

**MEDICAL DEVICE INNOVATION IN AMERICA:
TENSIONS BETWEEN FOOD AND DRUG LAW AND PATENT
LAW**

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I. INTRODUCTION

The medical device industry is tremendously important to health care in the United States. A steady stream of new or improved — but safe — medical devices, utilizing novel technological wizardry, is crucial to maintaining a state-of-the-art health care system. The legal structures regulating the introduction of medical devices must therefore strike a careful balance between promoting new and better devices and ensuring that devices on the market are safe and effective.

Medical devices are generally subject to review by the United States Food and Drug Administration (“FDA”) before they may be marketed. Although some devices must receive premarket approval from FDA before going to market, the vast majority of new medical devices are instead cleared through a premarket notification process called “510(k),” which merely requires a showing that a new device is “substantially equivalent” in terms of safety and effectiveness to an existing, legally marketed device. 510(k) is rapid, inexpensive, and popular among device manufacturers.

Meanwhile, patent protection — the usual legal mechanism for promoting innovation — is crucial for device manufacturers because it allows them to recover the high upfront costs of their research and development (“R&D”). Inventions must be “novel” and “non-obvious” to merit the monopoly rights conferred by a patent.

These two areas of law regulating the introduction of medical devices occasionally come into tension and raise serious questions about the process by which new medical devices enter the market. This Note is a survey of these areas of friction and examines:

- (1) the impact of lengthy regulatory delays on the effective term of a patent,
- (2) whether a device manufacturer may seek FDA clearance under the guise of substantial equivalence to an existing product yet claim novelty in a patent application,
- (3) whether a manufacturer admits infringement when claiming equivalence to a device covered by a patent,
- (4) the difficulties of dealing with two separate government agencies that may create an “inequitable conduct” defense in patent litigation,
- (5) whether equivalency for purposes of medical device approval amounts to equivalency for purposes of patent law’s “doctrine of equivalents,” and
- (6) the overall effect of medical device regulation on innovation when the process for bringing devices to market is fast and straightforward for recognizable devices, but expensive and complex for unfamiliar devices.

This Note proceeds as follows: Part II examines the regulatory environment for premarket medical device review. Part III provides a brief survey of the most relevant aspects of patent law doctrine and policy as applied to medical devices. Part IV then explores the areas in which medical devices are caught in possible conflict between patent law and food and drug law, with some consideration of how these pressure points may advance or retard innovation policy in this field. Part V concludes.

II. FDA'S MEDICAL DEVICE REGULATORY FRAMEWORK

As with drugs, FDA regulates the introduction, manufacture, and use of medical devices in the United States. The Federal Food, Drug, and Cosmetic Act ("FDCA") broadly defines a "medical device" as:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . which is . . . *intended for use in the diagnosis of disease* or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . or . . . *intended to affect the structure or any function of the body* . . . and which does not achieve its primary intended purposes through [chemical or metabolic action].¹

This broad definition encompasses such simple objects as tongue depressors and general-purpose lab equipment,² and includes extremely advanced devices like artificial hearts.³

A. The Medical Device Amendments of 1976

Since 1976, FDA has been charged with premarket oversight of medical devices.⁴ The Medical Device Amendments of 1976

1. Federal Food, Drug, and Cosmetic Act § 201(h), 21 U.S.C. § 321(h) (2006 & Supp. V 2011) (emphasis added).

2. *Is the Product a Medical Device?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm> (last updated Dec. 5, 2012). Notably, this definition of medical device does not limit its scope but merely serves to distinguish clearly medical devices from drugs. *See id.*

3. *E.g.*, *Product Classification*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=900> (last updated Dec. 14, 2012).

4. *See* H.R. REP. NO. 94-853, at 1 (1976). Before 1976, FDA did not have premarket power to review new devices for safety and effectiveness. *See* James M. Flaherty, Jr., *Defending Substantial Equivalence: An Argument for the Continuing Validity of the 510(k) Premarket Notification Process*, 63 FOOD & DRUG L.J. 901, 902 (2008). Congress was

(“MDA”)⁵ created the structure of the regulatory scheme still used today⁶ and, in recognition of the increasing regulatory burdens placed upon medical device companies, was meant to strike a careful balance between ensuring the safety of new devices while promoting the technological development of such devices.⁷

B. Three Classes, Three Types of Oversight

The MDA sought to balance the competing concerns of safety and innovation through a sliding scale approach, which requires FDA to categorize devices into three classes according to the degree of control needed to assure each device’s safety and effectiveness.⁸

Class I devices pose the least risk and need only comply with general controls.⁹ Examples of Class I devices include such items as gloves and bandages.¹⁰ Since the Food and Drug Administration Modernization Act of 1997 (“FDAMA”), Class I devices have been exempt from all forms of premarket review by default.¹¹

forced to respond to a series of public deaths and infertility incidents caused by intra-uterine devices with the Medical Device Amendments of 1976 (“MDA”). Diana M. Zuckerman, Paul Brown & Steven E. Nissen, *Medical Device Recalls and the FDA Approval Process*, 171 ARCHIVES INTERNAL MED. 1006, 1006 (2011).

5. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539.

6. *PMA Approvals*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm> (last updated June 18, 2009).

7. Flaherty, *supra* note 4, at 901.

8. PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 980 (3d ed. 2007); *Device Classification*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> (last updated Dec. 3, 2012); *PMA Approvals*, *supra* note 6.

9. General controls consist of conformance with Good Manufacturing Practices and prohibitions on adulterating or misbranding. *See General and Special Controls*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm> (last updated Dec. 5, 2012). This is essentially the same kind of limited regulation that was already utilized by FDA prior to the MDA. Harry W. Barron, Irving S. Rappaport & Bruce A. Johnson, *Medical Device and Patent Laws Clash?*, 34 FOOD DRUG COSM. L.J. 304, 309 (1979).

10. *General and Special Controls*, *supra* note 9. These examples also underscore the breadth of the definition of “medical device.”

11. Class I devices need only undergo premarket review if they are “intended for a use which is of substantial importance in preventing impairment of human health, or . . . present[] a potential unreasonable risk of illness or injury.” Food and Drug Administration Modernization Act, Pub. L. No. 105-115, § 206(a)(2), 111 Stat. 2296, 2339 (1997) (codified as amended at 21 U.S.C. § 360 (2006 & Supp. V 2011)); *see* CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. DEPT. OF HEALTH & HUMAN SERVS., U.S. FOOD & DRUG ADMIN., THE NEW 510(K) PARADIGM: ALTERNATE APPROACHES TO DEMONSTRATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS (FINAL GUIDANCE) 4–5 (1998), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf>; J. Matthew Buchanan, Comment, *Medical Device Patent Rights in the Age of FDA Modernization: The Potential Effect of Regulatory*

Class II devices are those for which general controls alone are inadequate guarantees of safety and effectiveness.¹² Examples of Class II devices include electrocardiographs, wheelchairs, catheters, hearing aids, x-ray equipment, and bone screws.¹³ Most Class II devices are subject to a form of premarket review known as 510(k), requiring notification to FDA at least ninety days before marketing.¹⁴

Class III devices are subject to the highest standards of premarket review. They are devices “for a use in supporting or sustaining human life” or those that “present[] a potential unreasonable risk of illness or injury.”¹⁵ Examples include heart valves, pacemakers, and implantable cardioverter defibrillators.¹⁶

Generally, before a Class III device may be marketed, it must undergo premarket approval (“PMA”), an onerous and exhaustive procedure that requires years of extensive investigation and clinical trials to demonstrate a device’s safety and effectiveness.¹⁷ All “new” devices are automatically categorized into Class III and must undergo PMA,¹⁸ but the MDA allows a manufacturer to avoid the PMA pro-

Streamlining on the Right to Exclude, 30 U. TOL. L. REV. 305, 325 (1999) (explaining the FDAMA’s exemption of Class I devices and the process by which interested parties can petition FDA to exempt any device). A large majority (74%) of Class I devices are exempt from all forms of premarket review altogether. *Device Classification*, *supra* note 8. Moreover, a few Class I devices are even exempt from Good Manufacturing Practices. *Medical Device Exemptions 510(k) and GMP Requirements*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm> (last updated Oct. 12, 2012); *see also* U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-09-190, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS 8–9 (2009) [hereinafter GAO 2009].

12. *See* Federal Food, Drug, and Cosmetic Act § 513, 21 U.S.C. § 360c (2006). In addition to general controls, Class II devices must comply with special controls, which include labeling requirements and postmarket surveillance. *General and Special Controls*, *supra* note 9.

13. *See* Barron et al., *supra* note 9, at 309; *General and Special Controls*, *supra* note 9; *Guidance on the Center for Devices and Radiological Health’s Premarket Notification Review Program*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm> (last updated June 18, 2009) [hereinafter *Premarket Guidance*].

14. *See* Federal Food, Drug, and Cosmetic Act § 510; *Device Classification*, *supra* note 8. The 510(k) process is discussed in detail *infra* Part II.C. Although not exempt by default, FDA has affirmatively exempted many Class II devices, such as wheeled stretchers and mercury thermometers. *E.g.*, *Medical Devices; Exemptions from Premarket Notification; Class II Devices*, 63 Fed. Reg. 3142, 3144 (Jan. 21, 1998); GAO 2009, *supra* note 11.

15. Federal Food, Drug, and Cosmetic Act § 510.

16. Jordan Paradise et al., *Evaluating Oversight of Human Drugs and Medical Devices: A Case Study of the FDA and Implications for Nanobiotechnology*, 37 J. L. MED. & ETHICS 598, 602 (2009).

17. *See* HUTT ET AL., *supra* note 8, at 1010–11; Flaherty, *supra* note 4, at 912–13; Shashank Upadhye, *Understanding Patent Infringement Under 35 U.S.C. § 271(e): The Collisions Between Patent, Medical Device and Drug Laws*, 17 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 16–17 (2001).

18. *See PMA Approvals*, *supra* note 6.

cess and utilize 510(k) instead if a device is “substantially equivalent” to a preamendments device.¹⁹ Today, roughly 60% of Class III devices reach the market this way.²⁰

C. The 510(k) Scheme

Compared to PMA, 510(k) offers an expeditious path to market and is used to clear the vast majority of medical devices.²¹ The program has the twin goals of ensuring the safety and effectiveness of new devices, and promoting innovation by reducing the obstacles to market introduction.²²

1. Overview

If the premarket notification pathway is available, a device manufacturer who wants to utilize it must submit a 510(k) at least ninety days before a device is to be marketed for the first time, or before making a significant modification to a currently marketed device.²³

Whereas a PMA demands extensive and meticulous documentation to demonstrate safety and effectiveness,²⁴ a 510(k) submission typically requires only identifying information and data sufficient to enable FDA to understand the substantial equivalence relationship

19. HUTT ET AL., *supra* note 8, at 987–88; *Device Classification*, *supra* note 8. In enacting the MDA, Congress anticipated that all Class III devices would eventually proceed through the PMA process. Rita F. Redberg, *Medical Devices and the FDA Approval Process*, 170 ARCHIVES INTERNAL MED. 1831, 1832 (2010); *see also* INST. OF MED., MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 168 (2011) (reporting that the Office of Technology Assessment contemplated that substantial equivalence would dissipate over time as the differences between preamendments and postamendments devices grew). Because this did not come to pass, the Safe Medical Devices Act of 1990 obligated FDA to “phase out” preamendments devices by either requiring PMA or reclassifying each one. GAO 2009, *supra* note 11, at 3. FDA has not complied with this directive, so many Class III devices to this day are still cleared for marketing through the 510(k) process. *See id.*

20. Redberg, *supra* note 19. This is a number well beyond the contemplation of the 1976 Congress that created this option as a temporary phase-out for preamendments device types. *See* HUTT ET AL., *supra* note 8, at 988.

21. GAO 2009, *supra* note 11 (reporting that, of the 33% of devices listed with FDA and not exempt from premarket review, approximately 94% entered the U.S. market via 510(k)).

22. Jeffrey Shuren, *A Letter from the Center Director*, U.S. FOOD & DRUG ADMIN. (Jan. 18, 2011), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM239451.pdf>. The original purpose of 510(k) was to permit manufacturers to easily make small improvements to devices already on the market before 1978, without compromising public safety, and in parity with the burden faced by preamendments manufacturers. *See* Redberg, *supra* note 19; Zuckerman et al., *supra* note 4, at 1007.

23. When a Premarket Notification Submission is Required, 21 C.F.R. § 807.81 (2012).

24. *See* LAWRENCE M. SUNG, MEDICAL DEVICE PATENTS 173–75 (2008).

between the new device and its predicate.²⁵ As 510(k) is merely a notification process, rather than an approval mechanism, FDA has ninety days to make an evaluation of substantial equivalence.²⁶

The 510(k) route is significantly easier, cheaper, and speedier than PMA. The average PMA review time is almost three times that of the average 510(k) (not including the four to five years needed to conduct clinical trials).²⁷ The average cost for FDA to review a PMA, as well as the fees FDA levies upon applicants, are each roughly fifty times the corresponding 510(k) costs (not including the staggering \$15 to \$20 million private costs of clinical trials when required for PMA).²⁸

Of the 3000 devices approved annually for marketing,²⁹ 99% are cleared through the 510(k) pathway,³⁰ and the rest undergo PMA.³¹ Even among Class III devices, greater than three-fourths do not undergo PMA.³² In sum, the backward-looking 510(k) process dominates the market entry of U.S. medical devices.

2. 510(k) Subject Matter and Predicate Devices

A “predicate device” is the older device to which a newer device claims substantial equivalence in a 510(k).³³ Three broad categories of devices may be used as predicates.³⁴ First, a new device can claim substantial equivalence to a preamendments Class III device.³⁵ Second, devices on the market by reason of 510(k) can be used as predicates.³⁶ Finally, any Class I or Class II device can be used as a predicate.³⁷

25. Information Required in a Premarket Notification Submission, 21 C.F.R. § 807.87; Content and Format of a 510(k) Summary, 21 C.F.R. § 807.92 (2012).

26. See *Premarket Notification (510k)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> (last updated Sept. 3, 2010).

27. Paradise et al., *supra* note 16.

28. *Id.*; see GAO 2009, *supra* note 11, at 15–16.

29. Shuren, *supra* note 22.

30. HUTT ET AL., *supra* note 8, at 992. 90% of Class I and II 510(k) submissions and 67% of Class III 510(k) submissions are ultimately cleared. GAO 2009, *supra* note 11, at 6.

31. See GAO 2009, *supra* note 11.

32. Zuckerman et al., *supra* note 4, at 1011.

33. SUNG, *supra* note 24, at 167.

34. A 510(k) may also claim multiple predicate devices to cover all features. *Id.*

35. *Premarket Notification (510k)*, *supra* note 26. Theoretically, FDA must eventually require PMA of all Class III devices, even preamendments devices. GAO 2009, *supra* note 11, at 3. To date, FDA has not published regulations requiring PMA of all Class III devices. See 21 C.F.R. §§ 814.100–814.126 (2012). Consequently, a majority of Class III devices still utilize 510(k). See GAO, *supra* note 11, at 16.

36. See *Premarket Notification (510k)*, *supra* note 26. This allows a lineage of 510(k) devices to be created, ultimately tracing back to a preamendments device. See INST. OF MED., *supra* note 19, at 87–88. Congress explicitly allowed this long-standing practice of daisy-chaining 510(k)s in this way in the Safe Medical Devices Act of 1990. Pub. L. No. 101-629,

3. Substantial Equivalence

Substantial equivalence is the basis of 510(k)'s guarantee that new devices will be at least as safe and effective as their predicates, since FDA does not freshly review these devices for safety and effectiveness as it does through PMA.³⁸

The FDCA's definition of substantial equivalence³⁹ outlines the following schematic: A device is automatically considered substantially equivalent to a predicate device if the two share the same intended use and technological characteristics, or if any different technological characteristics can be evaluated through accepted scientific methods and do not raise novel questions of safety and effectiveness.⁴⁰ Conversely, two devices are not substantially equivalent if the new features "could adversely affect safety or effectiveness in a way that is consequential under the conditions of intended use."⁴¹

To put this rubric in perspective, from 2005 to 2007, all devices deemed substantially equivalent had the same intended uses as their predicates, and 86% had the same technological characteristics.⁴²

§ 12, 104 Stat. 4511, 4523–24 (codified as amended at 21 U.S.C. § 360e), *amended by* Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012); *see* HUTT ET AL., *supra* note 8, at 998–99.

37. *See* GAO, *supra* note 11, at 3. New devices may be reclassified into Class I or Class II at the time of premarket review through the *de novo* 510(k) process, created by the FDAMA in 1997, when no other satisfactory predicate is available. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 207, 111 Stat. 2296, 2340 (codified as amended at 21 U.S.C. § 360c); Michael A. Swit, *The "de Novo" 510(k) Process and the Reclassification of Class III Devices*, REG. AFF. FOCUS, Mar. 2006, at 32, 32–33 *available at* <http://www.medicaldevices.org/sites/default/files/Swit--RAPSFFocusArticle--deNovo510k--March2006.pdf>; *see also* James G. Dickinson, *510(k) Caution Engulfs FDA — Predicate Choices Questioned*, MED. DEVICE & DIAGNOSTIC INDUS. (June 3, 2010), <http://www.mddionline.com/article/510k-caution-engulfs-fda—predicate-choices-questioned>.

38. *See* *Premarket Notification (510k)*, *supra* note 26.

39. Although the term "substantial equivalence" appeared in the MDA, it was initially defined substantively only by FDA regulation, which took a flexible, sliding-scale approach. *See* INST. OF MED., *supra* note 19, at 87. FDA based this definition on language from the MDA's legislative history. *See* *Premarket Guidance*, *supra* note 13; *see also* H.R. REP. NO. 94-853, at 36 (1976) ("The Committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness."). Congress eventually codified FDA's understanding in 1990 by amending the FDCA to include § 513(i). *See* INST. OF MED., *supra* note 19, at 87–88.

40. *See* FDA Action on a Premarket Notification, 21 C.F.R. § 807.100 (2012); *Premarket Guidance*, *supra* note 13. Examples of "different technological characteristics" include changes in materials, design, energy source, or other features. 21 C.F.R. § 807.100.

41. *Premarket Guidance*, *supra* note 13. In practice, this definition leaves many ambiguities, leading FDA to weigh a multitude of factors including intended use, design, energy consumption, materials, chemical composition, manufacturing process, labeling, biocompatibility, the disease to be treated or diagnosed, whether the device is for professional or lay use, the body part or type of tissue involved, and the frequency of use. *See id.*; *Premarket Notification (510k)*, *supra* note 26.

42. GAO 2009, *supra* note 11, at 7.

More than 50% of those devices determined *not* to be substantially equivalent had a new intended use or different technological characteristics from their predicates.⁴³ Overall, the vast majority of Class II and Class III submissions cleared through 510(k) do not deviate much from their predicates technologically: only 1% of all submissions in this period had a new intended use, and only 15% had new technological characteristics.⁴⁴ These data suggest that most devices cleared through 510(k) do so fairly easily and without an investigation of how new technological characteristics actually affect safety and effectiveness.

D. Innovation in the Medical Device Industry

In spite of its regulatory complexity, the U.S. medical device industry remains a pioneering, dynamic, and hugely lucrative field. Medical devices represent a \$188.8 billion industry in the United States⁴⁵ and a significant and rapidly growing share of the healthcare sector.⁴⁶ The industry's profit margin of 18% in 2002 was one of the highest in the U.S. private sector.⁴⁷

Nonetheless, both revenue and innovation are unbalanced in the industry. In the United States, the largest 2% of medical device companies produce more than half of all industry sales,⁴⁸ but, according to at least one member of the industry, "virtually all *revolutionary* medical device development" in the United States is driven by venture capitalists ("VCs") channeling funds into startup companies.⁴⁹ VCs invest \$2 to \$4 billion each year in medical devices,⁵⁰ although they are extremely sensitive to the regulatory environment and demand significant returns for their large upfront investments.⁵¹ Still, the amount of venture capital — which works as a rough proxy for the level of inno-

43. *Id.*

44. *Id.*

45. INST. OF MED., *supra* note 19, at 169–70.

46. See Asha S. Geire, *Price Wars and Patent Law: Reducing the Cost of Health Care Through Medical Device Price Transparency*, 12 TUL. J. TECH. & INTELL. PROP. 239, 247 (2009); D. Clay Ackerly et al., *Fueling Innovation in Medical Devices (and Beyond): Venture Capital in Health Care*, 28 HEALTH AFF., Dec. 2, 2008, at w70, <http://content.healthaffairs.org/content/28/1/w68.full.pdf>. Medical devices represent 45% of the annual venture capital investment in the U.S. healthcare sector as of 2007, up from 35% in 2004. *Id.*

47. Geire, *supra* note 46.

48. *Id.*

49. See Jack W. Lasersohn, Bd. Member, Nat'l Venture Capital Ass'n, Speech at FDA Public Workshop on Identifying Unmet Public Health Needs and Facilitating Innovation in Medical Device Development: Interagency Collaboration in Support of Medical Device Innovation 2, 4 (2010), available at <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM221031.pdf> (emphasis added).

50. See *id.* at 7.

51. See Ackerly et al., *supra* note 46 at w69.

vation in the field at any given time⁵² — is substantial in the medical device field.

III. A PRIMER ON PATENT LAW AND MEDICAL DEVICES

A. *The Foundations and Purpose of Patent Law*

Patent law is the classic legal embodiment of innovation policy in the United States.⁵³ A patent is an exclusive right, or a monopoly, to an invention, granted for a limited period of time.⁵⁴

Patents potentially solve the following problem: Innovation is extremely important to economic growth, but market failures occur in the absence of some form of legal exclusivity over intellectual output.⁵⁵ Because intellectual products are public goods,⁵⁶ but can be expensive on the front-end, pioneer inventors will be unable to overcome free-rider problems and recover their upfront costs in the absence of legal protection.⁵⁷ They will therefore either reduce their R&D to suboptimal levels or keep their discoveries secret.⁵⁸

By means of a limited monopoly, patent law seeks to stimulate innovation, promote dissemination of information, encourage development and commercialization, and enable cumulative or follow-on innovation.⁵⁹ The patent system grants a patentee the right to exclude others from making, using, importing, or selling the patented invention for a finite term.⁶⁰

52. *See id.* at w74.

53. The Constitution explicitly grants Congress the power to create a patent system for the express purpose of “promot[ing] the Progress of . . . useful Arts.” U.S. CONST. art. I, § 8, cl. 8. Interestingly, this is the only of Congress’s enumerated powers with a stated purpose.

54. *Patents*, U.S. PATENT AND TRADEMARK OFFICE, <http://www.uspto.gov/patents/index.jsp> (last updated Jan. 26, 2012).

55. Kristen Nugent, *Patenting Medical Devices: The Economic Implications of Ethically Motivated Reform*, 17 ANNALS HEALTH L. 135, 153 (2008).

56. Public goods are those which are naturally non-rival (one person’s usage does not reduce another’s enjoyment of them) and non-excludable (without legal or technological protection, it is difficult to prevent access to them). For example, if one person consumes an apple, nobody else can eat it. Therefore, an apple is a rival good. Yet information is non-rival: “He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me.” Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), *available at* http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html. While it is easy to prevent access to physical property, “ideas should freely spread . . . [naturally] incapable of confinement or exclusive appropriation.” *Id.* Information in its natural form, in the absence of legal or technological protection measures, is non-excludable.

57. Nugent, *supra* note 55.

58. *Id.* at 152–54. Secrecy is problematic because most innovation builds on earlier knowledge, and thus depends on that knowledge being publicly disclosed. *Id.* at 151–52.

59. Geire, *supra* note 46, at 243.

60. *See* 35 U.S.C. § 154 (2006 & Supp. V 2011).

Patents are a “limited” monopoly because their duration, or “patent term,” is finite (twenty years by default).⁶¹ Moreover, the scope of a patent’s legal protection is defined by — and limited to — its claims,⁶² which do not necessarily correspond to a single product or “embodiment” of the invention.⁶³ Patent infringement occurs when the claims of a plaintiff’s patent literally cover the technology used in a defendant’s product.⁶⁴

Therefore, “design-around,” which consists of creating a product that accomplishes a similar technological result while avoiding the claims of a patent, is often possible and permitted by patent law.⁶⁵ To deal with the problem of trivial design-around meant for nothing more than evasion of patent claims, patent law utilizes a judge-made “doctrine of equivalents” to broaden the scope of patent infringement.⁶⁶

B. Medical Device Patents

Inventions that cover medical devices often have extremely high upfront investments⁶⁷ and are easily duplicated at relatively low cost once disclosed to the public. Without patent protection in these fields, inventors and investors might flee to other industries.⁶⁸ Moreover, market failures that lead to suboptimal production are particularly insidious in the medical device sector, where human lives are at stake.⁶⁹

61. *Id.* Under certain circumstances, such as delays caused by the U.S. Patent and Trademark Office or FDA, the term of a patent can be modified. *See infra* Part IV.A.

62. *See* Barron et al., *supra* note 9, at 305. The claims describe the “metes and bounds of an invention in the same way that the legal description in a deed for a piece of real estate defines the property involved.” *Id.*

63. *See* Arthrocare Corp. v. Smith & Nephew, Inc., 310 F. Supp. 2d 638, 667 (D. Del. 2004), *vacated in part on other grounds*, 406 F.3d 1365 (Fed. Cir. 2005).

64. *See* SUNG, *supra* note 24, at 73 (“[E]ach and every claim limitation [must] be present in the accused product.”).

65. *See* Charles Allen Black, *The Cure for Deadly Patent Practices: Preventing Technology Suppression and Patent Shelving in the Life Sciences*, 14 ALB. L.J. SCI. & TECH. 397, 432 (2004) (citing *WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999)).

66. *See generally* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997) (describing the application and scope of the doctrine of equivalents). In a common formulation, a product or process that does not literally infringe a patent’s express terms may nonetheless be held to infringe the patent if it accomplishes “substantially the same function in substantially the same way to obtain the same result.” *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950) (quoting *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929)). This has become known as the triple identity test. *Warner-Jenkinson*, 520 U.S. at 19.

67. For example, these initial costs may derive from the need for extensive R&D, clinical trials, and regulatory procedures.

68. Nugent, *supra* note 55.

69. *Id.* at 139.

The Patent Act broadly extends the scope of subject matter protection to “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”⁷⁰

Medical devices and improvements upon medical devices easily satisfy this requirement.⁷¹ Indeed, patents are of paramount importance to medical device manufacturers⁷² because they are the primary means by which manufacturers erect barriers to market entry by competitors.⁷³ This use of patents enables manufacturers to realize their profits and recoup their immense upfront expenses.⁷⁴

Unsurprisingly, the most profitable medical device companies also hold patents in the greatest overall numbers.⁷⁵ Interestingly, however, because small, venture-backed startups often drive innovation in the industry,⁷⁶ they are much more likely to own and rely on patents.⁷⁷ As an example, one cross-industry study found that, within its sample of patents, while small companies owned less than one-third of the

70. 35 U.S.C. § 101 (2006). Courts have interpreted this to mean “anything under the sun that is made by man.” *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). There are relatively fixed boundaries to these categories, namely that “laws of nature, physical phenomena, and abstract ideas” are not patentable. *Id.* Recently, the Supreme Court and the Federal Circuit have begun to apply these limitations to an increasing number of patent types, some of which may represent peripheral patents obtained by medical device manufacturers. *See, e.g., Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1296–97 (2012) (patent enabling doctors to administer appropriate amounts of a drug merely claims a correlation, which is a law of nature); *Bilski v. Kappos*, 130 S. Ct. 3218, 3229–30 (2010) (patent claiming hedging against risk in commodities market is an abstract idea). *But see Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1354, 1357 (Fed. Cir. 2011), *vacated*, *Ass’n for Molecular Pathology v. Myriad Genetics*, 132 S. Ct. 1794 (2012) (patent claiming isolated human gene does not claim a product of nature and patent claiming cancer screening based upon cell growths does not claim an abstract idea). Although there is little doubt that medical devices themselves qualify as “machines,” certain other patents, such as a process performed by a medical device, may be on shakier ground. *See Mayo*, 132 S. Ct. at 1296–97 (patent on diagnostic technique invalid). The software that runs medical devices, patentable under current law, may also be in jeopardy as software patents have been under fire for some time. *See, e.g., Dan L. Burk & Mark A. Lemley, Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1687–88 (2003); Steve Lohr, *Microsoft’s AOL Deal Intensifies Patent Wars*, N.Y. TIMES (Apr. 9, 2012), <http://www.nytimes.com/2012/04/10/technology/microsoft-to-buy-aol-patents-for-more-than-1-billion.html?pagewanted=all>.

71. Nugent, *supra* note 55, at 138.

72. Burk & Lemley, *supra* note 70, at 1592 (medical device patentees are far more likely to assert their patents than patentees in other fields).

73. Eric P. Raciti & James D. Clements, *A Trap for the Wary: How Compliance with FDA Medical Device Regulations Can Jeopardize Patent Rights*, 46 IDEA 371, 371–72 (2006).

74. *See Buchanan, supra* note 11, at 306.

75. Geire, *supra* note 46.

76. INST. OF MED., *supra* note 19, at 170.

77. Ackerly et al., *supra* note 46, at w72.

patents, these companies obtained more than half of the medical device patents.⁷⁸

C. The Novelty and Non-Obviousness Requirements

Three significant prerequisites for an invention's patentability are the "utility," "novelty," and "non-obviousness" requirements.⁷⁹ To satisfy the novelty requirement, an invention must not have been "known or used by others . . . or patented or described in a printed publication."⁸⁰ Any document accessible to the public before the time a patent application is filed (known as a "prior art" reference) will render a patent claim invalid if all elements of that claim are disclosed within the "four corners" of the document.⁸¹ If that is the case, the claim is considered "anticipated" by the prior art.⁸²

The non-obviousness requirement holds that the subject matter of a patent must not have been "obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art."⁸³ The obviousness analysis asks whether the leap to the invention from a single prior art reference, or from a combination of multiple prior art references, is too trivial to deserve a patent in light of the state of the art.⁸⁴ Together, these two requirements prevent the patenting of material in the public domain.

IV. THE TENSIONS BETWEEN MEDICAL DEVICE REGULATION AND PATENT LAW

The interface of the regulatory environment governing new medical devices and patent law is "jagged and complicated."⁸⁵ While patent law requires that a technology be new, most medical devices are cleared through similarity to a preexisting device.⁸⁶ This tension may cause significant distortions in the economics of medical device mar-

78. John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 VAND. L. REV. 2099, 2128 (2000).

79. 35 U.S.C. §§ 101–103 (2006 & Supp. V 2011). Most medical device patents easily satisfy the utility requirement, which demands only that an invention accomplish the result that the claims purport to achieve. *See* Nugent, *supra* note 55, at 138. This is one difference from the pharmaceutical industry, where the utility requirement may do some work. *See, e.g., In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995); *In re Kirk*, 376 F.2d 936 (C.C.P.A. 1967).

80. 35 U.S.C. § 102(a) (2006 & Supp. V 2011).

81. *See* Raciti & Clements, *supra* note 73, at 379.

82. *Id.*

83. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 103, 125 Stat. 284, 287 (2011) (to be codified as amended at 35 U.S.C. § 103).

84. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 420 (2007).

85. Raciti & Clements, *supra* note 73, at 372.

86. *See* HUTT ET AL., *supra* note 8, at 992.

ket introduction.⁸⁷ The situation is not helped by the total absence of coordination between the two medical device gatekeeper agencies — FDA and the United States Patent and Trademark Office (“USPTO”).⁸⁸ This Part surveys the doctrinal and conceptual pressure points between the two fields and how some have been resolved.

A. Patent Terms and the Hatch-Waxman Act

The possibility of conflict between patent law and food and drug law has not been entirely ignored. Congress passed the 1984 Hatch-Waxman Act in part to remedy two distortions related to the patent term for drugs and devices.⁸⁹

First, no regulatory barriers normally prevent patentees from exclusively marketing products embodying their inventions immediately upon filing a patent with the USPTO. But because the initial phase of a medical device’s patent term may be consumed by FDA procedures rather than commercialization of a new product, the patent term experiences a de facto *shortening*.⁹⁰ One solution is to file for a patent later in the process, but doing so risks losing patentability, most significantly because novelty and obviousness are judged from the time of the patent’s filing.⁹¹

Second, because a patent’s exclusivity includes the rights to prevent others from merely making and using the claimed invention,⁹² a competitor may not even begin testing a potential competing product until after the patent expires. This is not problematic in most fields that are not subject to such heavy regulation because, in most circumstances, competitors can rapidly enter the market soon after the patent covering the relevant product expires. In the drug and medical device context, however, a competitor (such as a generic drug manufacturer) may not begin pursuing FDA approval or conducting U.S.-based clinical trials until the patent expires.⁹³ A competitor’s product would

87. The main distinction that, as we will see, helps resolve some tension is that 510(k) addresses functional equivalency (at least as safety and effectiveness are concerned), but patent law concerns itself with technological identity.

88. Not only are the two agencies in two different executive departments — FDA in the Department of Health and Human Services and the USPTO in the Department of Commerce — but manufacturers’ patent counsel and FDA counsel do not have open and continuous lines of communication. Raciti & Clements, *supra* note 73, at 372–73.

89. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 21 and 35 U.S.C.). This act is commonly known as the Hatch-Waxman Act.

90. See Upadhye, *supra* note 17, at 6.

91. 35 U.S.C. §§ 102–103 (2006 & Supp. V 2011).

92. *Patents*, *supra* note 54.

93. See Upadhye, *supra* note 17, at 6–7.

therefore not reach the market until long after the patent had expired, creating a de facto patent term *extension* for the patent holder.⁹⁴

1. § 156's Patent Term Extension

The Hatch-Waxman Act added 35 U.S.C. § 156, which is meant to remedy the de facto patent term reduction caused by FDA review by granting an extension to the patent term.⁹⁵ In theory, the extension provided by § 156 should exactly offset this lost time,⁹⁶ which may otherwise unfairly disadvantage drug and device manufacturers as compared to patentees in other industries.

Facially, the Hatch-Waxman Act applies only to patents covering drugs, but the Supreme Court has held that it applies equally to medical devices.⁹⁷ The extension is therefore available from the USPTO for medical device patents that claim a product or a method of using or manufacturing a product.⁹⁸ Nonetheless, the statute provides an extension only for patents on products that are subject to a “regulatory review period,” which in this context means PMA only.⁹⁹

This extension creates a lack of parity between PMA and 510(k) because the term of a patent that covers a product that enters the market through 510(k) cannot be extended under the Hatch-Waxman Act.¹⁰⁰ Although no manufacturer would prefer PMA, the asymmetry does somewhat reduce the appeal of the speedy 510(k) process. A robust patent term, even as measured in months, may be important to manufacturers of devices cleared through 510(k), whose competitors face relatively low barriers to entry and whose patents may be substantively weaker.¹⁰¹

94. *Id.* at 7. This is because such activity would involve making or using the patented invention.

95. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 156, 98 Stat. 1585, 1598. See Michelle A. Sherwood, *Medical Devices and Patent Term Extension Under the Hatch-Waxman Act*, LANDSLIDE, July/Aug. 2010, at 38, 39.

96. See 35 U.S.C. § 156 (2006 & Supp. V 2011).

97. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 661 (1990) (holding that medical device issues also arise under the FDCA).

98. Sherwood, *supra* note 95. Its magnitude is the administrative time (from PMA application until FDA approval) plus half the experimental time (from the commencement of clinical trials until PMA application). *Id.* There is an overall limit on the extension of five years. 35 U.S.C. § 156.

99. Buchanan, *supra* note 11, at 322; Sherwood, *supra* note 95.

100. Sherwood, *supra* note 95.

101. A patent on an improvement or new use for a product is generally considered weaker than a patent on the product itself as a machine or composition of matter.

2. § 271(e)(1)'s Infringement Exception

The Hatch-Waxman Act also added 35 U.S.C. § 271(e)(1), which mitigates the de facto patent term extension caused by FDA regulatory delays to competitor entry upon a patent's expiration.¹⁰² Section 271(e)(1) provides a safe harbor from patent infringement for conduct taken for purposes of procuring regulatory approval to market a device or drug.¹⁰³ To prevent a de facto extension of the patent term, this exception permits companies to engage in activity that would otherwise be infringing.

In *Eli Lilly & Co. v. Medtronic, Inc.*, the Supreme Court held that, for purposes of § 271(e)(1), making and using a patented device in pursuit of a PMA requirement qualified as "reasonably related" to obtaining regulatory approval, and, consequently, fell within the safe harbor provision.¹⁰⁴ However, the Court left unanswered the question whether § 271(e)(1) also applies to devices that do not require PMA, such as devices exempt from premarket review or those utilizing 510(k).¹⁰⁵ Nonetheless, the Federal Circuit, through its exclusive appellate jurisdiction over patent cases, held that § 271(e)(1) applies to all regulated medical devices (including those cleared by 510(k)),¹⁰⁶ and more recently, that devices not subject to premarket review (meaning devices exempt from review altogether) are *not* covered.¹⁰⁷ These holdings are consistent with the purposes of § 271(e)(1) because exempt devices do not face any FDA-related delay in marketing upon expiration of a relevant patent.¹⁰⁸

Unlike § 156, the safe harbor in § 271(e)(1) — if properly administered — creates an even playing field between medical device patents and most other types of patents. Although it may take less time in other fields to bring a product to market after the expiry of a covering patent (because R&D for a medical device can be more extensive than in other fields), the length of time taken by R&D is independent of any regulation. Section 271(e)(1) merely relieves medical device

102. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 156, 98 Stat. 1585, 1603; Upadhye, *supra* note 17, at 3.

103. 35 U.S.C. § 271(e)(1) (2006 & Supp. V 2011).

104. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665–66 (1990); *see also* Upadhye, *supra* note 17, at 25.

105. Buchanan, *supra* note 11, at 321–22. For a time, this issue was unsettled because the Court had elsewhere acknowledged the important differences between premarket approval and premarket notification. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996); Buchanan, *supra* note 11, at 314.

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

107. *See Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008).

108. *Cf.* Buchanan, *supra* note 11, at 322 (arguing — before *Proveris* was decided — that § 271(e)(1) probably would not immunize exempt devices because the Hatch-Waxman Act applies only to devices that undergo regulatory review).

companies of a distortion caused by the existence of the FDA regulatory framework.

Manufacturers may be nudged toward avoiding existing patents by developing entirely new products, which might require PMA before introduction, but would also likely entitle their inventors to robust patent protection.¹⁰⁹ In such circumstances, § 156 would compensate such an inventor for the time involved in the PMA process (but not a manufacturer that proceeds through 510(k), even when patentable). For the most part, however, the Hatch-Waxman Act removes the regulatory distortions to medical device patent terms, since the 510(k) process is a relatively weak regulatory barrier to begin with.

B. 510(k) as Prior Art

A 510(k) becomes a public document, accessible through the Freedom of Information Act or by FDA publication.¹¹⁰ Arguably, then, a 510(k) can be used to demonstrate a patent claim's obviousness or lack of novelty.¹¹¹ This risk is particularly salient because, by its nature, a 510(k) claims substantial equivalence to an existing device, thereby identifying (and possibly admitting the existence of) prior art that anticipates or renders obvious the patent. This could potentially render many medical device patents less valuable because each one's validity is clouded by additional prior art contained in 510(k) filings. It also may result in a trap for companies that accidentally disclose too much in their own 510(k)s and later create patentability problems for themselves.

The underlying problem with such an argument is that while a 510(k) discloses some technical aspects of a *product*, it does not necessarily disclose all elements of a *patent claim*. Patents cover inventions rather than particular products, and the legal rights granted by a patent are outlined by its "claims." A claim is invalid for lack of novelty (anticipation) when all of its elements exist in a single reference that predates the time of its filing.¹¹² Therefore, a 510(k) description often neither amounts to anticipation nor does it render claims obvi-

109. This is because, generally, patents covering an entirely new device are likely to be stronger than patents covering mere iterations on existing devices. As an analogy, a broad patent on the light bulb would cover all light bulbs, but a patent on an improved filament would cover only those light bulbs that used a similar filament.

110. Raciti & Clements, *supra* note 73, at 377.

111. See *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1376 (Fed. Cir. 2001). In the United States, there is a one-year grace period for inventors who disclose their inventions, but a 510(k) that discloses all the elements of a later patent claim can seriously compromise foreign patent rights. Michael Regitz, *How a 510(k) Submission Can Affect Your Patent*, MED. DEVICE & DIAGNOSTIC INDUS. (June 1, 2010), <http://www.mddionline.com/article/how-510k-submission-can-affect-your-patent>.

112. See Raciti & Clements, *supra* note 73, at 379.

ous because it relates to a product rather than an invention.¹¹³ Indeed, savvy companies that are aware of this distinction may choose predicate devices in their 510(k)s so as to claim equivalence in ways oblique to patent eligibility or to explicitly disclaim patent issues in their 510(k).¹¹⁴

Fortunately for device manufacturers, courts do not agree with anticipation-by-510(k) arguments when they are litigated. For example, the District of Delaware held that a 510(k) is not admissible to prove anticipation because a 510(k) compares two commercial embodiments, but the correct novelty or obviousness analysis involves comparing the prior art with the patent claims.¹¹⁵ With more elucidation, the Western District of Pennsylvania explained that admissions in a 510(k) do not relate to the limitations of a patent claim because a 510(k) is a demonstration of equivalent safety and efficacy to FDA, rather than a comparison of an older device to newer patent claims.¹¹⁶ Ultimately, for careful companies, a 510(k) itself (notwithstanding the product it claims equivalence to) should not prove to be too much of an obstacle to the patentability of new devices, and therefore the notion of anticipation by 510(k) is probably not a major distortion to the incentives involved in the introduction of medical devices.¹¹⁷ Device manufacturers will likely continue to use 510(k) when it best suits their needs, rather than elect the suboptimal PMA route solely to avoid anticipation by 510(k).

C. 510(k) as an Admission of Infringement

It is easy to see why a manufacturer of a device still covered by a patent would be agitated by a new device in the market that claims equivalency to that manufacturer's patented device. While FDA maintains that a determination of substantial equivalence should not have any bearing on a patent suit,¹¹⁸ parties to patent litigation argued for some time that a 510(k) should be admissible to prove infringe-

113. *Id.* at 377.

114. *See id.*

115. *Arthrocare Corp. v. Smith & Nephew, Inc.*, 310 F. Supp. 2d 638, 667 (D. Del. 2004), *vacated in part on other grounds*, 406 F.3d 1365 (Fed. Cir. 2005).

116. *Sunrise Medical HHG, Inc. v. AirSep Corp.*, 95 F. Supp. 2d 348, 406 (W.D. Pa. 2000).

117. It does not appear that anyone has utilized a 510(k) in making a case for obviousness. A 510(k) could, conceivably, demonstrate — by itself or with other prior art — the process of achieving the transition from an older device to newer patent claims, thus allowing a challenger to argue obviousness. We will have to wait and see how, if at all, this issue is resolved.

118. *Barron et al.*, *supra* note 9, at 316 (quoting 42 Fed. Reg. 42,525 (Aug. 23, 1977)).

ment,¹¹⁹ since it is at least probative of the similarity between two devices.¹²⁰

Until recently, the law was indeterminate, so it may be that manufacturers avoided using patented devices as predicates in their 510(k)s, even if they believed their newer devices were non-infringing. This uncertainty may have therefore discouraged innovation.¹²¹

Recently, the Federal Circuit indicated that a 510(k) is not an admission of infringement.¹²² The court cited favorably a lower court's reasoning that an assertion that a newer device *matches the safety and effectiveness profile of an older device* is not the same as an admission that a newer device's technology *infringes on a patent that covers the older device*.¹²³ Ultimately, 510(k) represents a completely separate regulatory regime from patent law, with different overall standards but some confusingly similar language.¹²⁴ This clarification in the law should remove whatever distortions existed for medical device manufacturers caused by fears that a 510(k) might be used against them.

D. The Doctrine of Equivalents

In an ordinary patent infringement case, the plaintiff asserts that its patent claims literally cover the defendant's product or activity.¹²⁵ Sometimes, however, the defendant comes very close to infringement, but somehow avoids the specific language of the claims, often through trivial — and intentional — design-around.¹²⁶ The doctrine of equivalents (“DoE”) holds that even though the patent claims may not read literally on a product, such a product may still infringe if it performs “substantially the same function in substantially the same way to obtain the same result” as a patent claim.¹²⁷

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

120. *See* FED. R. EVID. 401 (relevance); *see also* FED. R. EVID. 801(d)(2) (admissions by party-opponent are nonhearsay and therefore generally admissible); FED. R. EVID. 803(8) (public records exception to hearsay rule).

121. *See* Buchanan, *supra* note 11, at 326.

122. *See* *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1382 (Fed. Cir. 2010).

123. *See id.* This holding was consistent with a trend in the lower courts recognizing a distinction between what is compared in a 510(k) submission and what is compared in a patent infringement lawsuit. *See, e.g.*, *CardioVention*, 483 F. Supp. 2d at 840.

124. *See* *CardioVention*, 483 F. Supp. 2d at 840.

125. Barron et al., *supra* note 9, at 306. This means that each and every element of at least one claim applies to the defendant's product or activity. SUNG, *supra* note 24, at 73.

126. *See, e.g.*, *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 22 (1997).

127. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950) (quoting *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929)); Barron et al., *supra* note 9, at 307.

The language of substantial equivalence is familiar by this point because it is the same standard used to evaluate 510(k) applications. Of course, equivalence for purposes of 510(k) pertains to a comparison of two products' safety and effectiveness, but equivalence for purposes of the DoE pertains to a comparison of technology between the patent's claim language and the infringing product. The similarities in language nonetheless raise the possibility of conflict between two concepts of equivalence in distinct areas of law.¹²⁸ To claim patentability is to claim nonequivalence, yet a manufacturer explicitly claims equivalence in a 510(k).¹²⁹

It is possible that, because 510(k) involves a comparison between products rather than between a patent claim and a product, a statement of equivalence for purposes of FDA clearance should not be admissible to prove infringement under the DoE. On the other hand, the existence of a 510(k) may amount to a presumption of equivalency for purposes of the DoE.¹³⁰

Courts have generally opined that a 510(k) refers to a device as a whole, rather than each element, so it generally does not support a DoE argument.¹³¹ The comparison in a 510(k) is holistic, whereas the comparison in a patent case is piecemeal and rooted in each patent claim. However, courts have not definitively held that a 510(k) is categorically inadmissible for DoE purposes.¹³² Therefore, it remains true that, as compared to other types of inventions, there is a greater risk that medical devices cleared through 510(k) will infringe on a patent. The 510(k) process involves a possible admission of infringement *under the DoE*, even if, as discussed above, such an admission is not cognizable in the more straightforward infringement context.¹³³ This possibility of a 510(k) being accepted as an admission of infringement may deter innovation in devices that would be cleared through 510(k), which contravenes one of the primary purposes for the premarket notification program — the encouragement of new medical device technology. Conversely, this possibility may strengthen the patent rights of earlier pioneer medical device manufacturers.

128. Barron et al., *supra* note 9, at 304, 312.

129. *See id.* at 313.

130. *Id.*

131. *See, e.g.,* *Clintec Nutrition Co. v. Baxa Corp.*, 988 F. Supp. 1109, 1116 n.18 (N.D. Ill. 1997).

132. Under the classic maxim in patent law, “[t]hat which infringes, if later, would anticipate, if earlier.” *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889). Therefore, the logic in the anticipation context, where one could not show anticipation based on a 510(k), should carry over to the infringement context, even though no court has so held.

133. *See supra* Part IV.C and accompanying footnotes.

E. Inequitable Conduct

510(k) applicants, especially those seeking patents, are in a difficult position. On the one hand, they must inform FDA that their devices are similar to existing devices; on the other hand, they must assert to the USPTO that their devices are completely new and non-obvious.¹³⁴ Complying with these incongruous requirements can lead to an inequitable conduct defense in later patent litigation.

The inequitable conduct defense involves an intentional failure to disclose to the USPTO material prior art known to the patent applicant at the time of patent prosecution.¹³⁵ If the defense is successful, the patent will be deemed unenforceable.¹³⁶ This can be devastating, particularly for a small company that may have one or two key patents representing much or all of the company's technological value.¹³⁷

Medical device manufacturers are at particular risk for an inequitable conduct defense because, as the Federal Circuit held in *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*, 510(k) filings submitted to FDA can demonstrate what the manufacturer subjectively knew about prior art when it prosecuted its patent.¹³⁸ In that case, Bruno, a device manufacturer, filed its 510(k) after its patent application but before the patent issued, and never disclosed its 510(k) to the USPTO.¹³⁹ Bruno later asserted this patent against a competitor.¹⁴⁰ Despite Bruno's position that its 510(k) was only relevant to FDA (and thus did not need to be disclosed to the USPTO), the Federal Circuit agreed with the defendant that Bruno's 510(k) demonstrated knowledge of important prior art — the predicate device — that it did not disclose.¹⁴¹ Thus, the court held the patent unenforceable and affirmed an award of attorney fees.¹⁴²

Lower courts have not read *Bruno* to mean that all nondisclosures to the USPTO of a 510(k) that cites a competing medical device

134. Raciti & Clements, *supra* note 73, at 388–89.

135. See, e.g., *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011); Regitz, *supra* note 111. This is a judge-made rule.

136. Regitz, *supra* note 111. Note, however, that the inequitable conduct defense has been narrowed under the America Invents Act, as patentees may now be able to purge the taint of inequitable conduct through a “supplemental examination.” See Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 12, 125 Stat. 284, 325 (2011) (to be codified at 35 U.S.C. § 257).

137. See Regitz, *supra* note 111.

138. See *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1352 (Fed. Cir. 2005) (holding that a substantial equivalence determination can support an inequitable conduct finding).

139. See *id.* at 1350–51. The 510(k) disclosed similarities to products from another company. *Id.* at 1350.

140. *Id.* at 1350.

141. *Id.* at 1352.

142. *Id.* at 1355.

amount to per se inequitable conduct.¹⁴³ After all, not all claims of substantial equivalence are relevant to patentability, as many predicate devices lack the new technology that serves as the basis for a patent.¹⁴⁴ Still, manufacturers must tread carefully when submitting a 510(k) and a patent application close in time.¹⁴⁵ The fear of losing the ability to enforce a patent makes 510(k) a slightly more perilous route to market than PMA.¹⁴⁶

F. Conceptual Areas of Tension and 510(k)'s Effect on Innovation Policy

The ease of 510(k) as compared to PMA encourages the development of familiar products with familiar intended uses, instead of devices that address unsolved health needs. 510(k) is intended to strike a careful balance between ensuring that devices are safe and effective and encouraging innovation in the medical device sector,¹⁴⁷ but it is silent on which *types* of devices are encouraged. Overall, it is far from clear whether 510(k) and related regulations have a positive or negative effect on innovation because it is difficult both to disentangle device types and to determine how innovation should be measured in this context.¹⁴⁸ When it comes to the intersection between 510(k) and the patent system, we should note that only 15% of all Class II and Class III 510(k) applications are for devices with new technological characteristics of any kind.¹⁴⁹ Our analysis now turns to these devices and to those subject to PMA.

A common question in patent law theory is whether the patent system strikes the optimal balance between channeling new technology to the public through the promotion of innovation and ensuring that the product is widely available at a reasonable price.¹⁵⁰ Overbroad patent protection can stifle innovation and dissemination by reducing opportunities for follow-on innovation.¹⁵¹ This chilling effect may be particularly hazardous in the medical device field, where most manufacturers claim inspiration from an earlier device in their 510(k) ap-

143. *E.g.*, *Medtronic Xomed, Inc. v. Gyrus ENT LLC*, 440 F. Supp. 2d 1300, 1327 (M.D. Fla. 2006).

144. *See* Regitz, *supra* note 111.

145. *See id.*

146. This is especially so when a company's patent attorneys are unaware of filings by its FDA counsel.

147. *See* Flaherty, *supra* note 4, at 926–27.

148. *See* INST. OF MED., *supra* note 19, at 164–69. The Institute of Medicine noted that the information necessary to make such a determination does not yet exist, but recommended that FDA assemble a group to study the issue. *See id.* at 169, 194, 202–03.

149. GAO 2009, *supra* note 11, at 7.

150. Nugent, *supra* note 55, at 136.

151. *Id.* at 154–55.

plications. Even though improvements to existing devices can themselves be patent-eligible, those patent rights are often subordinate to “blocking patents” covering an earlier product.¹⁵² In other words, a manufacturer may need several licenses to market a new device, even if that manufacturer obtained patent protection for the improvements that are the device’s selling points.¹⁵³ Thus, while the 510(k) system provides an efficient path to market for improvements to existing devices,¹⁵⁴ the patent system could actually be harming innovation in this area.¹⁵⁵

There is, of course, a difference from a public policy perspective between introducing an improvement and building a wholly new device that solves a distinct problem. While a new device may be marketable without the need to obtain patent licenses from others, it can be difficult for new technology to compete in a system where the speed of FDA regulatory approvals favors old technology (or improvements on it) over new technology (which is more likely to require PMA).¹⁵⁶ Patents typically raise barriers to entry for competitors by creating monopolies, but the FDA approval process poses a separate obstacle to market entry in the medical device industry.¹⁵⁷ These obstacles, unfortunately, increase as a device’s unfamiliarity and novelty increase. Thus, manufacturers who wish to engage in disruptive innovation may ultimately be deterred by the incentive structure that nudges them toward marginal advances in the art.¹⁵⁸ This will remain the case except where revolutionary device pioneers are sufficiently profit-motivated to endure the PMA process.¹⁵⁹ The source and amount of funding for such devices can help in determining just how much innovation is present in this field.¹⁶⁰

Venture capital (“VC”) is of paramount importance to any discussion of new device generation, since the relative amount of VC money in any field roughly reflects the amount of innovation in that field.¹⁶¹

152. *Id.* at 138; Barron et al., *supra* note 9, at 306.

153. *See* Nugent, *supra* note 55, at 138.

154. *See* CTR. FOR DEVICES & RADIOLOGICAL HEALTH, *supra* note 11, at 1–2.

155. *See* Nugent, *supra* note 55, at 138.

156. Black, *supra* note 65, at 417.

157. *Id.*

158. This is not necessarily a bad situation. It is extremely important to have very high quality versions of the medical devices already on the market, and it is very useful to adapt older devices to new technology (such as smartphone applications). Creating novel approaches to solving familiar problems is essential. To a large degree, the public health requires continuing improvements upon existing devices *and* a steady stream of revolutionary devices.

159. *See* Black, *supra* note 65, at 417. The patent system surely helps encourage innovation that results in truly valuable patents. It might also help restore balance to the inventor’s choice between marginal and revolutionary innovation.

160. *See* Ackerly et al., *supra* note 46, at w74.

161. *Id.*

This may be the case because venture funding is, per dollar, three times more effective in producing patentable inventions than traditional corporate R&D¹⁶² (with patents themselves being a very good proxy for innovation). In addition to Medicare reimbursements, the VCs in the medical device industry care desperately about the patent landscape and the efficiency of FDA review.¹⁶³ These two legal considerations can dramatically affect a medical device company's ability to obtain new venture funding¹⁶⁴ and to conduct a successful exit strategy.¹⁶⁵ The relationship between patents and 510(k) is therefore of utmost importance to those funding many new medical devices.

The VC community, unsurprisingly, takes the position that FDA review ought to be more streamlined, particularly for revolutionary devices, most of which are developed by small, venture-backed companies.¹⁶⁶ While the 510(k) system is useful for — and encouraging of — “routine” products,¹⁶⁷ truly revolutionary advances are inappropriately taxed by the requirement that they undergo PMA.¹⁶⁸ VCs perceive FDA's risk aversion to be harming innovation and development of medical devices.¹⁶⁹ From their perspective, the FDA regulatory system is “broken” in its treatment of novel medical devices, and the approval process for new technology needs revision.¹⁷⁰

This take on medical device regulation is in some tension with the need to ensure the safety of truly novel devices, even though no one disputes the general desirability of promoting the development of such devices. Despite the cries of VCs against overregulation by FDA, at least one academic has advanced the argument that vigorous regulation might actually be in the long-term interest of VCs and innovators.¹⁷¹ According to this argument, even though it may initially appear that regulation increases costs, in the long run, patents and regulation might work together to increase and protect profits.¹⁷² After

162. *See id.* at w69.

163. *Id.* at w72.

164. Keith D. Lindenbaum & James D. Borchardt, *MX: A Head Start for Medical Device Start-Ups*, *MED. DEVICE & DIAGNOSTIC INDUS.* (Jan. 21, 2011), <http://www.mddionline.com/article/mx-head-start-medical-device-startups>.

165. *See INST. OF MED.*, *supra* note 19, at 170 (even if it means paying a premium, large companies wait until FDA review is successfully completed before acquiring a startup); Lindenbaum & Borchardt, *supra* note 164 (the average medical device company that goes public holds fifteen U.S. patents at the time of its initial public offering).

166. Lasersohn, *supra* note 49, at 13.

167. *Id.*

168. *Id.*

169. *Id.* at 16.

170. *Id.* at 2, 13, 16.

171. *See generally* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 *MICH. TELECOMM. & TECH. L. REV.* 345, 349 (2007) (arguing that FDA regulation actually protects profits).

172. *See id.* at 356.

all, increased regulatory hurdles increase barriers to entry for competitors, just like patent protection.¹⁷³ For truly novel devices, then, the existence of PMA as a later barrier to innovation might encourage innovation (when feasible) for a pioneer who believes that PMA will be more difficult for its competitors to overcome. At the same time, a robust regulatory system that ensures safety and effectiveness may increase public and physician confidence in medical devices, facilitating new devices' general acceptance in the market and increasing revenues for all device manufacturers.

V. CONCLUSION

Ultimately, medical device regulation, and 510(k) in particular, represents a tradeoff between permitting the expedient introduction of new devices and preserving the FDCA's protections of public health. These objectives are frequently in conflict, and the resulting confusion is greatly exacerbated when medical device regulation intersects with the patent system, our usual mechanism for promoting innovation. At the end of the day, it is impossible to say whether these conflicts are adequately resolved by legislation or case law or whether they have a major distorting or chilling effect on innovation. It is even difficult to assess whether 510(k) succeeds in either liberally permitting the introduction of new devices or ensuring that they are safe and effective. What can be said, however, is that the Byzantine regulatory system and the intricacies of patent law are both extremely important to the medical device industry and to the millions of people who benefit from outstanding devices. The intersection between the two is no less complex, and no less important.

173. *Id.*