statute simply states that “[w]hoever actively induces infringement of a patent shall be liable as an infringer.”⁶⁶ Induced infringement, as liability for an act of joint tortfeasance, requires an act of direct infringement in order to establish liability.⁶⁷ This direct infringement can be

a contributory infringer defined in § 271(c) is presumed to have specific intent or express purpose to cause another's infringement under the pre-1952 case law because he sells products which are specially adapted to a patent infringement.”)

⁶⁰ See 5 MOY, *supra* note 56, § 15:10 (“The provisions, particularly paragraph (c), set out a relatively detailed statement of when liability is to exist, and leave comparatively little room for additional case law development. The legislative history is replete with indications that Congress sought to replace the existing case law to some extent.”).

⁶¹ 35 U.S.C. § 271(a) (2006).

⁶² *Id.* § 271(b)–(c).

⁶³ *Id.* § 271(b).

⁶⁴ See, e.g., *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2069 (2011) (noting that willful blindness is sufficient to determine intent in induced infringement cases); *Tegal Corp. v. Tokyo Electron Co.*, 248 F.3d 1376, 1378–79 (Fed. Cir. 2001) (“‘Actively inducing,’ . . . requires an affirmative act of some kind.”); *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1569 (Fed. Cir. 1994) (“[J]urisdiction here cannot be based on a tortious *omission*, since active inducement of infringement requires the *commission* of an affirmative act.”) (emphasis in original).

⁶⁵ *Global-Tech*, 131 S. Ct. 2060.

⁶⁶ 35 U.S.C. § 271(b) (2006).

⁶⁷ See *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986). The notion that an act of direct infringement is required for one to be liable for inducement was revisited in *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012) (en banc), which is discussed below. See also *infra* Part III.B.

proven by direct testimony or circumstantial inference.⁶⁸ In general, inducing infringement requires a purposeful intent that direct infringement occurs, and that actual steps are taken to aid the direct infringement.⁶⁹ Plaintiffs claiming induced infringement must also show that the defendant had threshold knowledge and purposefully intended that the infringement occur.⁷⁰ Prior to the *Global-Tech* decision in May of 2011, it was unclear whether an induced infringement defendant must have known of the patent at issue prior to the inducing acts in order to be held liable.⁷¹ Also, before the *Global-Tech* decision, it was accepted that the threshold knowledge requirement was satisfied if a defendant to an induced infringement claim knew or should have known that their acts would result in another entity infringing a patent.⁷² The lower court in the *Global-Tech* case held that a deliberate indifference to a patent's existence is equivalent to actual knowledge of the patent's existence.⁷³ The Supreme Court clarified that it is not enough to show that a defendant to an induced infringement suit knew that there was a chance that the activities could violate a patent but paid no attention to the risk.⁷⁴ Instead, an induced infringement plaintiff must show that the defendant knew that the person being induced would violate the patent.⁷⁵ However, the Court utilized the doctrine of willful blindness to reach the same decision as the lower court⁷⁶ and officially endorsed use of the doctrine of willful blindness in civil suits for induced patent infringement.⁷⁷

⁶⁸ See 5 MOY, *supra* note 56, § 15:15; see also *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1219 (Fed. Cir. 2006) (stating that direct infringement can be proved by direct as well as circumstantial evidence).

⁶⁹ See *Beverly Hills*, 21 F.3d at 1569 (stating that inducement cannot be premised on an omission because “active inducement” under 35 U.S.C. § 271(b) requires “an affirmative act”).

⁷⁰ See *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 125 S. Ct. 2764, 2779 (2005).

⁷¹ See *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011).

⁷² *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1376 (Fed. Cir. 2010), *cert. granted*, 131 S. Ct. 458 (2010), *aff'd sub nom.*, *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011).

⁷³ See *SEB S.A.*, 594 F.3d at 1377.

⁷⁴ *Global-Tech*, 131 S. Ct. at 2068–72.

⁷⁵ *Id.* at 2067–69.

⁷⁶ *Id.* at 2068–72.

⁷⁷ *Id.* at 2068–69 (“The doctrine of willful blindness is well established in criminal law. Many criminal statutes require proof that a defendant acted knowingly or willfully, and courts applying the doctrine of willful blindness hold that defendants cannot escape the reach of these statutes by deliberately shielding themselves from clear evidence of critical facts that are strongly suggested by the circumstances. The traditional rationale for the doctrine is that defendants who behave in this manner are just as culpable as those who have actual knowledge.”).

*B. Induced Infringement Before and After Akamai Technologies, Inc. v. Limelight Networks, Inc.*⁷⁸

Direct infringement (infringement under 35 U.S.C. § 271(a)), as a strict liability tort, requires a single actor to perform all the steps of a patented method either personally or vicariously to find liability.⁷⁹ Induced infringement gives rise to liability only if the inducement leads to a direct infringement.⁸⁰ A method claim is infringed only if each and every step of the claimed method is performed.⁸¹

In *BMC Resources, Inc. v. Paymentech, L.P.*, the Federal Circuit held that to find induced infringement the inducement must give rise to a direct infringement and the infringement must be committed by a single actor.⁸² The Federal Circuit in *Akamai Technologies, Inc. v. Limelight Networks, Inc.* recognized that the result of *BMC* would immunize from liability a party (1) who performs some of the steps of a patented method himself and induces another to carry out the remaining steps⁸³ or (2) who induces multiple parties to collectively perform each and every step of the patented method.⁸⁴ However, a party who induces a single person to carry out all the steps would generally not be immunized from liability.⁸⁵ The Federal Circuit overturned the *BMC* decision recognizing that:

If a party has knowingly induced others to commit the acts necessary to infringe the plaintiff's patent and those others commit those acts, there is no reason to immunize the inducer from liability for indirect infringement simply because the parties have structured their conduct so that no single defendant has committed all the acts necessary to give rise to liability for direct infringement.⁸⁶

⁷⁸ 692 F.3d 1301 (Fed. Cir. 2012) (en banc).

⁷⁹ See *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1379, 1381 (Fed. Cir. 2007); see also *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1330 (Fed. Cir. 2008).

⁸⁰ See *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 526 (1972); see also *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341 (1961).

⁸¹ See *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1307 (Fed. Cir. 2012) (en banc)..

⁸² *BMC Res.*, 498 F.3d at 1379.

⁸³ *Akamai Technologies*, 692 F.3d at 1305 (citing to *Akamai Technologies, Inc., v. Limelight Networks, Inc.*, 614 F. Supp. 2d 90 (D. Mass. 2009), *aff'd*, 629 F.3d 1311 (Fed. Cir. 2010), *vacated*, 419 F. App'x 989 (Fed. Cir. 2011), *and rev'd and remanded*, 692 F.3d 1301 (Fed. Cir. 2012) (en banc)).

⁸⁴ *Akamai Technologies*, 692 F.3d at 1305 (citing to *McKesson Info. Solutions LLC v. Epic Sys. Corp.*, 2009 WL 2915778 (N.D. Ga. 2009)).

⁸⁵ See *Akamai Technologies*, 692 F.3d at 1309.

⁸⁶ *Id.*

Thus, the *Akamai* decision helps protect those with a patented method in an important way—by making it possible to find indirect infringement liability in some situations where multiple parties carry out some steps of the patented method and the combination of their actions add up to carrying out all steps of the patented method.⁸⁷

C. Exemption Under 35 U.S.C. § 271(e)(1)

There is an exemption to infringement that shields uses of a patented invention that are reasonably related to the development and submission of information to federal agencies.⁸⁸ This exception was enacted by the legislature in response to vigorous lobbying on behalf of generic drug manufacturers to reverse the opinion in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*⁸⁹ By enacting this statute, Congress reduced the rights of patent holders by permitting competitors to engage in acts that would reasonably generate data the FDA would use, thus reducing patent holders' sales in order to protect health care interests.⁹⁰ The exception also allows possible competitors to be poised and ready to enter the marketplace as soon as the patent expires.⁹¹ Without this exception a patent holder whose patentable subject matter was also subject to the requirements of the FDA would be given a de facto patent extension. This is because gathering data for safety and efficacy study submissions to the FDA could only be possible after the patent term has expired. Thus, the patent holder would be granted a period of time where the patent is no longer enforceable yet no competitors have been able to enter the market yet, because the FDA has not cleared their product.⁹²

Gathering safety and efficacy data reasonably related to submission to the FDA is now a well-known activity that is exempt from infringement liability.⁹³

⁸⁷ *See id.*

⁸⁸ 35 U.S.C. § 271(e)(1) (2006) (“It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”).

⁸⁹ *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1276 (N.D. Cal. 1991).

⁹⁰ *Id.* at 1276–77.

⁹¹ *Id.* at 1277.

⁹² *See Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997).

⁹³ *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990); *Telectronics Pacing Sys., Inc. v. Ventritex Inc.*, 982 F.2d 1520 (Fed. Cir. 1992); *Chartex Int'l PLC v. M.D. Pers. Prods. Corp.*, No. 92-1556, 5 F.3d 1505 (Fed. Cir. 1993) (unpublished opinion).

Specifically, activities that have been held to be reasonably related to gathering safety and efficacy data for submissions to the FDA include: (1) displaying necessary information for clinical testing at trade shows in order to facilitate the clinical trial, including obtaining clinical investigators;⁹⁴ (2) performing consumer studies that provide information for the design of the product to be approved, including studies on the clarity of usage instructions;⁹⁵ (3) raising funds to cover the costs of submitting information to the federal agency;⁹⁶ (4) manufacturing the infringing product when most of the products manufactured are used to generate data for the submission;⁹⁷ (5) informing customers that the product will soon be commercially available;⁹⁸ and (6) selling the device at cost to obtain data on the device's operation in clinical trials.⁹⁹ Also, data gathered from safety and efficacy studies required for submission to the FDA are not restricted to use only in the submission to the FDA; the data can be used, for example, for fund raising and other business purposes.¹⁰⁰ Further, the actions of an infringer are not necessarily outside the exemption because, for example, the otherwise infringing uses either failed to generate information in which a federal agency was interested or generated more information than turned out to be necessary to secure FDA approval.¹⁰¹

The standard used to determine if the actions are reasonably related to a federal agency submission is whether it would have been objectively reasonable for a party, in the alleged infringer's situation, to believe that there was a decent prospect that the "use" in question would directly contribute to the generation of kinds of information that are likely to be relevant in processes by which the federal agency would rely on when deciding whether to approve the product.¹⁰² It is important to note that the exemption does not necessarily terminate with the submission of information to the federal agency, so long as it is objectively reasonable for the company in the alleged infringer's position to believe that continued data gathering would, relatively directly, contribute to the generation of

⁹⁴ *Telectronics Pacing Sys.*, 982 F.2d at 1523 ("[S]uch demonstrations constitute an exempt use reasonably related to FDA approval, because device sponsors are responsible for selecting qualified investigators and providing them with the necessary information to conduct clinical testing.").

⁹⁵ *Chartex Int'l*, No. 92-1556, at *3, 5 F.3d 1505.

⁹⁶ *Intermedics*, 775 F. Supp. at 1281.

⁹⁷ *Id.* at 1282.

⁹⁸ *Abtox, Inc. v. Exitron Corp.*, 888 F. Supp. 6 (D. Mass. 1995), *aff'd*, 122 F.3d 1019 (Fed. Cir. 1997), *and opinion amended on reh'g*, 131 F.3d 1009 (Fed. Cir. 1997).

⁹⁹ *Intermedics*, 775 F. Supp. at 1289.

¹⁰⁰ *Telectronics Pacing Sys., Inc. v. Ventritex Inc.*, 982 F.2d 1520, 1525 (Fed. Cir. 1992).

¹⁰¹ *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 207 (2005); *Intermedics*, 775 F. Supp. at 1280.

¹⁰² *See Merck*, 545 U.S. at 200.

a kind of data relevant to the federal agency's inquiry.¹⁰³ This gives those seeking FDA approval considerable leeway to engage in infringing activities especially since it can be difficult to determine what types and quantities of information will be required to attain the FDA's approval.¹⁰⁴

D. What Inducement to Infringe and 35 U.S.C. § 271(e)(1) Mean to Morse and Edison

The Federal Circuit and the United States Supreme Court seem to be moving in the direction of further protecting patented methods as is illustrated by the *Global Tech* and *Akamai* cases. Edison is excited that courts expanded liability for inducement to infringe to include multiple parties carrying out the method. However, these expansions do not deter Morse who is excited about the prospect of being able to take a catheter and use it to do some clinical testing and promotion, including clinical testing on Edison's patented method of using the catheter, and be protected from infringing by 35 U.S.C. § 271(e)(1). While Morse would very likely not be able to legally market the device for Edison's patented method of use without actively inducing infringement¹⁰⁵ until the patent expires, he can still pursue approval for Edison's method of use and not be liable to Edison as long as he stands behind the shield of 35 U.S.C. § 271(e)(1).

While this is not ideal to Morse, since he cannot enter the market until Edison's patent expires,¹⁰⁶ he is still excited to know that he can have conversations about the approval that he is seeking from the FDA and the data he is gathering for approval in order to secure financial backing, obtain clinical investigators, and manufacture some catheters. Morse knows that all of this activity will undercut some of Edison's sales of the catheter in the process, since Edison currently has a monopoly on the patented method.

Expectedly, Morse does not want to wait twenty years for the patent to expire to enter the market and start seeing cash flow. To this end, he does a little research into off-label use to see if he can sell the same catheter that Edison's popular method of use requires, but label it for a different method of use, even though his

¹⁰³ *Intermedics*, 775 F. Supp. at 1282.

¹⁰⁴ *Id.* at 1280 (“[I]t will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win that agency's approval.”); see also 21 C.F.R. § 312.22(b) (2012) (“The amount of information on a particular drug that must be submitted . . . depends upon such factors as the novelty of the drug, the extent to which it has been studied previously, the known or suspected risks, and the development phase of the [product].”).

¹⁰⁵ See *infra* Part V (discussing how FDA submissions and requirements have been used as evidence in infringement suits).

¹⁰⁶ See *infra* Part V (discussing how FDA submissions and requirements have been used as evidence in infringement suits).

secret goal is to sell the device knowing that the people he is selling to will use the device for Edison's patented method.

IV. OFF-LABEL USE

The FDA has never had the power to regulate the practice of medicine;¹⁰⁷ it merely has authority to regulate the introduction of medical devices into the commercial market.¹⁰⁸ To make certain that the FDA is not allowed to interfere with the practice of medicine, Congress enacted legislation stating that the FDA shall not “limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”¹⁰⁹

It has been said that off-label uses of medical devices (using a device for some other purpose than that for which it has been granted FDA approval) is an accepted and necessary corollary of the FDA’s mission to regulate in the area of commercial medical devices without directly interfering with the practice of medicine.¹¹⁰ The Supreme Court recognized this notion by noting that off-label use promotes the mission of the FDA.¹¹¹ Further, the FDA itself recognizes the value of off-label uses.¹¹²

The acceptance of off-label uses in the medical community stems from the knowledge that not every use of a medical device beneficial to the practice of medicine will be scrutinized by the FDA for approval. Certain approaches to utilizing medical devices may only be reported on extensively in medical literature, and new uses for FDA approved medical devices are often discovered

¹⁰⁷ See *In re Orthopedic Screw Prods. Liab. Litigation*, MDL No. 1014, 9408-0002, 1996 WL 107556, at *3 (E.D. Pa. 1996) (“[T]he ‘decision whether or not to use a drug for an off-label purpose is a matter of medical judgment[,] not of regulatory approval.’”) (alteration in original) (quoting *Klein v. Biscup*, Nos. 68615, 68659, at *13 (Ohio Ct. App. Feb. 15, 1996)).

¹⁰⁸ See *Regulation of Medical Devices: Background Information for International Officials*, FDA, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070958.htm#1> (last visited Feb. 16, 2013).

¹⁰⁹ 21 U.S.C. § 396 (2006).

¹¹⁰ See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 76–77 (1998) (noting that the “FDA itself recognize[s] the value and propriety of off-label use”).

¹¹¹ *Buckman*, 531 U.S. at 350.

¹¹² 12 FDA DRUG BULLETIN: USE OF APPROVED DRUGS FOR UNLABELED INDICATIONS 4–5 (1982), available at http://www.circare.org/fda/fdadrugbulletin_041982.pdf (“Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling.”).

through opportune observations and innovations.¹¹³ Public acceptance of off-label use is further justified on the grounds that by allowing physicians greater freedom to practice medicine patients are given treatment at lower costs because requiring FDA approval for all treatments would require significant time and money to achieve approval, thereby driving up the cost of the treatment.¹¹⁴ Acceptance of off-label use is further bolstered by the myriad of illnesses and disease with popular off-label treatments, including cancer, heart disease, AIDS, kidney disease, and osteoporosis.¹¹⁵ To illustrate the extent to which off-label use has permeated the practice of medicine, some studies suggest that off-label uses make up twenty-five to sixty percent of all prescriptions written each year.¹¹⁶

A. Court Enforced Liability of Off-Label Use with Promotion

If the FDA finds that a company is promoting their product for an unapproved use, they can take civil and criminal action, with penalties including payment of large fines and enjoinder of marketing activities.¹¹⁷ While the FDA can give hefty fines to a manufacturer for promoting its product for an off-label use,¹¹⁸ the liability of the manufacturer may not end there. Courts recognize a potential liability for a manufacturer's negligence in promoting its product for a non-approved use.¹¹⁹

In *Sita v. Danek Medical, Inc.*, the defendant was charged with negligence for the promotion of an off-label use of a bone screw.¹²⁰ The plaintiff alleged that the

¹¹³ *Id.*

¹¹⁴ N.J. STAT. ANN. § 26:1A-36:9(g) (West 2012) (“‘Off-label’ use of FDA-approved drugs provides efficacious drugs at a lower cost. To require that all appropriate uses of a drug undergo approval by the FDA may substantially increase the cost of drugs and delay or even deny patients’ ability to obtain medically effective treatment. FDA approval for each use would require substantial expenditure and time to undergo the clinical trials necessary to obtain FDA approval.”)

¹¹⁵ See Beck & Azari, *supra* note 110, at 80.

¹¹⁶ See *id.*

¹¹⁷ *In re Orthopedic Cone Screw Prod. Liab. Litigation*, 159 F.3d 817, 828 (3d Cir. 1998) (“[A] device cleared under § 510(k) cannot lawfully be marketed for a use other than the use specified in the clearance. Thus, if such a device is marketed for another purpose, the manufacturer may be civilly and criminally sanctioned and the marketing enjoined.” (citing 21 U.S.C. § 331–332 (2006))); see also *FDA News Release: FDA Fines American Red Cross \$16 Million for Prior Failures to Meet Blood Safety Laws*, FDA, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm216156.htm> (last visited Feb. 16, 2013).

¹¹⁸ 21 U.S.C. § 331 (2006) (“The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.”).

¹¹⁹ See *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 262 (E.D.N.Y. 1999); see also *Proctor v. Davis*, 682 N.E.2d 1203, 1215 (Ill. App. Ct. 1997).

¹²⁰ See *Sita*, 43 F. Supp. 2d at 263.

defendants promoted the off-label use by funding seminars, textbooks, and universities to teach off-label procedures using the bone screws.¹²¹ The court stated:

To prevail, plaintiff must establish that [the doctor] was influenced by illegal marketing efforts which, in effect, made the use of [the bone screws] . . . in the pedicles of the spine so prevalent that the off-label use of such screws became the standard of care in [the doctor's] medical community.¹²²

The court held that the plaintiff's evidence was sufficient to overcome summary judgment on this issue; however, under the informed intermediary doctrine¹²³ no reasonable jury could conclude that the doctor's continued use of the bone screws was caused by defendant's promotion.¹²⁴

To contrast, in *Proctor v. Davis*, the Illinois Court of Appeals found that a manufacturer participated in and encouraged the providing of misleading information about its drug to hospital staff.¹²⁵ This finding relied on evidence that the defendant gave financial support and drug supplies to the hospital staff, as well as made contributions to journal articles.¹²⁶ Further, the court noted that the manufacturer is held to the standard of an expert, and since the manufacturer knew of the use in question, promoted the use, failed to warn against the dangers of such a use, and the medical community did not know of the risks of using the product at the time the injury in question was incurred, the manufacturer had a duty to warn of the risks associated with the use and was liable for the injuries caused by the off-label use.¹²⁷

At this point it is unclear what actions are required by courts to hold someone liable for promoting their product for off-label use. However, it is known that there must be a causal connection between the manufacturer's actions and the physician's actions. This connection is generally required to be strong due to the medical profession's independence and presumed expertise.

¹²¹ *See id.*

¹²² *Id.*

¹²³ RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(d) (1998) (“A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings . . .”).

¹²⁴ *Sita*, 43 F. Supp. 2d at 264.

¹²⁵ *Proctor v. Davis*, 682 N.E.2d 1203, 1211–12 (Ill. App. Ct. 1997).

¹²⁶ *Id.* at 1208.

¹²⁷ *Id.* at 1214.

B. Do Courts Hold Liability for Off-Label When One Knows of the Use but Doesn't Promote the Use?

The issue of whether a manufacturer can be held liable for a use of its product that is off-label, even when the manufacturer did not promote its product for the use that caused the injury was addressed in *Davenport v. Medtronic, Inc.*¹²⁸ The plaintiff in *Davenport* suffered from Parkinson's disease and had a tremor control system surgically implanted that ultimately did not control the tremors he suffered from.¹²⁹ The plaintiff sued for negligence, breach of implied and express warranties, and strict product liability.¹³⁰ In deciding whether the claims were capable of surviving summary judgment, the court first determined whether the claims were preempted by 21 U.S.C. § 360(k).¹³¹ The court concluded that the only claim preempted by the Medical Device Amendments (MDA) was the implied warranty of merchantability claim,¹³² because the defendant utilized the FDA's Pre-Market Approval (PMA) process in getting privileges to market the product,¹³³ the FDA imposed specific federal requirements relating to the product,¹³⁴ and the accepted standards of design and manufacture for products in the state would be different from, or in addition to, the requirements imposed by the FDA.¹³⁵ In disposing of the remainder of the claims, the court reasoned that the plaintiff has not demonstrated that the device in question violates the federally

¹²⁸ *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419, 426 (E.D. Pa. 2004).

¹²⁹ *See id.* at 427.

¹³⁰ *Id.* at 428.

¹³¹ 21 U.S.C. § 360(k) (2006) is part of the Medical Device Amendments (MDA) to the Federal Food, Drug, Drug, and Cosmetic Act (“[N]o state or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.”).

¹³² *Davenport*, 302 F. Supp. 2d at 442.

¹³³ *Id.* at 432.

¹³⁴ *Id.* at 434.

¹³⁵ *Id.*; *see also* *Medtronic, Inc., v. Lohr*, 518 U.S. 470, 512 (1996) (upholding the notion that a 510(k) doesn't have preemptory power). The notion that a PMA application has preemptive power, while a 510(k) application does not, was later upheld in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323–25 (2008), where the Court answered two questions. First, did the FDA establish requirements applicable to Medtronic's catheter? *Id.* at 321–22. And, second, if so, does the plaintiff's common-law claims rely upon any requirement of state law that is different from or in addition to the FDA's requirements? *Id.* at 323. In answering the second question, the Court distinguished *Lohr*, where the Court concluded that a 510(k) substantial equivalence determination did not establish requirements for the device in question from the present case on the grounds that the PMA process used in the present case established specific requirements for the manufacture of the catheter in question. *See id.* at 323–30.

imposed regulations in some way.¹³⁶ Notably, this test is consistent with the tests used by other districts in similar cases.¹³⁷

In *Medtronic, Inc. v. Lohr*, the Supreme Court held that “the ‘substantial equivalence’ provision [of a 510(k) submission does] not pre-empt the [defendant’s] design [defect] claims.”¹³⁸ The Court, however, left open whether PMA approval would have preemptory power under 21 U.S.C. § 360(k).

The Supreme Court had a chance to visit the issue of whether PMA approval would have preemptory power¹³⁹ in the case of *Riegel v. Medtronic, Inc.*¹⁴⁰ In *Riegel*, the plaintiff had a catheter, subjected to FDA approval through the PMA process, rupture in his coronary artery while undergoing heart surgery.¹⁴¹ The plaintiff sued for breach of implied warranty, negligence, and strict liability.¹⁴² Unlike the court in *Davenport*, the Court in *Riegel* determined that the claims were not based on the defendant’s violation of federal law, but instead were based on general common law tort liability.¹⁴³ The Court then determined that the state tort negligence, breach of implied warranty, and strict liability claims were all preempted by the MDAs to the Federal Food, Drug, and Cosmetics Act.¹⁴⁴

In summary, a 510(k) application has no preemptory power on state tort liability claims under 21 U.S.C. § 360(k), but a PMA does have such preemptory power if the claimant is not claiming that the defendant violated a federal regulation.

¹³⁶ *Davenport*, 302 F. Supp. 2d at 435–37.

¹³⁷ See *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 799 (8th Cir. 2001) (“[The plaintiff] has presented no evidence that [the manufacturer] violated federal regulations or refused to add warnings drafted by the FDA, changed FDA-approved labels failed to meet regular reporting requirements, [or] failed to report a known hazard to the FDA”); see also *Kozma v. Medtronic, Inc.*, 925 F. Supp. 602, 603 (N.D. Ind. 1996) (“Defendant has offered considerable proof that it complied with FDA regulations in every aspect of the design, manufacture and labeling of its pulse generator and leads. This evidence is sufficient to shift the burden to the Plaintiffs to produce evidence that the Defendant had not complied with FDA regulations in manufacturing the specific pacemaker involved in this case.”).

¹³⁸ *Lohr*, 518 U.S. at 494.

¹³⁹ The effect of holding that the PMA process has preemptory power would be a bar to state common-law claims that challenge the effectiveness or safety of a medical device marketed in a form that received premarket approval from the FDA. See *Riegel*, 552 U.S. at 316.

¹⁴⁰ *Id.* at 312.

¹⁴¹ *Id.* at 320.

¹⁴² *Id.* at 320, 330 (“The District Court held that the MDA pre-empted the [plaintiffs’] claims of strict liability; breach of implied warranty; and negligence The Second Circuit affirmed.”).

¹⁴³ *Id.* at 328.

¹⁴⁴ See *id.* at 326–29.

In cases where a court determines that the claims are not preempted by the 21 U.S.C. § 360(k) learned intermediary doctrine, the requirement that the physician read or rely on an affirmative statement of the manufacturer can be used to bar a plaintiff from relief.¹⁴⁵ Some courts have even gone so far as to suggest that a manufacturer will not be liable in the case of an inadequate warning if the physician knew of the risk.¹⁴⁶ Another noteworthy holding is that claims alleging that a defendant made misrepresentations to the FDA are preempted under the FDA.¹⁴⁷

C. What Off-Label Use Means for Morse

The proof that a plaintiff must provide to be successful on a claim for manufacturer negligence, namely, demonstrating that the physician relied on the manufacturer's statements in their decision to perform off-label treatments, and that the physician did not have independent knowledge of a risk that an adequate warning would have communicated, is quite a high threshold to meet. This, combined with the courts' willingness to uphold the learned intermediary doctrine, the MDA's preemption clause interpretation by the Supreme Court, and many courts requiring proof that a physician would rely on a warning if a warning were given, create a high bar for holding a defendant liable absent proof of promoting an off-label use. If a defendant has promoted the off-label use, courts would be more likely to hold the defendant liable. However, the proof that has been required to hold the defendant liable is still quite high because of the assumed independence and expertise of the medical profession.

Since Morse is using the 510(k) process, he needs to be careful not to promote his catheter for an off-label use, because the 510(k) approval process has no state

¹⁴⁵ See *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162–64 (4th Cir. 1999) (utilizing the learned intermediary doctrine to bar the plaintiff from relief in a failure-to-warn case where the plaintiff was injured by a doctor who was using a bone screw for an off-label use).

¹⁴⁶ See *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1365 (S.D. Fla. 2007) (“[F]ailure of the manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of a patient’s injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated.” (quoting *Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir. 1995))); *Motus v. Pfizer*, 196 F. Supp. 2d 984, 995–98 (C.D. Cal. 2001) (stating that the plaintiff failed to prove that the prescribing physician would have acted differently had an adequate warning been made); *Minisan v. Danek Med., Inc.*, 79 F. Supp. 2d 970, 978 (N.D. Ind. 1999) (“[E]ven if the manufacturer provides inadequate information . . . the manufacturer will not be liable if the plaintiff’s physician independently knew of the risks and failed to advise the plaintiff.” (citing *Wheat v. Sofamor*, S.N.C., 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999))).

¹⁴⁷ *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (“So, for example, a state-law claim that the defendant made misrepresentations to the FDA is preempted because such a claim would not exist absent the federal regulatory scheme established by the FDCA.” (citing *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 352–53 (2001))).

tort claim preemptory power. Notwithstanding that, Morse can promote his device for one use, but the use that he promotes does not limit what a physician does with the device. If Morse knows about his catheter being used for Edison's patented, off-label method, he should adhere to some safe practice guidelines to avoid promoting the off-label use. If he takes steps, like training employees on only the FDA approved methods of use, keeping promotional materials strictly limited to the approved method of use, and keeping any documents or advertising and promotional materials free from references to off-label uses, he will likely not have to worry about his activity being suspicious or leading to liability.

Morse is also excited about the prospect of possibly being able to indirectly fund entities and endeavors that educate about off-label uses of his catheter without being liable to anyone, like the manufacturers in *Sita*.¹⁴⁸

Further, Morse can feel relatively safe from liability for fraud on the FDA. His intent to sell the catheter, while knowing that it will be used for Edison's patented method of use, will likely never become known after he has received approval from the FDA, because the claim will either be preempted, or the burden of proof required for liability would likely be too high to attain.

At this point things are looking up for Morse. While all this is pretty good news, it still isn't enough for Morse who needs to know how far he can go before he is liable to Edison for his actions. Morse knows that the clinical trial exception in 35 U.S.C. § 271(e)(1) was enacted to allow competitors to enter the marketplace as soon as a patent expires, and he would like to be poised to market the catheter for Edison's patented use as soon as Edison's patent expires. To this end, Morse is wondering how far in advance of the expiration of Edison's patent might he be able to get FDA approval, without being held liable for infringement.

V. IS SIMPLY OBTAINING FDA APPROVAL SUFFICIENT FOR INDUCED INFRINGEMENT LIABILITY?

The labels, instructions for use, and indications and usage sections of the FDA requirements have all been used as evidence of the intent to encourage a direct infringement.¹⁴⁹ These FDA requirements have also been used as evidence to

¹⁴⁸ See *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 263, 265 (E.D.N.Y. 1999).

¹⁴⁹ See *Wyeth v. Sandoz, Inc.*, 703 F. Supp. 2d 508, 521 (E.D.N.C. 2010) ("The instructions on Sandoz's label and Sandoz's submission . . . is undisputed circumstantial evidence of Sandoz's specific intent to induce the direct infringement of doctors, pharmacists, and patients."); *Abraxis Bioscience, Inc. v. Navinta, LLC*, 640 F. Supp. 2d 553, 570–71 (D.N.J. 2009) ("Statements in a package insert that encourage infringing use of a drug product are alone sufficient to establish intent to encourage direct infringement." (citing *AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp. 2d 615 (D.N.J. 2009))), *rev'd*, 625 F.3d 1359 (Fed. Cir. 2010).

establish actual infringement.¹⁵⁰ Also, communications with the FDA and product literature associated with an FDA submission have been used as evidence concerning whether infringement has occurred.¹⁵¹ However, actual infringement remains a requirement for liability to be held in induced infringement cases.¹⁵² Since medical devices are generally not subject to the Hatch-Waxman Amendments,¹⁵³ which state that simply filing an Abbreviated New Drug Application (ANDA) can itself be an act of infringement, the filing of an application to the FDA under 510(k) or PMA requirements is not in and of itself sufficient to support a claim for infringement of a method of using a medical device.¹⁵⁴

A. Enjoining Morse Through a Declaratory Judgment Suit

In *Sierra Applied Sciences, Inc. v. Advanced Energy Industries, Inc.*, the Federal Circuit stated their test for upholding a declaratory judgment action to enjoin a potential infringer from acting.¹⁵⁵ The two part test requires “both (1) an explicit threat or other action . . . which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.”¹⁵⁶

In *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, the Federal Circuit affirmed a district court's decision that a declaratory judgment action to enjoin a potential future infringer was not immediate enough when the future infringer had

¹⁵⁰ See *Bayer Schera Pharma AG v. Sandoz, Inc.*, 741 F. Supp. 2d 541, 548 (S.D.N.Y. 2010) (“The ‘Indications and Usage’ section of . . . [the] FDA-approved label . . . [Make clear that] the FDA has not approved the method-of-use set forth in the [patent].”); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 98 F. Supp. 2d 362, 378 (S.D.N.Y. 2000) (“[T]he Roxane Package Insert states, ‘For control of severe chronic pain in patients, this drug should be administered on a regularly scheduled basis, every 12 hours.’ On these bases, the Court finds that Roxicodone SR satisfies the final limitation of Claim 2 of the ‘912 patent.”) (citation omitted).

¹⁵¹ See *Bayer Schera Pharma AG*, 741 F. Supp. 2d at 548 (“[T]he FDA's letter approving Bayer's NDA for Yasmin, make clear—as a matter of law—that the FDA has approved Yasmin only for use as an oral contraceptive.”).

¹⁵² See *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006); see also *Gen. Surgical Innovations, Inc. v. Origin Medisystems, Inc.*, No. 99-1382, 99-1390, 250 F.3d 761 (Fed. Cir. 2000) (unpublished opinion); *Abraxis*, 640 F. Supp. 2d at 570–71.

¹⁵³ See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (noting that 35 U.S.C. § 271(e)(1) was enacted as a result of the Hatch-Waxman amendments and is an important exception to the rule that medical devices are not covered under the Hatch-Waxman amendments).

¹⁵⁴ See *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1525–27 (Fed. Cir. 1992).

¹⁵⁵ 363 F.3d 1361, 1373 (2004).

¹⁵⁶ See *id.* (citing *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993)).

just begun clinical trials.¹⁵⁷ Part of the court's reasoning relied on the fact that the approval applied for is not always what ultimately gets approved for marketing.¹⁵⁸ So the question becomes, at what point in the FDA approval process do the requirements necessary to sustain a declaratory judgment action against a potential future infringer become satisfied, if ever?

District courts have cautioned that “subjecting the defendants to an infringement litigation . . . may run afoul of the Congressional policy underlying the [35 U.S.C.] section 271(e)(1) exemption. The purpose of the clinical trials exemption is to expedite the arrival of generic drugs on the market upon the expiration of a patent”.¹⁵⁹ The Federal Circuit has held that nine months is too remote.¹⁶⁰ However, courts have recognized the importance of having infringement questions answered at their earliest possible stage, and that FDA approval is good cause for bringing a declaratory judgment action regarding infringement claims.¹⁶¹

Glaxo, Inc. v. Novopharm, Ltd. is a case in which the requirements for standing to bring a declaratory judgment action were met.¹⁶² In *Glaxo*, the Federal Circuit agreed that, although the plaintiff was currently shielded from liability under 35 U.S.C. § 271(e)(1), the court could still hear the plaintiff's action where FDA approval was imminent and there was evidence that the defendant was preparing to import its product while there was a patent still in force.¹⁶³

In summary, courts have been reluctant to determine if future infringement would occur if FDA approval would be granted. This is because there is no

¹⁵⁷ See *Telectronics*, 982 F.2d at 1527 (Fed. Cir. 1992) (“At the commencement of the suit, Ventritex's device had only recently begun clinical trials [T]he district court could have correctly ruled that the case lacked sufficient immediacy and reality to meet the actual controversy requirement under the Declaratory Judgment Act, 28 U.S.C. § 2201 (1988), and that it had no jurisdiction to hear the declaratory judgment count.”).

¹⁵⁸ See *id.* (“There was no certainty that the device when approved would be the same device that began clinical trials; product changes during testing are contemplated by statute, 21 U.S.C. § 360(j)(g)(w)(C)(iii) (1988) . . .”).

¹⁵⁹ *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 112 (D. Mass. 1998); see also *Telectronics*, 982 F.2d at 1525 (“By permitting the testing and regulatory approval process to begin well before a controlling patent had run its course, Congress must have intended to allow competitors to be in a position to market their products as soon as it was legally permissible.”).

¹⁶⁰ *Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990) (“Here, Lang failed to meet the actual controversy requirement necessary to maintain Count I under the Declaratory Judgment Act. The accused infringing ship's hull would not be finished until at least 9 months after the complaint was filed.”).

¹⁶¹ See *Amgen*, 3 F. Supp. 2d at 113 (outlining the warning that “[t]here may be . . . events prior to FDA approval that would constitute good cause”).

¹⁶² 110 F.3d 1562 (Fed. Cir. 1997).

¹⁶³ *Id.* at 1571.

guarantee that the product approved would be the same as that applied for—the FDA process is long and there is no guarantee that approval will be granted at all. To make a statement on such a device that it is immune from infringement under 35 U.S.C. § 271(e)(1) could undermine the policy behind the statute. However, courts have recognized that FDA approval, especially when combined with other compelling circumstances, can be sufficient cause to bring a declaratory judgment suit against a potential infringer.¹⁶⁴

In the end, there is no liability for infringement for simply seeking and getting FDA approval. A successful declaratory judgment claim in situations such as these would result in a court ruling on whether or not using the product in the approved way would constitute infringement. This is not a determination that one is liable for induced infringement if a customer uses the device for the approved use. However, in all likelihood, such a situation would be sufficient to conclude that the customer was induced to infringe. The requisite intent needed to prove induced infringement would come from the indications and usage and the instructions for use.

B. What Declaratory Judgments Mean for Morse

Morse will be able to apply for FDA approval of Edison's patented method of use as soon as he is able and ready to do so. He will be able to undercut some of Edison's sales through the clinical trials required to gain FDA approval, as long as he is careful not to use the catheter for Edison's use after he is no longer shielded under 35 U.S.C. § 271(e)(1). After he gets approval and abstains from promoting the device for Edison's patented use, Edison can sue for a declaratory judgment on the grounds that if the device were used in the approved manner, then that act is an infringing one. This is fine by Morse who knows that all of the clinicians that helped him gain FDA approval, all of the trade shows he attended, and all of the fund raising events he held, are all indirect promotions for utilizing his device for Edison's popular method of use.¹⁶⁵ Morse can leverage this power by getting as many people involved in the FDA approval process as reasonably possible to still be under the protection of 35 U.S.C. § 271(e)(1).

VI. SUMMARY

Edison obtained a patent and FDA approval for a method of using a medical device that turned out to be popular and lucrative enough for Morse to desire entry into the market to undercut some of Edison's sales. Morse learned that he can apply for approval to market a different method of using the same catheter that Edison's patented method uses and promote the use of that catheter for a use

¹⁶⁴ See *id.*; see *supra* note 161 and accompanying text.

¹⁶⁵ See *supra* Part III.C.

that is different from Edison's without being liable for infringement. If Morse learns that physicians are using the catheters that he is selling for Edison's use, he will likely not be liable to Edison if he is careful not to promote the catheter for Edison's patented method. In fact, it is unlikely Edison will be able to sustain an induced infringement claim, because Morse likely failed to exhibit the requisite intent to induce the physician to use the catheter in the infringing way. Moreover, any claims based on state tort claims, or fraud on the FDA, will likely be insufficient to sustain liability because of the strength of the learned intermediary doctrine and the preemptory power of the MDA. To gain a further foothold on Edison's market, Morse can apply for FDA approval for Edison's patented method and enjoy protection under 35 U.S.C. § 271(e)(1). Thus, he will be able to undercut some of Edison's sales and be poised to promote his catheter for Edison's patented use the day that the patent expires. The end result is that Edison's ability to exercise his right to exclude others from using his method of using the catheter is limited by 35 U.S.C. § 271(e)(1), the doctrines of off-label use, the learned intermediary doctrine, and 21 C.F.R. § 360(k) that preempts some state tort claims.

VII. POSSIBLE SOLUTIONS TO THE REDUCED VALUATION OF METHOD OF USE MEDICAL DEVICE PATENTS

One possible solution is that the FDA requires persons that are pursuing approval for using a medical device to affirmatively disclaim that their approved use does not include other uses of the same device. This requirement could be readily visible in the labeling of the device sold by the manufacturer and visible to the physicians that are using the device. However, this solution, by affirmatively disclaiming other uses of the device, is implicitly recognizing the other approved uses of the device. Thus, this proposed solution may have the opposite effect than that which is desired, that is, the proposed solution may actually encourage the device to be used for other methods. This is especially true given the FDA's refusal to regulate the medical practice, and a court's recognition of the propriety and value of off-label uses.

A better way to curb the negative effects on the valuation of the method of using a medical device is to recognize medical devices as being covered by the Hatch-Waxman amendments, specifically recognizing a pseudo-infringement suit for filing a 510(k) FDA application for a method of using a medical device that has already been approved, and is patented. This would allow courts to declare that the FDA approval being sought would be an act of infringement if the approval sought was actually carried through. This would basically allow courts a more lenient immediacy requirement in deciding whether they have jurisdiction to hear a declaratory judgment action. In doing so, courts, combined with the FDA, may be able to curb the effect of 35 U.S.C. § 271(e)(1), which allows a

manufacturer to indirectly promote a product for infringing uses through clinical trial studies. However, this curbing effect comes at the cost of more FDA regulation. The FDA would be required to provide something akin to the Orange Book used for pharmaceutical drugs for medical devices, and also, it would likely create more litigation.

Regardless of whether any of the possible solutions presented are implemented, it is clear that those seeking a patent on a method of using a medical device should secure proper counsel in drafting their patent and pursuing FDA approval. The claims of the patent should be drafted, as much as possible, such that a single, direct infringer could infringe the method without an easy work around. Such claim drafting techniques can help avoid the intent and knowledge requirements that are required to prove multi-party induced infringement. In pursuing FDA approval of a patented method, competent counsel should be employed to oversee the paperwork and clinical testing results submitted for FDA approval to make sure that the actions fall under the 35 U.S.C. § 271(e)(1) shield. Also, when it is known that a medical device has a patented off-label use, it is critical that the manufacturer refrain from promoting that use of the medical device. Competent counsel will be able to help the manufacturer take steps to avoid such claims, such as by providing some proper disclaimers and possible language to use in promoting the device to avoid promoting the device for the off-label use. In this way, the minefield that is the legal landscape for methods of using medical devices can be navigated more safely and efficiently.