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The Evolving 510(k) System and its Effect on Patent Litigation

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THE EVOLVING 510(K) SYSTEM AND ITS EFFECT ON PATENT LITIGATION

Jessica Alm[†]

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I. INTRODUCTION

The 510(k) application process for approving lower-risk medical devices under the Food and Drug Administration (FDA)¹ has recently come under criticism for its lack of adequately measuring the safety and effectiveness of medical devices.² To remedy this situation, the FDA created a taskforce to study the current 510(k) system.³ This taskforce recently submitted its recommendations to the FDA as to what changes need to be made to increase the effectiveness of the 510(k) application process.⁴

The regulation of medical devices came into effect with the Medical Device Amendments of 1976 (MDA).⁵ These amendments were passed to encourage the research and development of medical devices but also “to protect the public from harm caused by the use of medical devices.”⁶ The MDA created the system of premarket approval for medical devices.⁷ It also created an exception whereby devices that could claim substantial equivalence to an already legally marketed device did not have to undergo the premarket approval process.⁸ This exception is currently referred to as the 510(k) approval process.

The goal of this note is to examine how the proposed changes to the 510(k) system may affect future patent litigation. This will be done by examining the background of the FDA approval process in detail and then exploring the changes that have been proposed to the 510(k) process. Next, this article will examine how the 510(k) approval process affected determinations of patent validity and patent infringement claims in the past. Finally, this article will analyze how the proposed changes to the 510(k) approval process may affect patent validity and patent infringement claims going forward.

¹ 21 U.S.C. § 360e (2006).

² Letter from Jeffrey Shuren, Dir., Ctr. for Devices & Radiological Health, FDA, to the American Public (on file with the FDA), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239451.pdf>.

³ *Id.*

⁴ COMM. ON THE PUB. HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, INST. OF MED., MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 1 (2011) [hereinafter Committee on Effectiveness of 510(k) Process].

⁵ Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. §§ 301–392 (2006)).

⁶ William Stute, *Note: Federal Preemption and the Medical Device Amendments: Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), 23 WM. MITCHELL L. REV. 949, 956 (1997).

⁷ 21 U.S.C. § 360e (2006).

⁸ *See id.* § 360e(b)(1)(B).

II. BACKGROUND TO THE FDA MEDICAL DEVICE APPROVAL PROCESS

This section sets out how the FDA regulates medical device manufacturers, looking specifically at how it approves medical devices based upon their risk level. Medical devices are put into one of three classes based upon the level of risk they pose to the patient.

A. *Medical Device Regulatory Classification System*

The FDA established three different regulatory classes for medical devices⁹ dependent upon the level of control necessary to determine their safety and effectiveness.¹⁰ Medical devices that are given a Class I status consist of low-risk medical devices which require only general control under the FDA.¹¹ The standard of general control is applied to all medical devices and requires medical device manufacturers to follow basic regulations to ensure the safety and effectiveness of their medical devices.¹² Medical devices can be given Class I status in two different ways. The first is if the device is not represented for use as a life supporting or life-saving means, or is needed to prevent impairment of human health.¹³ The second is if the device “does not present a potential unreasonable risk of illness or injury.”¹⁴

Medical devices that are given Class II status are moderate-risk devices that require both general controls and special controls.¹⁵ Special controls are supposed to provide assurance of the safety and effectiveness of the device.¹⁶ Special controls for Class II status medical devices include “promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines . . . recommendations, and other appropriate actions as the Secretary deems necessary”¹⁷

⁹ 21 U.S.C. § 360c (2006).

¹⁰ U.S. Food and Drug Admin., *Device Classification*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> [hereinafter *Device Classification*] (last updated Apr. 27, 2009).

¹¹ See 21 U.S.C. § 360c(a)(1)(A) (2006).

¹² See *id.* § 360c(a)(1)(A)(i); U.S. Food and Drug Admin., *General Controls for Medical Devices*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm> (last updated May 13, 2009).

¹³ 21 U.S.C. § 360c(a)(1)(A)(ii)(I) (2006).

¹⁴ *Id.* § 360c(a)(1)(A)(ii)(II).

¹⁵ *Id.* § 360c(a)(1)(B).

¹⁶ *Id.*; see also U.S. Food and Drug Admin., *General and Special Controls*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm> (last updated Apr. 23, 2009).

¹⁷ 21 U.S.C. § 360c(a)(1)(B) (2006).

Medical devices that are given Class III status are high-risk medical devices that require both general controls and premarket approval.¹⁸ Premarket approval is a complex and comprehensive system for proving the safety and effectiveness of devices that are purported for use in supporting or sustaining human life, or devices that may present unreasonable risks of illness or injury.¹⁹ The requirements for obtaining premarket approval are set forth in 21 U.S.C. § 360e.²⁰

As such, the regulatory class is generally dispositive of the manner in which the FDA approves a medical device for marketing.²¹ Class I and Class II medical devices may be exempt from any approval process if they are either pre-amendment devices that have not been significantly changed or modified, or if they are specifically exempt by regulation.²² Otherwise, Class I and Class II medical devices must be approved for market by the FDA through the submission of a 510(k) application.²³ Class III medical devices must be approved under a Premarket Approval application, unless the device is a preamendment device and premarket approval has not been called for.²⁴

B. *Background of the 510(k) Process*

The 510(k) process of approving a medical device is a quicker and less demanding way to bring a device to market as compared to the premarket approval process. The main goals of the 510(k) program are to facilitate innovation by allowing medical devices to come to market faster, while ensuring that all medical devices are safe and effective.²⁵ The 510(k) program requires that

¹⁸ See *id.* § 360c(a)(1)(C).

¹⁹ *Id.*

²⁰ (2006); see also U.S. Food and Drug Admin., *Premarket Approval (PMA)*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm> [hereinafter *Premarket Approval*] (last updated Jan. 24, 2012).

²¹ See *Premarket Approval*, *supra* note 20.

²² U.S. Food and Drug Admin., *Class I/II Exemptions*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm> (last updated May 13, 2009). Preamendment devices refer to devices that had been marketed in the U.S. prior to the Medical Device Amendments of 1976. *Id.* The Medical Device Amendments were intended to give the FDA authority over the approval of medical devices depending on their safety and effectiveness. See *Medical Device Amendments of 1976*, *supra* note 5.

²³ 21 U.S.C. § 360e (2006); see also *Device Classification*, *supra* note 10.

²⁴ *Device Classification*, *supra* note 10.

²⁵ U.S. Food and Drug Admin., *510(k) and Science Report Recommendations: Summary and Overview of Comments and Next Steps*, 1 (2011) [hereinafter *510(k) and Science Report Recommendations*], <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239449.pdf> (last visited Apr. 18, 2012).

all Class I and Class II medical device manufacturers (except those that are exempt) submit their 510(k) application ninety days before they plan on bringing their product to market.²⁶

Under the current regulations, a 510(k) submission should include basic information about the device including the name of the device, what class the device falls within, and information about the company marketing the device.²⁷ A submission must include information that will be used to market the device, including proposed labeling and advertising materials.²⁸ Title 21 of the Code of Federal Regulations states in section 807.87(e) that “[w]here applicable, photographs or engineering drawings should be supplied.”²⁹ One must also include a brief description of the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device which may include what materials are used to manufacture the device, the physical properties of the device, and the design of the device.³⁰

One must also include a statement of substantial equivalence to a predicate device in the form of “a statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement.”³¹ This means direct comparison of the proposed medical device to the “predicate [device]”, to which the 510(k) submission is claiming equivalence.³²

C. Confidentiality of the 510(k) Application

The FDA lists the name, manufacturer, and the 510(k) summary of all approved 510(k) applications on their website within a month of their approval.³³

²⁶ 21 C.F.R. § 807.81 (2012).

²⁷ 21 C.F.R. § 807.87(a)–(d) (2012); *see also* U.S. Food and Drug Admin., *Content of a 510(k)*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm> [hereinafter *Content of a 510(k)*] (last updated Mar. 15, 2012) (listing other elements required to ensure that the 510(k) is complete).

²⁸ 21 C.F.R. § 807.87(e) (2012).

²⁹ *Id.*

³⁰ *Id.* § 807.92(a)(4).

³¹ *Id.* § 807.87(f).

³² *Id.* § 807.92(a)(3).

³³ U.S. Food and Drug Admin., *510(k) Clearances*, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm> [hereinafter *510(k) Clearances*] (last visited Mar. 24, 2012); *see, e.g.,* U.S. Food and Drug Admin., *January 2011 510(k) Clearances*, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm242640.htm> (last updated Apr. 21, 2011).

Typically, all medical devices that are approved are listed on the FDA's website unless the 510(k) application can be deemed confidential.³⁴ A medical device 510(k) application can be deemed confidential if the device is not on the market and it has been made clear that the manufacturer does not intend to market the device within ninety days of the 510(k) submission.³⁵ To ensure confidentiality one must request that the 510(k) application be kept confidential by stating that no notification has been made to anyone about the intent to someday market the device, and the commissioner must agree that the intent to market the device should be kept as confidential commercial information.³⁶

III. PROPOSED CHANGES TO THE 510(K) PROCESS

The 510(k) process has come under criticism lately for not being a sound system to approve devices for market.³⁷ The 510(k) system works by evaluating a medical device's safety and effectiveness by comparing the new medical device to another medical device that is considered a substantial equivalent of the new medical device.³⁸ Thus, a medical device may be approved under the 510(k) system if it could be deemed substantially equivalent to another medical device that was also approved under the 510(k) system, *ad infinitum*. This leads to a situation where a medical device that is approved through a 510(k) application may be based upon a substantially equivalent medical device that was on the market prior to 1976, and as such has never been approved by the FDA.³⁹

In August 2010, the FDA's Center for Devices and Radiological Health (CDRH) released the preliminary reports from their 510(k) Working Group that was established to review the 510(k) process and propose changes to the program.⁴⁰ The FDA also asked the Institute of Medicine (IOM) to create a task force to review the 510(k) system as an outside party. The IOM created the Committee on the Public-Health Effectiveness of the FDA 510(k) Clearance Process and released their recommendations to the FDA in July 2011.⁴¹

³⁴ See *510(k) Clearances*, *supra* note 33.

³⁵ 21 C.F.R. § 807.95(b) (2012).

³⁶ *Id.* §§ 807.95(b)(1)-(2).

³⁷ See, e.g., Letter from Jeffrey Shuren, *supra* note 2, at 1.

³⁸ See 21 C.F.R. §§ 807.87(j) (2012); see also *Content of a 510(k)*, *supra* note 27.

³⁹ David R. Challoner & William W. Vodra, *Medical Devices and Health — Creating a New Regulatory Framework for Moderate-Risk Devices*, 365 NEW ENG. J. MED. 977, 978 (2011), available at <http://www.nejm.org/doi/full/10.1056/NEJMp1109150>.

⁴⁰ *510(k) and Science Report Recommendations*, *supra* note 25, at 1.

⁴¹ Committee on Effectiveness of 510(k) Process, *supra* note 4, at 3.

A. *The Institute of Medicine's Recommendations*

In a letter from David Challoner⁴² to Jeffrey Shuren⁴³ sent July 20, 2011, the IOM stated it was their opinion that the 510(k) process “generally is not intended to evaluate the safety and effectiveness of medical devices and, furthermore, cannot be transformed into a premarket evaluation of safety and effectiveness.”⁴⁴ Thus, IOM’s recommendations focused not on what changes should be made to the 510(k) system but rather on what changes need to be made overall to develop a more rational regulatory framework for medical devices.⁴⁵

The IOM’s report concluded that the 510(k) process lacks the legal basis to be a reliable premarket screen of the safety and effectiveness of moderate-risk devices.⁴⁶ The IOM also focused on the fact that the postmarket surveillance which should be required for medical devices is basically nonexistent under the current 510(k) system.⁴⁷ The IOM suggested that the FDA work to develop a new framework for an integrated pre-market and post-market regulatory system that would focus more intently on the safety and effectiveness of each device throughout its life cycle.⁴⁸ The IOM suggested that the new regulatory system utilize the following six criteria:

[B]e based on sound science; be clear, predictable, straightforward, and fair; be self-sustaining and self-improving; facilitate innovation that improves public health by making medical devices available in a timely manner and ensuring their safety and effectiveness throughout their lifecycle; use relevant and appropriate regulatory authorities and standards throughout the life cycle of devices to ensure safety and effectiveness; and be risk-based.⁴⁹

B. *Overview of FDA's Proposed Changes*

In the preliminary reports released in August 2010, the FDA’s Task Force and Working Group suggested fifty-five changes to improve the 510(k) program and

⁴² Chair for the Committee on the Public-Health Effectiveness of the FDA 510(k) Clearance Process

⁴³ Director of Center for Devices & Radiological Health

⁴⁴ Letter from David Challoner, Chair, Comm. on the Public-Health Effectiveness of the FDA 510(k) Clearance Process, Inst. of Med., to Jeffrey Shuren, Dir., Ctr. for Devices & Radiological Health, Food and Drug Admin. (July 20, 2011) (on file with IOM).

⁴⁵ *Id.* at 2.

⁴⁶ Committee on Effectiveness of 510(k) Process, *supra* note 4, at 3.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

use of science.⁵⁰ The FDA stated in its report, *510(k) and Science Report Recommendations*, that it planned to implement a portion of the report's recommendations in 2011 by taking twenty-five actions which it laid out in its Plan of Action included in the report.⁵¹ The recommendations that will be implemented first will be those that foster innovation, enhance regulatory predictability, and improve patient safety.⁵² The changes that will be implemented include issuing guidance to provide greater clarity about the 510(k) program and improving training for CDRH staff and industry.⁵³ In January 2012, the FDA published a list of the accomplishments they had made under their 510(k) Plan of Action.⁵⁴ The changes that the FDA plans to make that may affect the area of patent law are further discussed below.

1. Adoption of the Use of an "Assurance Case" Framework for 510(k) Submissions

An assurance case is a formal method to prove the validity of a particular claim by a party submitting a convincing argument along with supporting evidence.⁵⁵ Implementing an assurance case framework for 510(k) applications would mean that all information that is submitted to the FDA concerning the description of the device and the intended use of the product would need to be submitted in a more detailed section of the 510(k) application.⁵⁶ Using an assurance case framework would mean that each 510(k) submission would be held to a higher level of completeness and it may prevent early submissions that take too long to correct, thus burdening the FDA review process. To begin to implement this suggestion, the FDA began a pilot program to study the use of an assurance framework for infusion pumps⁵⁷ to determine whether an assurance case framework should be broadly applied.⁵⁸

⁵⁰ *510(k) and Science Report Recommendations*, *supra* note 25, at 3.

⁵¹ *Id.*

⁵² *Id.* at 2.

⁵³ *Id.*

⁵⁴ U.S. Food and Drug Admin., *CDRH Plan of Action for 510(k) and Science*, 1 (2012) [hereinafter *CDRH Plan of Action for 510(k) and Science*], <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM276316.pdf>.

⁵⁵ *510(k) and Science Report Recommendations*, *supra* note 25, at 16.

⁵⁶ *Id.*

⁵⁷ An infusion pump is a Class II medical device intended for use in a health care facility to pump fluids into a patient in a controlled manner. 21 C.F.R. § 880.5725 (2012).

⁵⁸ *CDRH Plan of Action for 510(k) and Science*, *supra* note 54, at 1.

2. *Submit All Scientific Information Regarding Safety and/or Effectiveness*

The 510(k) Working Group also recommended changing the statutory test of 21 C.F.R. § 807.87 to explicitly require anyone submitting a 510(k) application to submit a list and brief description of all scientific information that is known or should be known regarding the safety and/or effectiveness of a new device.⁵⁹ Because this recommendation may become burdensome (especially if the information is not known but would need to be discovered because it should be known), the FDA decided to implement this recommendation on a case-by-case basis.⁶⁰ Thus, the FDA has decided to create device-specific guidance to instruct 510(k) submitters as to when they should submit information about the safety and effectiveness of a new device. Further, they will initially only require 510(k) submitters to submit information that is already known.⁶¹

3. *Submission of Photographs and Schematics*

Under the current 510(k) system, photographs and schematics are sometimes submitted with a 510(k) application; the FDA has found this information to be helpful in making a determination of substantial equivalence.⁶² The FDA therefore decided to change the system to require the submission of detailed photographs and schematics in order to help improve reviewer efficiency and effectiveness.⁶³ To effectively implement this change, the FDA held a public meeting on April 7, 2011 to get public feedback on the change.⁶⁴ The results of this public meeting were not available at the time this article was completed.

4. *Submission of Manufacturing Process Information*

The CDRH already has the ability to request manufacturing information for some devices, but there has been no clarity given about when the ability will be used or should be used.⁶⁵ The change recommended by the CDRH is to provide greater clarity about when this right will be or should be exercised.⁶⁶ The CDRH plans on implementing this recommendation by providing guidance on when the manufacturing information will be requested and pointing to the fact that they will be interested in getting manufacturing information for higher-risk devices.⁶⁷ This

⁵⁹ *510(k) and Science Report Recommendations*, *supra* note 25, at 17.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.* at 8.

⁶³ *Id.* at 8–9.

⁶⁴ *CDRH Plan of Action for 510(k) and Science*, *supra* note 54, at 1.

⁶⁵ *510(k) and Science Report Recommendations*, *supra* note 25, at 19.

⁶⁶ *Id.*

⁶⁷ *Id.*

recommendation will be initially implemented on a case-by-case basis for higher-risk devices and will be tailored to address relevant issues specific to that type of device.⁶⁸

5. Use of “Multiple Predicates”

Under the current 510(k) program, a manufacturer of a medical device can use a “multiple predicate” or “split predicates” when claiming that its device is substantially equivalent to an existing device.⁶⁹ This means that a comparison can be made to one existing device to show the same “intended use” while a comparison can be made to a different existing device to show the new device’s “technological characteristics”.⁷⁰ The 510(k) Working Group recommended that the CDRH develop guidance on the appropriate use of more than one predicate, while at the same time exploring the possibility of explicitly disallowing the use of “split predicates.”⁷¹ This change would mean that in order to submit a 510(k) application that would be approved, a medical device manufacturer would have to use the same predicate device and claim that their device is substantially equivalent to the predicate device in terms of both intended use and technological characteristics. At the time of this writing, the CDRH had completed a preliminary study to review how safe and effective medical devices are when they claim more than one predicate device.⁷² The CDRH’s current plan of action is to implement guidance to clarify when it is appropriate to use multiple predicates, while continuing to monitor what effect these changes might make.⁷³

6. A New Subset of Class IIb Devices

One major change the FDA recommended is the creation of a new subset of medical devices called Class IIb.⁷⁴ The Class IIb devices would potentially require that clinical information, information about manufacturing processes, and additional evaluation in the postmarket setting be required under the 510(k) program for a particular subset of higher risk Class II devices.⁷⁵ The FDA explains that they are not proposing a brand new class of devices. Rather they would try to group higher-risk Class II devices under a “Class IIb” setting when

⁶⁸ *Id.* at 19–20.

⁶⁹ *Id.* at 14.

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² U.S. Food and Drug Admin., *Medical Device Reporting (MDR) Rate in 510(k) Cleared Devices Using Multiple Predicates*, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm275629.htm> (last updated Nov. 12, 2011).

⁷³ *510(k) and Science Report Recommendations*, *supra* note 25, at 14.

⁷⁴ *Id.* at 17.

⁷⁵ *Id.*

filing a 510(k) application so that those device manufacturers are aware that more information would likely be requested by the FDA before their 510(k) application would be approved under the new guidelines.⁷⁶ The FDA further explained that there would be no clear-cut delineation between what qualified as a Class IIa or Class IIb device.⁷⁷ Rather the classification would be determined based upon prior approved devices, and new devices would not be classified into Class IIa or IIb until the FDA had time to meet with and talk to the submitters.⁷⁸ The FDA had not provided a timeline for implementing this recommendation at the time of this writing.⁷⁹

7. Publicly Available 510(k) Searchable Database

The 510(k) Working Group recommended that the CDRH develop a searchable database for all verified 510(k) applications.⁸⁰ It recommended that this database include the 510(k) summary, photographs and schematics of the device (to the extent that they do not contain proprietary information), and information showing how the current 510(k) application is similar to its claimed predicate device(s).⁸¹ Industry participants raised concerns about having detailed schematics, drawings, and/or photographs available to the public because of the increased potential for patent infringement and reverse engineering.⁸² The FDA has explained that the ‘photographs or schematics’ referred to by the Working Group is actually only one photograph or one schematic given by the 510(k) submitter to be used in the database, thus not giving away proprietary information.⁸³ Due to this concern, the FDA held a public meeting on April 7, 2011 to receive public comments about this recommendation.⁸⁴ At the time of this writing, the FDA had not publically announced how it planned to proceed in regards to photographs and schematics going forward.

⁷⁶ *Id.* at 18.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *See id.* at 19.

⁸⁰ *Id.* at 20.

⁸¹ *Id.*

⁸² *Id.* at 21.

⁸³ *Id.* at 21.

⁸⁴ U.S. Food and Drug Admin., *510(k) Implementation: Discussion of an On-line Repository of Medical Device Labeling, and of Making Device Photographs Available in a Public Database Without Disclosing Proprietary Information*, April 7, 2011, <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm243829.htm> (last updated May 13, 2011).

IV. ISSUES WITH PATENT VALIDITY

The following section analyzes how the 510(k) application may play into the validity of patents. As will be explained below, some courts have considered the 510(k) application materials when determining patent validity and some courts have decided that 510(k) materials should not be allowed to play into the determination. There is currently no binding rule about how 510(k) application materials can or should play into determining the validity of a patent during litigation.

A. *Elements to Consider When Determining the Validity of a New Patent*

There are four different criteria that patent applications have to fulfill before the patent application will be granted: that the invention be a new process, machine, manufacture, or composition of matter;⁸⁵ that the invention be useful;⁸⁶ that the invention be novel;⁸⁷ and that the invention be non-obvious.⁸⁸ The following sections evaluate how the 510(k) application may play into the requirements of patentability and the filing of the patent application.

1. *Novelty*

Section 102 of the Patent Act sets out the conditions for patentability.⁸⁹ Section 102 reads in part:

A person shall be entitled to a patent unless- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States⁹⁰

This section sets out the concept of novelty in terms of anticipation. “[I]f a device or process has been previously invented (and disclosed to the public), then it is

⁸⁵ 35 U.S.C. § 101 (2006).

⁸⁶ *Id.*

⁸⁷ *Id.* § 102.

⁸⁸ *Id.* § 103.

⁸⁹ *Id.* § 102.

⁹⁰ *Id.* § 102(a)–(b).

not new, and therefore the claimed invention is ‘anticipated’ by the prior invention.”⁹¹

In *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, the plaintiffs argued that the defendants patent was not valid because it was “anticipated.”⁹² This argument was founded in part on the fact that the defendant had filed a 510(k) application with the FDA for the approval of their medical device one year before they filed their patent.⁹³ The defendant argued that while they filed their 510(k) application over a year before they filed their patent application, the 510(k) application was not made “public” as required by § 102 because the 510(k) application was not made public until they were within a year of filing their patent application.⁹⁴ The court held that while it was known that a 510(k) application had been filed, it cannot, by clear and convincing evidence, show that the medical device was known such as to anticipate the patent.⁹⁵

In *Arthrocare Corp. v. Smith & Nephew, Inc.*, the defendant tried to argue that the 510(k) application materials that had been submitted to the FDA should have been admitted into evidence as relevant to the issue of anticipation.⁹⁶ Particularly the defendant “charge[d] that the submissions demonstrate that the commercial embodiments of the patents in suit have the same principles of operation as prior art devices.”⁹⁷ The court ruled that the 510(k) application materials were not admissible as evidence, because the 510(k) submissions claimed equivalence to commercial embodiments and not the particular claims of the asserted prior art.⁹⁸

In *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, the jury considered the 510(k) applications in their decision that every element for finding anticipation was fulfilled.⁹⁹ The district court overruled the jury’s decision and found that the elements for anticipation were not found, but was subsequently overruled by the Federal Circuit.¹⁰⁰ The Federal Circuit rested their decision on the fact that the jury’s decision was not against the great weight of the evidence.¹⁰¹

⁹¹ Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1369 (Fed. Cir. 2008).

⁹² *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, 634 F. Supp. 2d 1293, 1308 (D. Fla. 2008).

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.* at 1310.

⁹⁶ *Arthrocare Corp. v. Smith & Nephew, Inc.*, 310 F. Supp. 2d 638, 667 (D. Del. 2004).

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1372 (Fed. Cir. 2001).

¹⁰⁰ *Id.* at 1380.

¹⁰¹ *Id.* at 1376.

As seen from the previous decisions, the issue of whether 510(k) applications materials should play into the finding of novelty for patent applications is not resolved.¹⁰² Some courts have allowed the 510(k) application to go to the jury as evidence,¹⁰³ while other courts are less certain about whether or not the 510(k) application contains relevant information for finding anticipation under § 102.¹⁰⁴

2. *Obviousness*

Section 103 of the Patent Act sets out the criteria of non-obviousness for patent applications.¹⁰⁵ Section 103 reads in part as:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.¹⁰⁶

As set out in *Perfect Web Technologies, Inc. v. InfoUSA, Inc.*, a determination of obviousness requires consideration of the “(1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, (3) the level of ordinary skill in the pertinent art, and (4) secondary considerations of nonobviousness.”¹⁰⁷

In *Johnson & Johnson Vision Care*, the plaintiff also claimed that the defendant’s patent application was obvious due to the submission of the 510(k) application.¹⁰⁸ It argued that the predicate devices listed in the 510(k) application and the prior art listed on the patent application disclosed the technology in the patent application and thus deemed the patent obvious.¹⁰⁹ The court denied the

¹⁰² See *supra* notes 91, 92, 96, 99 and accompanying text.

¹⁰³ See *Mentor H/S, Inc.*, 244 F.3d 1365.

¹⁰⁴ See *Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp.*, 634 F. Supp. 2d 1293 (D. Fla. 2008); *Arthrocare Corp. v. Smith & Nephew, Inc.*, 310 F. Supp. 2d 638 (D. Del. 2004).

¹⁰⁵ 35 U.S.C. § 103 (2006).

¹⁰⁶ *Id.* § 103(a).

¹⁰⁷ *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1327 (Fed. Cir. 2009) (*citing* *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007)).

¹⁰⁸ *Johnson & Johnson Vision Care, Inc.*, 634 F. Supp. 2d at 1307.

¹⁰⁹ *Id.* at 1317.

defendant's motion for summary judgment but never explicitly stated if its decision rested upon the use of the 510(k) application materials.¹¹⁰

B. Inequitable Conduct Before the United States Patent and Trademark Office

The other issue to consider when evaluating the validity of a patent is how the applicant conducts itself before the United States Patent and Trademark Office (USPTO). In *Mentor H/S, Inc.*, the district court concluded that the:

[J]ury's verdict was against the great weight of the evidence because [the defendant] asserted in his 510(k) application to the FDA that his prototype was similar in design to the [substantially equivalent device], but then failed to disclose his opinion regarding the similarity of the products to the PTO during prosecution of the . . . patent.¹¹¹

The Federal Circuit reversed the district court's decision on inequitable conduct after finding that the jury's decision was not against the great weight of the evidence, thus finding that the defendant had not represented himself in an inequitable manner before the USPTO.¹¹²

As evidenced in the jury's decision in *Mentor H/S, Inc.* and by the panel of Federal Circuit judge's decision that the district court erred in ruling contrary to the jury's findings, the 510(k) application materials were used as evidence to determine whether inequitable conduct before the USPTO had taken place.¹¹³ Thus, it appears as if the 510(k) application materials may sometimes be used in considerations of inequitable conduct and that the 510(k) materials may be submitted as evidence to the jury.

V. INTERSECTION WITH PATENT LITIGATION

The following sections examine how the use of 510(k) application materials, particularly the substantial equivalence claim that is made on 510(k) applications, intersects with patent litigation. It has been decided by the Supreme Court that the substantial equivalence claim made on 510(k) application materials is not an admission of infringement. But there is currently no binding rule as to how 510(k) application materials may play into other considerations during patent infringement litigation.

¹¹⁰ *Id.* at 1319 (holding that "there is sufficient evidence to create a triable issue of fact on the issue of obviousness").

¹¹¹ *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1372 (Fed. Cir. 2001).

¹¹² *Id.* at 1378.

¹¹³ *Id.* at 1365.

A. *Eli Lilly and Co. v. Medtronic, Inc.*

Eli Lilly was decided by the Supreme Court in 1990 and analyzed the intersection between patent infringement and the materials that are submitted to the FDA for medical device approval.¹¹⁴ The Court held that the alleged infringer's use of a patented invention to develop and submit information for marketing approval of medical devices under the Federal Food, Drug and Cosmetic Act was not infringement.¹¹⁵ This decision was based on section 271(e) of the Patent Act. Section 271(e) of the Patent Act states that:

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 . . . 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.¹¹⁶

The parties to this suit argued whether the text, which appears to apply to pharmaceutical drugs, was intended by Congress to apply to medical devices.¹¹⁷ The Court ultimately held that Congress intended to extend this protection to medical devices.¹¹⁸

Since this decision it has come to be widely held that substantial equivalent claims that are made in 510(k) applications cannot be construed as admissions of direct infringement.¹¹⁹ This may have led to the general idea that 510(k) application materials are not admissible as evidence at trial, but recent court cases may cause some to hesitate.¹²⁰ While courts still hold that the prior art used on FDA 510(k) applications are not an admission of direct infringement,¹²¹ there have been some recent decisions that allow the use of 510(k) materials to be considered in patent litigation cases as supporting materials to other claims.¹²²

¹¹⁴ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

¹¹⁵ *Id.* at 668–69.

¹¹⁶ 35 U.S.C. § 271(e)(1) (2006).

¹¹⁷ *Eli Lilly & Co.*, 496 U.S. at 665.

¹¹⁸ *Id.* at 679.

¹¹⁹ *See, e.g.*, *Am. Med. Sys., Inc. v. Laser Peripherals, LLC*, 712 F. Supp. 2d 885, 905 (D. Minn. 2010); *Sunrise Med. HHG, Inc. v. Airsep Corp.*, 95 F. Supp. 2d 348, 406 (W.D. Pa. 2000).

¹²⁰ *See, e.g.*, *U.S. Surgical Corp. v. Hospital Prods. Int'l Pty., Ltd.*, 701 F. Supp. 314 (D. Conn. 1988) (allowing the admission of 510(k) materials as evidence for deciding whether infringement has happened.).

¹²¹ *See Eli Lilly & Co.*, 496 U.S. 661.

¹²² *See, e.g.*, *U.S. Surgical Corp.*, 701 F. Supp. 314.

B. Patent Infringement

Since *Eli Lilly*, courts have repeatedly held that the 510(k) application is not an admission of patent infringement,¹²³ but they have considered allowing the 510(k) to be admitted at trial as evidence in patent infringement cases.¹²⁴ This section reviews some of the concerns that arise when considering the intersection between the FDA's 510(k) process and patent litigation, especially in light of the recently proposed changes to the FDA 510(k) process.

1. Direct Infringement

Direct infringement of a patent occurs when “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent”¹²⁵ Courts have typically applied a two-part test to determine whether direct infringement has occurred.¹²⁶ The first step, commonly known as claim construction, is to define the meaning and scope of the patent claims alleged to be infringed.¹²⁷ The second step is to compare those claims to the alleged infringing device.¹²⁸

In *United States Surgical Corp. (USSC) v. Hospital Products International Pty. Ltd.*, the plaintiff was bringing an action for infringement of its surgical stapling device against the defendant.¹²⁹ The court stated that:

[T]he defendants have gone so far as to cause statements to be made that may be construed as admissions of infringement. For example, on October 28, 1980, HPI submitted to the United States Food and Drug Administration a § 510(k) pre-market notification . . . [that] stated in the notification that these devices were equivalent to their USSC counterparts. . . . Similarly, on November 16, 1981, SCI submitted to the FDA a second § 510(k) pre-market notification to announce its intention to sell its ILA anastomosis

¹²³ See, e.g., *Am. Med. Sys., Inc.*, 712 F. Supp. 2d at 905 (citing *CardioVention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 840 (D. Minn. 2007)).

¹²⁴ See, e.g., *U.S. Surgical Corp.*, 701 F. Supp. at 347.

¹²⁵ 35 U.S.C. § 271(a) (2006).

¹²⁶ *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996).

¹²⁷ *Id.* (citing *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 821 (Fed. Cir. 1992) (abrogated on other grounds)).

¹²⁸ *Id.* at 976. Direct infringement occurs where each limitation of at least one claim of the patent is found exactly in the alleged infringer's product. See, e.g., *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1577 (Fed. Cir. 1989); *Panduit Corp. v. Dennison Mfg. Co.*, 836 F.2d 1329, 1330 n.1 (Fed. Cir. 1987).

¹²⁹ *U.S. Surgical Corp.*, 701 F. Supp. at 317.

surgical stapling equipment. The SCI device was stated to be “substantially equivalent” to USSC’s GIA surgical stapler¹³⁰

The court ultimately held that HPI did in fact infringe upon USSC’s surgical stapling device patents.¹³¹ This decision did not rely solely on the information provided in the 510(k) application, but the court did consider the information provided in the 510(k) application and allowed it to be admissible as evidence for the plaintiff to prove that infringement had taken place.¹³²

In contrast, the 510(k) application materials were not allowed in court to prove direct infringement in *American Medical Systems, Inc. v. Laser Peripherals, LLC*.¹³³ In *American Medical Systems*, the plaintiff relied on the defendant’s representation made to the FDA in the form of the 510(k) that claimed its product was substantially equivalent to the plaintiff’s invention. The court, following the majority trend, decided this was not an admission of infringement, because substantial equivalence means something different in the FDA context than it does in the patent infringement context.¹³⁴ It appears as if the court choose not to decide whether the 510(k) application should be admissible as evidence on its face, but rather decided that the information would be confusing to a jury and may distract from the litigation at hand.

A similar justification was used for not considering the 510(k) application material in *Sunrise Medical HHG, Inc. v. Airsep Corp.*¹³⁵ The court stated that they placed no reliance on the 510(k) application as “[i]ts sole purpose was to demonstrate to the FDA that the [infringing product] was as safe and effective as the [patented invention]. That purpose was accomplished without any discussion of the differences between the two devices”¹³⁶

Courts have tended to rule that the 510(k) application materials are not admissible as admissions of infringement, but they have yet to determine whether the 510(k) application materials should be considered when looking at a claim for

¹³⁰ *Id.* at 347.

¹³¹ *Id.* at 352–53. The court found that the defendant failed to prove the plaintiff’s patents were invalid or unenforceable and that the plaintiff had proven its claim for infringement. *Id.*

¹³² *Id.* at 347.

¹³³ 712 F. Supp. 2d 885, 905 (D. Minn. 2010).

¹³⁴ *Id.* at 905. The court here relied on the ruling in *CardioVention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830 (D. Minn. 2007), where the court decided in a case of patent validity that the 510(k) information was not admissible to show invalidity of a patent because admission of the 510(k) application materials would be misleading and unfairly prejudicial. *CardioVention, Inc.*, 483 F. Supp. 2d at 840.

¹³⁵ *Sunrise Med. HHG, Inc. v. Airsep Corp.*, 95 F. Supp. 2d 348, 406 (W.D. Pa. 2000).

¹³⁶ *Id.* at 406. The court does not cite any other opinions regarding whether or not to consider 510(k) application materials in patent litigation. *Id.*

direct infringement. For example, the court in *United States Surgical Corporation* decided to take the 510(k) application materials into account when deciding whether direct infringement has happened,¹³⁷ while the courts in *American Medical Systems, Inc.*, and *Sunrise Medical HHG, Inc.* decided not to consider the 510(k) application materials because they did not find them applicable to a finding of direct infringement.¹³⁸ Without a precedential decision of whether the 510(k) application materials should be admissible as evidence to support a finding of direct infringement, companies should be careful about the information that is included in their 510(k) applications.

2. Contributory Infringement

Contributory infringement is set out in the Patent Act in § 271(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.¹³⁹

In order to establish contributory infringement the party must first establish direct infringement.¹⁴⁰ A panel of Federal Circuit judges has explained that contributory infringement is premised on the idea that any defendant who has shown sufficient culpability should be held liable, even if he was not a direct infringer and even if he did not intend to cause or contribute to infringement.¹⁴¹

In *United States Surgical Corporation*, it was found that the defendant had directly infringed on the plaintiff's patents.¹⁴² The court then turned to consider whether the defendant was liable for contributory infringement of the plaintiff's

¹³⁷ *U.S. Surgical Corp.*, 701 F. Supp. at 347.

¹³⁸ *Am. Med. Sys., Inc.*, 712 F. Supp. 2d at 905; *Sunrise Med. HHG Inc.*, 95 F. Supp. 2d at 406.

¹³⁹ 35 U.S.C. § 271(c) (2006).

¹⁴⁰ *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341 (1961).

¹⁴¹ *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990). This has been further explained that there can be no contributory infringement without knowledge that the component was especially adapted for a particular use in a known patent. *Id.*

¹⁴² *U.S. Surgical Corp.*, 701 F. Supp. 314. *United States Surgical Corporation* considers the 510(k) application in their analysis of contributory infringement because they considered the 510(k) application in their analysis of direct infringement and found that the patents had been directly infringed upon. *Id.*

patents. The court ruled that the defendant was liable for contributory infringement, and again the 510(k) application was considered as evidence in considering contributory infringement and was not disallowed.¹⁴³

3. *Infringement Under the Doctrine of Equivalents*

“An accused device that does not literally infringe a claim may still infringe under the doctrine of equivalents if each limitation of the claim is met in the accused device either literally or equivalently.”¹⁴⁴ The doctrine of equivalents can be applied in cases of patent infringement where each element of a claim is not literally infringed, but rather where the difference between the infringing product and the claimed limitation are insubstantial to someone who possesses an ordinary skill in the particular art.¹⁴⁵ A panel of Federal Circuit judges has cautioned that courts may not compare the accused product with the commercial embodiment of the patented invention, but it must be compared to the claims that exist individually in the patent.¹⁴⁶

University of Florida Research Foundation, Inc. v. Orthovita shows how the 510(k) application materials may have a role in determining infringement by equivalents.¹⁴⁷ In *University of Florida Research Foundation, Inc.*, the plaintiffs made a claim for infringement by equivalence, which they planned to prove in part by submitting the 510(k) application materials as evidence of infringement by equivalence.¹⁴⁸ The court found that the “FDA submission [is] fatally deficient in that [it] compare[s] the accused [infringing product], not to the patent claims, but to the commercial embodiment of the patentee’s invention”¹⁴⁹ Relying on the advice of the Federal Circuit,¹⁵⁰ the court decided that the 510(k) application materials were not suitable as evidence because they did not compare the alleged infringed product to the patent claims but rather to the commercial product.¹⁵¹

¹⁴³ *Id.* at 350.

¹⁴⁴ *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1459 (Fed. Cir. 1998) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39–41 (1997); *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 935 (Fed. Cir. 1987) (en banc)).

¹⁴⁵ *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 25 (1997) (citing *Graver Tank & Mfg. Co., Inc. v. Linde Air Products Co.*, 339 U.S. 605, 609 (1950)).

¹⁴⁶ *Zenith Labs. v. Bristol Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994).

¹⁴⁷ No. 1:96-CV-82-MMP, 1998 WL 34007129, at *23 (N.D. Fla. Apr. 20, 1998).

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ Under the doctrine of equivalents the parallel between the infringed product and the patented invention must be made to the individual patent claims and not to the commercial product. *Zenith Labs.*, 19 F.3d at 1423.

¹⁵¹ *Univ. of Fla. Research Found., Inc.*, 1998 WL 34007129, *23.

Similar to the case of direct infringement, the court has not ruled whether the 510(k) application materials should be allowed as evidence of infringement by equivalence. Rather the court decided not to consider the 510(k) application materials on the grounds that they compared the infringing device to the available commercial product and not the patent claims. Without a precedential ruling on this matter, the same concerns arise in light of considering how a 510(k) application may play into patent litigation in the future.

4. *Willful and Deliberate Conduct*

Medical device companies may view what happened in *United States Surgical Corporation* as a warning of how the 510(k) application materials could affect their patent infringement litigation.¹⁵² If a court finds that an infringer acted willfully and deliberately they “may increase the damages up to three times the amount found or assessed.”¹⁵³ In order to determine whether the infringer acted in bad faith the court should consider the elements set out in *Bott v. Four Star Corp.*:

- (1) [W]hether the infringer deliberately copied the ideas or design of another;
- (2) whether the infringer, when he knew of the other’s patent protection, investigated the scope of the patent and formed a good-faith belief that it was invalid or that it was not infringed, and
- (3) the infringer’s behavior as a party to the litigation.¹⁵⁴

In *United States Surgical Corporation*, the 510(k) application materials were considered as evidence in finding direct and contributory infringement. Furthermore, all evidence that was submitted for the finding of infringement was considered in determining whether there was a finding of willful and deliberate conduct.¹⁵⁵ The court decided that the evidence that was made available throughout the course of the trial did show willful and deliberate conduct. This evidence included the 510(k) application materials that had been presented throughout the course of the trial.¹⁵⁶

While the 510(k) application was not conclusive for the finding of willful and deliberate conduct it was considered as a piece of the evidence that eventually lead to that finding. Medical device producers should be aware of this decision

¹⁵² *U.S. Surgical Corp.*, 701 F. Supp. 314.

¹⁵³ 35 U.S.C. § 284 (2006); see *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 923 F.2d 1576, 1579 (Fed. Cir. 1991) (finding that enhanced damages may be awarded in patent infringement action only as penalty for infringer’s increased culpability, namely willful infringement or bad faith).

¹⁵⁴ *Bott v. Four Star Corp.*, 807 F.2d 1567, 1572 (Fed. Cir. 1986).

¹⁵⁵ *U.S. Surgical Corp.*, 701 F. Supp. at 351.

¹⁵⁶ *Id.*

when they decide what information should be included in their 510(k) applications.

C. Validity of Resulting Patent

In *CardioVention, Inc. v. Medtronic, Inc.*, the court ruled that 510(k) materials were not admissible at trial to determine validity of patents.¹⁵⁷ In *CardioVention*, both parties brought motions *in limine*. The plaintiff was seeking a declaration that the defendant's patents were invalid or unenforceable, and the defendant requested that the court exclude any evidence concerning its listing of the plaintiff's device as a predicate device on its 510(k) application to the FDA.¹⁵⁸ The court ruled that the

Admission of the 510(k) evidence would be misleading and unfairly prejudicial to Medtronic. It would also cause undue delay and a waste of time because the parties would litigate the meaning of the FDA regulatory system and the difference between that and the standards for the claims before the jury.¹⁵⁹

The court further stated that the fact that the two inventions in question were substantially equivalent, as defined in terms of the FDA, was not the same as if they were determined substantially equivalent in the trade secret context.¹⁶⁰ Ultimately the court ruled that “[e]ven if the notification is some slight evidence of similarity between the [infringing device] and the [patented invention], this relevance is substantially outweighed by the danger of confusion, of misleading the jury, of undue delay, and of waste of time.”¹⁶¹

In *CardioVention*, the court decided that the 510(k) application materials were not admissible as evidence in determining the invalidity or unenforceability of the plaintiff's patents because the 510(k) application materials would be misleading to the jury.¹⁶² The court based this decision on the majority trend to not allow 510(k) application materials into patent infringement litigation, as it is widely held that the substantial equivalence claim on the 510(k) application is not an admission of infringement.

¹⁵⁷ *CardioVention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 840 (D. Minn. 2007).

¹⁵⁸ *Id.* at 834. Plaintiff also asserted claims of breach of contract, misappropriation of trade secrets, unfair competition, and intentional interference with prospective economic advantage. *Id.*

¹⁵⁹ *Id.* at 840.

¹⁶⁰ *Id.*

¹⁶¹ *Id.* at 841.

¹⁶² *Id.* at 840.

VI. ANALYSIS OF HOW THE FDA 510(K) PROCESS MAY AFFECT PATENT
LITIGATION MOVING FORWARD

Patent law and regulatory law are both important things to consider when developing and marketing medical devices. Medical device manufacturers must be able to protect their invention while at the same time getting FDA approval of their invention. Patent law and regulatory law go hand-in-hand in this aspect, as a medical device manufacturer cannot market his device without first getting FDA approval. At the same time they have to weigh the benefit of patenting a device, sometimes before the FDA has approved the device. Because of the pairing of these two areas of law in medical device manufacturing, it is important to consider the policy justifications behind both systems.

The FDA is charged with “promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.”¹⁶³ Further, the FDA is intended to protect the public health by ensuring that there is a reasonable assurance of the safety and effectiveness of devices that are intended for human use.¹⁶⁴ In comparison, the widely cited justification for the patent system is to promote innovation while at the same time giving the public access to new technologies.¹⁶⁵ This justification for the patent system works because people disclose their inventions to the USPTO, which puts the technology in the hands of any person wanting to access it, and in turn the patent owner gets the right to exclude others from using the invention for a period of twenty years.

When considering the policy justifications of both systems, it appears as if there are some similarities between the two. One main similarity is that both systems are based on the general idea that they are concerned with helping the general public. There is also a similarity in the fact that both have an underlying goal of promoting innovation. The FDA claims to do this by regulating the health field, which helps alleviate consumers’ concerns about new drugs and devices. The patent system claims to do this by rewarding inventors so they disclose their inventions.

One question that remains unanswered is whether the policy justifications of the two systems need to be similar to work efficiently together. It is arguable that they do not have to have the same policy justifications to work well together, but that it would make things easier for medical device manufacturers if they did. More specifically, it may not matter so much whether the underlying policy goals

¹⁶³ 21 U.S.C. § 393(b)(1) (2006).

¹⁶⁴ *Id.* § 393(b)(2).

¹⁶⁵ 1 R. CARL MOY, *MOY’S WALKER ON PATENTS* § 1:26 (4th ed. 2010).

are perfectly aligned but whether the two systems have similar goals moving forward.

A. Analysis of How the Changes to the 510(k) System Will Affect Patent Validity

Courts have not agreed whether the 510(k) application should be admissible as evidence in determining the validity of patents, as evidenced in the above-cited decisions.¹⁶⁶ Thus, it is important for medical device manufacturers to be aware of what information they are releasing in their 510(k) applications. As evidenced by the decision in *Mentor H/S, Inc.*,¹⁶⁷ it is also important for medical device manufactures to consider what information they disclose to the USPTO, as the 510(k) application materials can be used in considering whether inequitable conduct has taken place.

When considering the changes that are being made to the 510(k) process, it is important to think about how this may affect patent validity questions. The proposed change to switch the 510(k) application to be based upon an assurance case framework means that manufacturers will need to state detailed claims about the effectiveness and safety of their device.¹⁶⁸ It also means that incomplete 510(k) applications will not be looked at. The result of this change will be that 510(k) applications will need to include a more detailed description of a device and its intended use, which means there is potentially more information available that can be used in evaluating patent validity. This information may be admissible if the patent application is filed more than a year after the 510(k) application is submitted (concerning novelty) or if there is a claim of infringement (as a party defending against an infringement case could use a more detailed analysis to prove that the patent was anticipated or obvious and thus invalid).

There are also changes proposed that would require a medical device manufacturer to submit more specific information with their 510(k) application.¹⁶⁹ These changes include: providing scientific evidence, providing photographs and schematics, and providing manufacturing process information. This additional information that may be required may also be used to point to the fact that a claimed invention is anticipated or obvious.

The major concern that arises when comparing the changes to the 510(k) system with the patent process is related to the publicly available database.¹⁷⁰

¹⁶⁶ See *supra* Part IV.

¹⁶⁷ *Mentor H/S, Inc. v. Med. Device Alliance Inc.*, 244 F.3d 1365 (Fed. Cir. 2001).

¹⁶⁸ See *supra* Part III.B.1.

¹⁶⁹ See *supra* Part III.B.2–4.

¹⁷⁰ See *supra* Part III.B.7.

Under the current system only the 510(k) summary is made public when a device is approved through the 510(k) process.¹⁷¹ The proposed change to the 510(k) system would include photographs, schematics, or drawings published with every 510(k) application that has been approved, as well as information regarding how the current device is similar to the claimed predicate device.¹⁷² The concern that arises under this situation in relation to patent validity is whether submitting the 510(k) application would be considered a disclosure of the invention. While one has a year window in which to file their patent application after the disclosure of their invention,¹⁷³ publishing a more comprehensive 510(k) summary on the FDA website could lead to trouble for those who fail to file their patent application in a timely fashion. There is currently no binding precedential rule that states whether or not the 510(k) application can be used as a means of showing that the device was anticipated or obvious.¹⁷⁴ Publishing more detailed 510(k) applications in a publically searchable database may prove to be problematic until it is determined how the 510(k) application may play into determining the validity of a patent.

B. Analysis of How the Changes to the 510(k) System May Affect Patent Litigation

In light of the changes that are being made to the 510(k) system, medical device companies will also need to be especially aware of how the information in their 510(k) application may play into patent litigation cases.

The concern that arises out of the switch to an assurance case framework¹⁷⁵ is that because medical device manufacturers will be required to give a more detailed description of how their device is similar to the predicate device they are claiming, it may lead to more findings of patent infringement. Courts have typically held that the 510(k) application materials are not admissible as evidence in patent litigation cases because the FDA's definition of a 'substantial equivalent' is different than the definition of a 'substantial equivalent' in a patent context.¹⁷⁶ But if a manufacturer is required to provide a detailed claim of how their device is similar to the substantial equivalent, the later courts may follow the

¹⁷¹ 21 C.F.R. § 807.95(d) (2010). The 510(k) summary needs to include enough information to provide a basis for finding a claim of substantial equivalence. This includes, among other things, identification of the claimed substantially equivalent device, description of the current device, a description of the devices intended use, and a summary of the technological characteristics of the current device compared to the claimed substantial equivalent. *Id.* § 807.92(a).

¹⁷² See *supra* Part III.B.7; see also *510(k) and Science Report Recommendations*, *supra* note 25, at 20.

¹⁷³ 35 U.S.C. § 102(b) (2006).

¹⁷⁴ See cases cited *supra* Part IV.

¹⁷⁵ See *supra* Part III.B.1.

¹⁷⁶ See *supra* Part V.B; see, e.g., *Am. Med. Sys., Inc.*, 712 F. Supp. 2d at 905 (D. Minn. 2010) (citing *CardioVention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 840 (D. Minn. 2007)).

decision in *United States Surgical Corporation* and allow the 510(k) application materials into cases considering patent infringement.¹⁷⁷

The changes that will require more information to be given in the 510(k) application (providing scientific evidence, providing photographs and schematics, and providing manufacturing process information)¹⁷⁸ may also have the same effect on patent litigation. That is, with more detailed information being disclosed in the 510(k) application, more courts may be likely to consider the 510(k) application materials in patent litigation cases.

There is also a concern that having to provide more detailed information will cause problems with people infringing devices claimed on 510(k) applications that may be published in the 510(k) database.¹⁷⁹ Providing photographs or schematics to the general public, along with more detailed 510(k) summaries, may cause issues with reverse engineering. While the FDA claims confidential information will still be kept confidential,¹⁸⁰ there is a concern that the increase in the amount of information that is given to the FDA through the 510(k) process may lead to more problems. More detailed information about the intended use of a device and more detailed information about how the current device is substantially equivalent to the claimed predicate device, paired with photographs or schematics, may lead to more problems than predicted.

Considering the formation of a new class of devices, Class IIb devices, the same concerns arise.¹⁸¹ Class IIb device 510(k) applications are going to be required to have more detailed information submitted, including the three changes listed above.¹⁸² Devices that are classified as Class IIb devices are going to have larger hurdles to overcome in order to get their 510(k) approval, which in turn means a lot more information will be released. This raises a lot of concern about how this information may lead to others reverse engineering the devices and/or how the information released under the 510(k) application may play into future patent litigation.

Another concern arises out of the limited use (or potential elimination) of using multiple predicates on a 510(k) application.¹⁸³ If a party is held to only claim substantial equivalence to one device there may be a greater link drawn between the technological characteristics of the current device and the claimed

¹⁷⁷ See *U.S. Surgical Corp.*, 701 F. Supp. at 347.

¹⁷⁸ See *supra* Part III.B.2-4.

¹⁷⁹ See *supra* Part III.B.7.

¹⁸⁰ See *510(k) and Science Report Recommendations*, *supra* note 25, at 20.

¹⁸¹ See *supra* Part III.B.6.

¹⁸² *510(k) and Science Report Recommendations*, *supra* note 25, at 17-18.

¹⁸³ See *supra* Part III.B.5.

predicate device. Again, there may be a situation where the courts follow the idea in *United States Surgical Corporation* and allow these materials to be submitted in patent infringement cases due to the higher level of information being disclosed and the more direct link being made between the two devices.¹⁸⁴

As the 510(k) system gets more rigorous there is uncertainty about how it will affect the area of patent law. Since the *Eli Lilly* decision, it has been widely held that the substantial equivalence claimed in the 510(k) application cannot be held as an admission of direct infringement.¹⁸⁵ But there is currently no binding ruling that is widely held as precedent on how 510(k) application materials can play into other aspects of patent litigation. And until there is a binding ruling or statutory language spelling it out, medical device manufacturers need to be especially aware of what information they are releasing in their 510(k) applications to the FDA.

VII. CONCLUSION: HOW INVENTORS MAY PROTECT THEMSELVES UNDER THE NEW 510(K) STRUCTURE

Medical device manufacturers would be wise to be very careful with the information they disclose in their 510(k) applications moving forward. They have two main options moving forward. The first will be to supply all information the FDA asks for in great detail to ensure that their 510(k) application is approved in a timely manner. If this first approach is taken it will be important for medical device manufactures to be aware of how the information they are releasing may be used in determining the validity of their patent application or how the information may play into future patent infringement claims. The second option is to release as little information as necessary under the new changes. The danger in choosing this option is that the CDRH may decide it is not sufficient and the medical device manufacturers may be asked for additional materials, which could slow down the approval of their device for marketing.

While neither choice is a good option, medical device companies may be better protected by trying to release only the information that is necessary, taking the risk that it may slow down the approval of their device for market. This approach is the best strategy for medical device manufacturers until there is statutory language or a binding ruling defining exactly how 510(k) application materials may play into patent litigation.

¹⁸⁴ See *U.S. Surgical Corp.*, 701 F. Supp. at 347.

¹⁸⁵ See *Eli Lilly & Co.*, 496 U.S. at 665–70 (1990). See also, e.g., *Am. Med. Sys., Inc. v. Laser Peripherals, LLC*, 712 F. Supp. 2d 885, 905 (D. Minn. 2010); *Sunrise Med. HHG, Inc. v. Airseep Corp.*, 95 F. Supp. 2d 348, 406 (W.D. Pa. 2000).