



Medical Device Innovation In America: The Tensions Between Food and Drug Law and Patent Law

Citation

Adam Lewin, "Medical device innovation in America: The tensions between food and drug law and patent law" (April 2012).

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

Adam Lewin

Harvard Law School, Class of 2012

April 2012

Submitted in Satisfaction of the Course Paper Requirement for Food and Drug Law

ABSTRACT

Medical devices are an extraordinarily large and important component of the delivery of healthcare services. This Paper examines the manner in which they are introduced into commerce and the ways in which legal privileges and encumbrances upon medical devices affect their dynamics in the market. The usual way of regulating introduction of new products to promote innovation is through the patent system. With medical devices, a complex regulatory framework also governs their market introduction. These two independent bodies of law are occasionally in tension, producing a number of distortions and unusual incentives for manufacturers of medical devices. This Paper aims to understand the medical device regulatory context in detail and to survey these pressure points, with an emphasis on how the interaction between food and drug law and patent law relates to innovation policy.

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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 medical devices, utilizing new technological wizardry, is crucial to maintaining an up-to-date and state-of-the-art health care system. And yet patients need and deserve assurances that medical devices are safe and effectiveness. The legal structures regulating the introduction of medical devices must 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. Brand new categories of devices, like new drugs, must receive premarket approval (“PMA”) from FDA before going to market, a difficult and expensive process requiring clinical trials. However, the vast majority of new medical devices are cleared instead through a premarket notification process referred to as “510(k),” which merely requires a showing that the new device is “substantially equivalent” in terms of safety and effectiveness to an existing, legally marketed device. The 510(k) process is rapid, inexpensive, and popular among device manufacturers.

Meanwhile, it is very important for innovative new medical devices to receive patent protection in order to enable recovery of the high costs of upfront research and development. As the usual legal mechanism for promoting innovation, patent law re-

quires that new inventions be “novel” and “non-obvious” to merit the monopoly rights that it confers.

These two areas of law regulating the introduction of medical devices occasionally may come into tension and raise serious questions about the process by which new medical devices come to market. For example, may a manufacturer seek FDA clearance under the guise of “substantial equivalence” to an existing product and yet claim novelty in a patent application? Does a manufacturer admit infringement when claiming equivalence to a device covered by a patent? How is innovation affected overall when the process for bringing recognizable devices (or improvements upon them) to market is fast and straightforward, but bringing an unfamiliar device to market is expensive and complex? Is our legal system in practice striking an optimal balance between promoting the development of new devices and yet ensuring the safety and effectiveness of those that reach the market?

The analysis of this Paper proceeds as follows. Part II explains the regulatory environment for premarket medical device review in detail, which is essential for understanding how it interacts with patent law. Part III provides a brief survey of the most important and relevant aspects of patent law doctrine and policy as applied to medical devices. Part IV then examines several of the areas in which medical devices find themselves caught in possible conflict between patent law and food and drug law. This Part

also offers some consideration of how these pressure points may advance or retard innovation policy in this important, complex, and dynamic field. Part V concludes.

II. THE FDA’S MEDICAL DEVICE REGULATORY FRAMEWORK

As with drugs, FDA regulates the introduction, manufacture, and use of medical devices in the United States. For purposes of delineating the scope of FDA’s medical device oversight, the Federal Food, Drug, and Cosmetic Act (“FDCA”) supplies an extremely broad definition. A “medical device” is:

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

This definition is broad enough to encompass such simple objects as tongue depressors, and applies counter-intuitively to such articles as general-purpose lab equip-

¹ Federal Food, Drug, and Cosmetic Act § 201(h), 21 U.S.C. § 321(h) (2010) (emphasis added).

ment, when used in a manner within the statute's definition.² Medical devices range from these simple examples to extremely advanced devices like artificial hearts.³

A. The Medical Device Amendments of 1976

FDA is charged with oversight of medical devices, but until 1976, its regulatory authority was limited to postmarket review.⁴ Congress was forced to respond following a series of public deaths and infertility incidents caused by intra-uterine devices.⁵ The resulting Medical Device Amendments of 1976 ("MDA")⁶ created the structure of the regulatory scheme still used today⁷ and, in recognition of the increasing regulatory burdens placed upon medical device companies, was meant to strike a careful balance between scrutiny to avoid safety hazards and continued promotion of the development of new medical devices.⁸

It is important to keep in mind the factual backdrop against which the MDA were passed. The medical device landscape was different in 1976 than it is today. For

² *Is The Product A Medical Device?*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm> (last updated Mar. 1, 2010). Notably, the most significant limitation in the definition of medical device is meant not to limit its scope, but to distinguish medical devices from drugs. *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 Mar. 5, 2012).

⁴ See James M. Flaherty, Jr., *Defending Substantial Equivalence: An Argument for the Continuing Vitality of the 510(k) Premarket Notification Process*, 63 FOOD & DRUG L.J. 901, 902 (2008) (before 1976, FDA did not have premarket power to review new devices for safety and effectiveness).

⁵ Diana M. Zuckerman, Paul Brown, & Steven E. Nissen, *Medical Device Recalls and the FDA Approval Process*, 171 ARCHIVES INTERNAL MED. 1006, 1006 (2011); see also H.R. REP. No. 94-853 (1976).

⁶ Pub. L. No. 94-295, 90 Stat. 539.

⁷ *PMA Approvals*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm> (last updated June 18, 2009).

⁸ Flaherty, *supra* note 4, at 901.

the most part, device technology then was comparatively much more straightforward than contemporary mechanical wizardry, and very few devices were permanently implanted or intended to sustain life as many are today.⁹

B. Three Classes, Three Types of Oversight

The MDA were meant to balance competing concerns of safety and innovation through a sliding scale approach, requiring FDA to categorize devices into three classes according to the degree of control needed to assure safety and effectiveness.¹⁰ The class a device belongs to depends not on its physical or technological characteristics, but rather its indications for use and intended use.¹¹ Device classifications are publicly available in comprehensive form.¹²

1. Class I Devices

Class I devices are subject to the least burdensome regulation and need only comply with general controls, which consist of prohibitions on adulterating or misbranding and conformance with good manufacturing practices.¹³ This is essentially the same kind of limited regulation that was already utilized by FDA prior to the MDA.¹⁴

⁹ Zuckerman et al., *supra* note 5, at 1007.

¹⁰ *PMA Approvals*, *supra* note 7; PETER BARTON HUTT, RICHARD A. MERRILL, & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS* 980 (3d ed. 2007).

¹¹ *Device Classification*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> (last updated Apr. 27, 2009).

¹² See generally 21 C.F.R. §§ 862–892 (2010).

¹³ See *Device Classification*, *supra* note 11.

¹⁴ Harry W. Barron, Irving S. Rappaport, & Bruce A. Johnson, *Medical Device and Patent Laws Clash?*, 34 *FOOD DRUG COSM. L.J.* 304, 309 (1979).

Examples of Class I devices include such low risk items as gloves, bandages, and dental floss.¹⁵

The reality of today's world is that a large majority — 74% — of Class I devices are exempt from all forms of premarket review altogether.¹⁶ Indeed, since the Food and Drug Administration Modernization Act of 1997 (“FDAMA”), Class I devices are exempted by default, and are only subject to premarket review if “intended for a use of substantial importance in preventing impairment to human health, or . . . present[] a potential unreasonable risk of illness or injury.”¹⁷ Forceps and reading glasses are two examples of devices that are exempt from premarket review.¹⁸

2. Class II Devices

Class II devices are those for which general controls cannot, by themselves, provide adequate guarantees of safety and effectiveness.¹⁹ Examples of Class II devices include electrocardiographs, wheelchairs, catheters, hearing aids, x-ray equipment, and

¹⁵ *Device Classification*, *supra* note 11. These examples also underscore the breadth of the definition of “medical device.”

¹⁶ *Id.* Moreover, a few devices are even exempt from GMP. *Id.* FDA maintains a list of exemptions at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm>.

¹⁷ Pub. L. No. 105-115, § 206, 111 Stat. 2296; *see* J. Matthew Buchanan, Comment, *Medical Device Patent Rights in the Age of FDA Modernization: The Potential Effect of Regulatory 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); *The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, U.S. FOOD & DRUG ADMIN. (March 20, 1998), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf>.

¹⁸ 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 9 (2009) [hereinafter GAO 2009].

¹⁹ *See* Federal Food, Drug, and Cosmetic Act § 513, 21 U.S.C. § 360c (2010).

bone screws.²⁰ In addition to general controls, special controls apply to Class II devices, which consist of labeling requirements and postmarket surveillance to ensure performance standards are met.²¹

Most Class II devices are subject to a form of premarket review known as the 510(k) process (so named after its section number in the FDCA), requiring notification to FDA at least 90 days before marketing.²² However, FDA has affirmatively exempted some Class II devices from all forms of premarket review,²³ although they are not exempt by default as are Class I devices. Examples of exempt Class II devices include wheeled stretchers and mercury thermometers.²⁴

3. Class III Devices

Class III devices are those subject to the highest standards of premarket review. FDA organizes devices into Class III when performance standards or general controls cannot ensure their safety and effectiveness; broadly, these are devices that are “for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health” or that “present[] a potential un-

²⁰ Barron et al., *supra* note 14, at 309; *Device Classification*, *supra* note 11; *Guidance on the Center for Devices and Radiological Health’s Premarket Notification Review Program*, U.S. FOOD & DRUG ADMIN. (June 30, 1986), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm> (last updated June 18, 2009).

²¹ *Device Classification*, *supra* note 11.

²² See Federal Food, Drug, and Cosmetic Act § 510, 21 U.S.C. § 360 (2010); *Device Classification*, *supra* note 11. The 510(k) process is discussed in detail in Part II.C., *infra*.

²³ FDA publishes their Class II exemptions in the Federal Register. For an example of one such publication, see Medical Devices; Exemptions From Premarket Notification; Class II Devices, 63 Fed. Reg. 3142-01 (Jan. 21, 1998).

²⁴ GAO 2009, *supra* note 18, at 8.

reasonable risk of illness or injury.”²⁵ Members of this last category include heart valves, pacemakers, and automated external defibrillators.²⁶

In general, premarket approval (“PMA”) is required from FDA before a Class III device may be marketed.²⁷ A PMA is an onerous and exhaustive procedure, requiring extensive investigation and clinical trials to demonstrate a device’s safety and effectiveness.²⁸ A PMA can cost millions and take years to complete.

To avoid a substantial disruption in the medical device industry, the MDA “grandfathered” devices legally marketed prior to 1978 (“preamendments” devices) so that they could remain on the market without a PMA.²⁹ However, all *new* devices are automatically pigeonholed into Class III (and therefore require PMA).³⁰ Once again, to preserve parity between preamendments and postamendments devices, an exception was included in the MDA. A new device — despite its Class III status — may avoid the PMA process and go through 510(k) instead if it is “substantially equivalent” to a preamendments device, until FDA begins to require PMA for that preamendments device

²⁵ See Federal Food, Drug, & Cosmetic Act § 510, 21 U.S.C. § 360c (2010); *Device Classification*, *supra* note 11.

²⁶ *Id.*; *Guidance on the Center for Devices and Radiological Health’s Premarket Notification Review Program*, *supra* note 20.

²⁷ See 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 (2000).

²⁸ See HUTT ET AL., *supra* note 10, at 1010–11; Flaherty, *supra* note 4, at 912–13.

²⁹ See *id.* at 906–07; see also HUTT ET AL., *supra* note 10, at 987. However, FDA retained the authority to require preamendments categories of devices to undergo PMA before marketing. See Upadhye, *supra* note 27, at 17.

³⁰ *PMA Approvals*, *supra* note 7.

type.³¹ Roughly 60% of Class III devices reach the market through this mechanism today, a number well beyond the contemplation the 1976 Congress that created this option as a temporary phase out for preamendments device types.³²

C. The 510(k) Scheme

The 510(k) program, which represents an expeditious path to market as compared to PMA, is used to clear the vast majority of devices for marketing.³³ The program has the twin — and not always compatible — goals of ensuring the safety and effectiveness of new devices and promoting medical device innovation by minimizing the burdens to marketing them.³⁴ 510(k) represents the careful balance that medical device regulation strives to achieve. On the one hand, liberally allowing the marketing of new devices promotes their innovation, attracts inventors and investors to the field, and lowers

³¹*Device Classification*, *supra* note 11; see HUTT ET AL., *supra* note 10, at 987–88. The MDA anticipated that all Class III devices would proceed through the PMA process once FDA began requiring it. Rita F. Redberg, *Medical Devices and the FDA Approval Process*, 170 ARCHIVES INTERNAL MED. 1831, 1832 (2010); see also INSTITUTE OF MEDICINE, 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 18, at 3, 16. FDA has not complied with this directive, so most Class III devices to this day are cleared for marketing through the 510(k) process. *Id.*

³² Redberg, *supra* note 31, at 1832; HUTT ET AL., *supra* note 10, at 988.

³³ GAO 2009, *supra* note 18, at 8–9 (reporting that 98% of premarket review is through 510(k)).

³⁴ Jeffrey Shuren, *A Letter from the Center Director*, U.S. FOOD & DRUG ADMIN. (Jan. 21, 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 Zuckerman et al., *supra* note 5, at 1007; Redberg, *supra* note 31, at 1832.

the ultimate cost to patients. Meanwhile, FDA must provide reasonable assurances to the public that these devices are safe and effective for their indicated uses.

1. Overview

If the premarket notification pathway is available, a device manufacturer must submit a 510(k) at least 90 days before a device is to be marketed for the first time.³⁵ A 510(k) must also be submitted before a currently marketed device is to be significantly modified in ways that could impact its safety or effectiveness or that alter its intended use.³⁶

Whereas a PMA demands extensive and meticulous documentation to demonstrate safety and effectiveness,³⁷ a 510(k) submission typically includes simply: (1) the device's name, class, proposed labels, and intended use; (2) a statement of substantial equivalence to a predicate device, with data; (3) data demonstrating the effects of changes or modifications that could affect safety or effectiveness, if any; and (4) a summary that enables FDA to understand substantial equivalence, which identifies the predicate device and compares the new device's intended use and technological characteristics.³⁸

³⁵ When a premarket notification submission is required, 21 C.F.R. § 807.81 (2010).

³⁶ *Id.*

³⁷ See LAWRENCE M. SUNG, MEDICAL DEVICE PATENTS 173–74 (2008 ed.).

³⁸ Information required in a premarket notification submission, 21 C.F.R. § 807.87 (2010); Content and format of a 510(k) summary, 21 C.F.R. § 807.92 (2010).

Essentially, a 510(k) must provide enough information for FDA to make a substantial equivalence determination. Although clinical trials are not necessary, FDA usually needs some data to make this evaluation, which usually consists of statistics such as intended use, physical composition, and method of operation.³⁹ Performance data are only required where there is an important difference between the two devices, such as a change in intended use or technology, or if the descriptions alone do not convince FDA of correspondence in performance.⁴⁰

Because 510(k) is a notification process, rather than an approval mechanism, the burden is on FDA to make an evaluation of substantial equivalence (and to determine whether the 510(k) route is even available). After 90 days, the applicant may proceed to market if FDA has remained silent.⁴¹ FDA clearance of a 510(k) signifies merely that: clearance, and not approval.⁴² FDA's acquiescence to a 510(k) is only an indication that it considers the new device to be substantially equivalent to a predicate, and therefore

³⁹ *Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program*, *supra* note 20.

⁴⁰ *Id.* In addition, FDA recently announced that it will issue guidance to clarify some uncertainty about when manufacturers must submit performance data. News Release, U.S. Food & Drug Admin., FDA to improve most common review path for medical devices (Jan. 19, 2011), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm240418.htm>

⁴¹ *Premarket Notification (510k)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> (last updated Sept. 3, 2010).

⁴² *Id.*

marketable, but “does not in any way denote official approval of the device” the way a PMA does.⁴³

The 510(k) route is significantly easier, cheaper, and speedier than PMA. For most 510(k) applications, it is only an exercise in comparison to existing devices — rather than establishment of safety and effectiveness anew — so clinical data are not required.⁴⁴ Whereas FDA reaches 60% of PMA decisions within 180 days, it reaches 90% of 510(k) decisions within 90 days.⁴⁵ Whereas the average PMA review time is nearly nine months (plus four to five years needed to conduct clinical trials), the average 510(k) review time from beginning to end is three months.⁴⁶ Whereas a PMA fee averages about \$200,000 and costs FDA \$870,000 (plus the staggering \$15–20 million private cost of clinical trials), the 510(k) fee averages about \$3,700 and costs FDA \$18,200.⁴⁷

As a result, it is difficult to overstate the importance of 510(k) as a tool for bringing novel devices to market. More than 8,000 new medical devices are introduced annually in the United States.⁴⁸ Of these, a majority (67%) are exempt from premarket re-

⁴³ *Id.* It is misbranding to represent that a device is FDA approved when it has merely been cleared through the 510(k) process. *Id.*; see also *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 925 n.3 (9th Cir. 2010) (evaluating a contention that a device was misbranded, having been referred to as “approved”).

⁴⁴ GAO 2009, *supra* note 18, at 14–15.

⁴⁵ *Id.* at 15. 98% of all 510(k) decisions are reached within 150 days. *Id.*

⁴⁶ Jordan Paradise, Alison W. Tisdale, Ralph F. Hall, & Efrosini Kokkoli, *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).

⁴⁷ *Id.*; GAO 2009, *supra* note 18, at 15.

⁴⁸ Redberg, *supra* note 31, at 1831.

view altogether.⁴⁹ The remainder is the roughly 3,000 devices that undergo FDA review before marketing, 98% of which do so through the 510(k) pathway.⁵⁰ The remaining 50–70 devices each year require PMA, representing less than 1% of all new devices.⁵¹ Even among Class III devices, greater than three-fourths do not undergo PMA.⁵² In sum, the 510(k) process, which is backward-looking to existing devices, dominates the market entry of U.S. medical devices.

Because of its relative simplicity and ease, 510(k) is characterized as “manufacturer friendly.”⁵³ It comes as no surprise, then, that medical device companies care a great deal about whether their new devices qualify for the 510(k) conduit. From their perspective, using 510(k) can amount to months or years shaved off their premarket review time⁵⁴ and presents the much easier task of finding data demonstrating equivalence rather than the herculean undertaking of conducting clinical trials.⁵⁵ As a result, device makers have become extremely aggressive in pursuing the 510(k) pathway.⁵⁶ One well-publicized example of a company going to extremes to avoid PMA involved a company called ReGen that manufactured a device called Menaflex, which is a pad

⁴⁹ GAO 2009, *supra* note 18, at 8–9.

⁵⁰ HUTT ET AL., *supra* note 10, at 992; Shuren, *supra* note 34. 90% of Class I or II 510(k) submissions and 67% of Class III 510(k) submissions are ultimately cleared. GAO 2009, *supra* note 18, at 6.

⁵¹ *Id.* at 8–9; 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, 374 (2006).

⁵² Zuckerman et al., *supra* note 5, at 1011.

⁵³ Flaherty, *supra* note 4, at 913.

⁵⁴ See Barron et al., *supra* note 14, at 308.

⁵⁵ See Raciti & Clements, *supra* note 51, at 374.

⁵⁶ Asha S. Geire, Comment, *Price Wars and Patent Law: Reducing the Cost of Health Care Through Medical Device Price Transparency*, 12 TUL. J. TECH. & INTELL. PROP. 239, 249–50 (2009).

used in repairing a torn meniscus that acts as a shock absorber between knee bones with the hope of mitigating the rate of recurrent tears.⁵⁷ After ReGen’s clinical trials confronted record-keeping issues, it decided to attempt to use 510(k) as an alternative to restarting.⁵⁸ ReGen claimed a shoulder implant and a hernia treatment as predicates, which FDA twice rebuked.⁵⁹ After enlisting members of Congress to personally write to FDA’s commissioner, bringing in scientists from outside FDA labs, and becoming involved in the selection process for the convention of a special panel of outside physicians, FDA cleared ReGen’s third 510(k) application.⁶⁰

2. 510(k) Subject Matter and Permissible Predicate Devices

A “predicate device” is the older device to which a newer device claims substantial equivalence in a 510(k). Three broad categories of device may be legally used as predicates in a 510(k), and a 510(k) may claim multiple predicate devices so that all features of a new device are covered.⁶¹

First, a new device — even one in Class III — can claim substantial equivalence to a preamendments Class III device.⁶² This how most Class III devices are cleared

⁵⁷ Alicia Mundy, *Political Lobbying Drove FDA Process*, WALL ST. J., Mar. 6, 2009, at A1. The market for this device was potentially very large; one million meniscus repairs are performed annually in the United States. *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.* FDA’s reasoning was that weight-bearing forces in the knee are very different than those observed in the shoulder or abdomen, so the previous devices offered no guarantee of the safety or effectiveness of Menaflex. *See id.*

⁶⁰ *Id.*

⁶¹ SUNG, *supra* note 37, at 167.

⁶² *Premarket Notification (510k)*, *supra* note 41.

through 510(k) rather than PMA, as described above. Manufacturers may avail themselves this opportunity for their Class III devices until FDA begins to require PMA for (or reclassifies) the predicate.⁶³ In addition, postamendment Class III devices in general cannot be used as predicates if cleared through PMA.⁶⁴

Second, devices on the market by reason of 510(k) can be used as predicates.⁶⁵ This allows a lineage of 510(k) devices to be created, ultimately tracing back to a pre-amendments device.⁶⁶ The ability to daisy-chain 510(k)s in this way, long allowed informally by FDA, was endorsed by Congress in the Safe Medical Devices Act of 1990 (“SMDA”).⁶⁷

Finally, devices that have been reclassified from Class III to Class II or Class I may be used as predicates; moreover, any Class II or Class I device can go through 510(k).⁶⁸ New devices may be reclassified at the time of premarket review through the “de novo” 510(k) process, created by the FDAMA in 1997, which can be used to reclassify a Class III device when no other satisfactory predicate is available.⁶⁹ The de novo pro-

⁶³ See *id.*

⁶⁴ See Stanley S. Wang & John J. Smith, *Potential Legal Barriers to Increasing CMS/FDA Collaboration: The Law of Trade Secrets and Related Considerations*, 58 FOOD & DRUG L.J. 613, 615 (2003).

⁶⁵ See *Premarket Notification (510k)*, *supra* note 41.

⁶⁶ See INSTITUTE OF MEDICINE, *supra* note 31, at 87–88.

⁶⁷ Pub. L. No. 101-629, 104 Stat. 4511; see HUTT ET AL., *supra* note 10, at 998–99.

⁶⁸ *Premarket Notification (510k)*, *supra* note 41.

⁶⁹ Pub. L. No. 105-115, § 207, 111 Stat. 2296; Michael A. Swit, *The “de Novo” 510(k) Process and the Reclassification of Class III Devices*, RAPS FOCUS, March 2006, at 32, 32, available at <http://www.medicaldevices.org/sites/default/files/Swit--RAPSFocusArticle--deNovo510k--March2006.pdf>; James G. Dickinson, *510(k) Caution Engulfs FDA—Predicate Choices Questioned*, MED. DEVICE & DIAGNOSTIC INDUSTRY (June 3, 2010), <http://www.mddionline.com/article/510k-caution-engulfs-fda—predicate-choices-questioned>.

cess was meant to mitigate the 1976 MDA's problem that truly innovative devices would be outside the scope of 510(k) and therefore, ironically, be penalized by their own novelty in the form of a PMA obligation.⁷⁰ This was in spite of the fact that many new devices more closely matched the risk profile of a Class I or Class II device, even as their originality prevented a claim of substantial equivalence to those devices. The FDAMA was intended to tie the rigor of premarket review to the risk of a particular kind of device, and so the de novo process was created for lower risk — but new — devices.⁷¹ To utilize this procedure, a manufacturer submits a 510(k), which will be rejected for lack of substantial equivalence with a proper predicate device.⁷² At that point, the manufacturer can file a de novo petition with FDA, in which it may suggest a Class and explain the degree of control necessary to ensure the device's safety and effectiveness.⁷³ The manufacturer must show that the device would have been substantially equivalent to a Class I or II device, if one existed.⁷⁴ After FDA publishes its classification in the Federal Register, the device can be used as a predicate.⁷⁵

A 510(k) is also required when a manufacturer makes changes to an existing, legally marketed device. FDA employs a special process for this incremental 510(k),

⁷⁰ See Swit, *supra* note 69, at 32. This is because new devices are automatically placed into Class III, at least initially. *Id.*

⁷¹ See *id.*; SUNG, *supra* note 37, at 171.

⁷² Swit, *supra* note 69, at 33.

⁷³ *Id.*

⁷⁴ SUNG, *supra* note 37, at 171.

⁷⁵ See Swit, *supra* note 69, at 33.

known appropriately as a “Special 510(k).”⁷⁶ This type of 510(k) is most closely analogous to the second scenario outlined above, because it references the 510(k) used to clear the existing device. It is an appealing procedure because it is processed within 30 days.⁷⁷ Special 510(k)s are appropriate for changes that retain a device’s intended use and do not amount to an alteration of the device’s “fundamental scientific technology.”⁷⁸ For example, a manufacturer may properly submit a Special 510(k) when changing a device’s energy type, environmental specifications, ergonomics, dimensions, software, or packaging.⁷⁹ On the other hand, a more central alteration such as a change from a metal blade to a laser in a surgical device would not be appropriate.⁸⁰ Changes in materials can sometimes be cleared through a Special 510(k), if those materials are inconsequential to the safety or effectiveness of the device.⁸¹ Ultimately, this mechanism facilitates small but potentially useful technological tweaks by permitting rapid times to market for them.

3. Substantial Equivalence

To truly understand the 510(k) process, one must appreciate the legal standards FDA uses to evaluate substantial equivalence. 510(k) is grounded in substantial equivalence.

⁷⁶ *The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, *supra* note 17.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *See id.* For example, a change in a material that contacts body tissue to one that has not yet been used in any predicate device is usually not appropriately cleared through a Special 510(k). *Id.*

lence, which is the basis for its assurances of medical device safety and effectiveness. For this, devices cleared through a 510(k) must have some guarantee that they are at least as safe and effective as a predicate device, because FDA does not freshly review these devices for safety and effectiveness through PMA.⁸² Indeed, FDA is only empowered to issue an order of substantial equivalence once it concludes as such.⁸³

Although the term “substantial equivalence” appeared in the MDA, it was only ever defined substantively by FDA regulation, which took a flexible, sliding-scale approach.⁸⁴ Substantial equivalence under this paradigm varied greatly, from mere equivalence in labeling and descriptive information for low-risk devices, to performance data requirements for high-risk devices.⁸⁵ Frightened that a judicial decision might disrupt its regulatory edifice, FDA persuaded Congress to codify its understanding, which it did in 1990 by amending the FDCA to include § 513(i).⁸⁶

This now-statutory definition outlines the following schematic for determining substantial equivalence: First, a device is automatically considered substantially equivalent

⁸² *Premarket Notification (510k)*, *supra* note 41.

⁸³ See *The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, *supra* note 17.

⁸⁴ See INSTITUTE OF MEDICINE, *supra* note 31, at 87–88. FDA based its interpretation on language from the MDA’s legislative history. *Guidance on the Center for Devices and Radiological Health’s Premarket Notification Review Program*, *supra* note 20; see H.R. REP. No. 94-853, at 36–37 (1976) (“The committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness.”).

⁸⁵ See *The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, *supra* note 17.

⁸⁶ See INSTITUTE OF MEDICINE, *supra* note 31, at 88.

lent to a predicate device if the two share the same intended use and technological characteristics.⁸⁷ If the new device has the same intended use but *different* technological characteristics as the predicate,⁸⁸ it is substantially equivalent if: (1) the change in technology does not raise novel questions of safety and effectiveness as compared to the predicate, and (2) the new device is otherwise at least as safe and effective as the predicate.⁸⁹ Conversely, two devices are not substantially equivalent if the new features “could affect safety or effectiveness in a way that is consequential under conditions of intended use.”⁹⁰ A device with a new intended use presents a more difficult case for substantial equivalence.

Ultimately, this statutory definition leaves many ambiguities and may fail to generate the flexible approach that accounts for varying risk among device types. Thus, a substantial equivalence determination in practice (and the quantity of information required to make such a determination) utilizes a multitude of factors weighed by FDA. Some of these include: intended use, design, energy consumption, materials, chemical composition, manufacturing process, labeling, biocompatibility, the disease to be treat-

⁸⁷ FDA action on a premarket notification, 21 C.F.R. § 807.100 (2010); *Guidance on the Center for Devices and Radiological Health’s Premarket Notification Review Program*, *supra* note 20.

⁸⁸ Examples of “different technological characteristics” include changes in materials, design, energy source, or other features. 21 C.F.R. § 801.100 (2010).

⁸⁹ *Id.*

⁹⁰ *Guidance on the Center for Devices and Radiological Health’s Premarket Notification Review Program*, *supra* note 20.

ed or diagnosed, whether the device is for professional or lay use, the body part or type of tissue involved, and the frequency of use.⁹¹

To put this rubric in perspective and provide some real-world context, from 2005-2007, all devices determined to be substantially equivalent had the same intended uses as their predicates, and 86% had the same technological characteristics.⁹² On the other hand, more than 50% of those devices determined *not* to be substantially equivalent had a new intended use or different technological characteristics from their predicates.⁹³ Overall, the vast majority of submissions are cleared easily: only 1% of all submissions in this period had a new intended use, and only 15% had new technological characteristics.⁹⁴ These data suggest that most devices cleared through 510(k) do not venture beyond their predicates technologically.

In order to fulfill the requirement that a new device cleared through 510(k) be substantially equivalent to a *legally marketed* device, FDA requires that the device used as a predicate remain legally marketed; in other words, FDA must not have removed the predicate device from the market.⁹⁵ More than this, FDA has begun to insist on bet-

⁹¹ *Id.*; *Premarket Notification (510k)*, *supra* note 41.

⁹² GAO 2009, *supra* note 18, at 7.

⁹³ *Id.*

⁹⁴ *See id.*

⁹⁵ *See* 21 C.F.R. § 807.100 (2010). Nonetheless, a device that is off the market because of a voluntary recall or for obsolescence or unprofitability reasons may still be used as a predicate. Alarming, in 2009, 29% of devices applying for 510(k) cited predicates no longer on the market. *See* Industry reacts to proposed changes to 510(K) program, MASSDEVICE (Aug. 4, 2010), <http://www.massdevice.com/news/update-industry-reacts-proposed-changes-510k-program>.

ter performing predicate devices than has been seen in the past. A manufacturer's incentive is to proceed with the predicate device that will best facilitate the 510(k) process (even a poorly performing one), rather than a well performing predicate that presents the best reflection of the new device's safety and effectiveness profile.⁹⁶ In recognition of this problem, FDA announced that it may begin rejecting poorly performing predicates when better ones are available.⁹⁷

The use of good quality, well performing predicate devices is extremely important, in part because of a well-recognized phenomenon known as "equivalence creep" or "piggybacking."⁹⁸ This practice, which has seen daylight since the passage of the SMDA in 1990 formally permitted FDA's longstanding informal policies, consists of claiming substantial equivalence to another postamendment device that itself was cleared through the 510(k) process.⁹⁹ By this mechanism, the incremental differences between successive devices that do not substantially impact safety and effectiveness (and therefore allow for 510(k) clearance) can cumulate to a large disparity between earlier and later devices. A lineage of devices can be nearly impossible for FDA to recreate,¹⁰⁰ undermining 510(k)'s assurances of safety and effectiveness.¹⁰¹

⁹⁶ See Dickinson, *supra* note 69.

⁹⁷ *Id.*

⁹⁸ HUTT ET AL., *supra* note 10, at 998–99.

⁹⁹ *Id.*; see also INSTITUTE OF MEDICINE, *supra* note 31, at 88, 230.

¹⁰⁰ *Id.* at 81

¹⁰¹ Indeed, this process has been criticized even in the popular press, which referred to it as a "daisy-chain system of regulation, in which new devices simply piggy-back on earlier ones, without any [independent]

D. Does 510(k) Adequately Strike a Balance Between Protection and Promotion?

1. Device Recalls and Public Discontent

A series of high profile recalls has produced a challenge to the 510(k) program in the press and in the court of public opinion. Between 2005 and 2009, 3,510 medical devices were voluntarily recalled,¹⁰² including newsworthy recalls such as Johnson & Johnson's ASR hip implants and surgical meshes made by Boston Scientific.¹⁰³ Overall, 71% of the recalls in this period were for devices cleared through 510(k), and many of these were Class III devices or otherwise high-risk.¹⁰⁴ For example, one case involved an inferior vena cava filter, which was Class II devices cleared through the Special 510(k) process that fractured in 25% of patients.¹⁰⁵ In spite of later recalls such as these, hasty 510(k) clearances remain extremely profitable for device companies.¹⁰⁶

Because of how thin the 510(k) review process can be, recalls of devices cleared through the 510(k) process have led to outcry from a number of prominent institutions. Public Citizen's Peter Lurie opined that "the 510(k) process is a loophole that's swal-

examination of their safety." Barry Meier, *Medical Device Approval Process Is Called Flawed*, N.Y. Times, July 30, 2011, at B1.

¹⁰² U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-556T, MEDICAL DEVICES: FDA'S PREMARKET REVIEW AND POSTMARKET SAFETY EFFORTS 11 (2011) [hereinafter GAO 2011].

¹⁰³ Debra Sherman, *Consumer Reports taps ire over bad medical devices*, REUTERS, Mar. 12, 2012, available at <http://www.reuters.com/article/2012/03/12/us-devices-idUSBRE82B1CX20120312> (reporting J&J's recall in response to high failure rates where patients experienced pain, joint dislocation, and damage to the heart, thyroid, and central nervous system due to cobalt and chromium poisoning); see also Barry Meier, *Hip Device Phaseout Followed F.D.A. Data Request*, N.Y. TIMES, Mar. 23, 2012, at B1.

¹⁰⁴ Zuckerman et al., *supra* note 5, at 1006–07.

¹⁰⁵ Redberg, *supra* note 31, at 1832.

¹⁰⁶ See Geire, *supra* note 56, at 250.

lowed the law.”¹⁰⁷ The president of the National Research Center for Women and Families stated that what is “most worrisome about the 510(k) process is whether products that are made out of a new material or using a new technology can realistically be considered safe without clinical trials or a thorough review.”¹⁰⁸ Consumer’s Union (the advocacy arm of Consumer Reports) has begun to campaign for change in the medical device approval process.¹⁰⁹

Courts and commentators have also criticized the 510(k) process as lacking in the strength needed to assure safety and effectiveness.¹¹⁰ Even the Supreme Court has had occasion to comment on it, observing that 510(k) clearances “provide little protection to the public” because 510(k) is “focused on *equivalence*, not safety.”¹¹¹

Worst of all, patients, the end users and beneficiaries of medical devices, typically know nothing of the regulatory process by which they reach market. Most simply assume that FDA plays a heavy hand in regulating them for safety, and are “livid” when they learn how most devices are actually cleared.¹¹² Unfortunately, these discoveries

¹⁰⁷ Flaherty, *supra* note 4, at 922.

¹⁰⁸ *Id.*

¹⁰⁹ Sherman, *supra* note 103. Unsurprisingly, the medical device trade group AvaMed has pushed back, warning that greater regulation would stifle innovation in medical devices. *Id.*

¹¹⁰ *E.g.*, Flaherty, *supra* note 4, at 903.

¹¹¹ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (emphasis in original) (internal quotations omitted). The Supreme Court nonetheless recognizes the difficult balance that 510(k) attempts to strike in medical device regulation. *See Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001) (“While the § 510(k) process lack’s the PMA review’s rigor . . . [its] flexibility is a critical component of the framework under which the FDA pursues its difficult (and often competing) objectives.”).

¹¹² Sherman, *supra* note 103.

usually arise in circumstances where patients are too concerned with major medical problems to become involved in FDA-related activism.¹¹³

2. The GAO Report and FDA's Proposed New Rules for 510(k)

Congress, observing some of these issues, required the Government Accountability Office ("GAO") to study the 510(k) process as part of the FDA Amendments Act of 2007.¹¹⁴ GAO released its findings in 2009. It determined that the 510(k) process is not designed to ensure safety in the first instance, but that a large number of high-risk Class III devices enter the market through 510(k) nonetheless.¹¹⁵ GAO's view is that program, overall, has become too lax. GAO recommended that FDA take action to comply with the SMDA's directive to require PMA for all Class III devices (or reclassify them).¹¹⁶ FDA agreed with this recommendation, but two years later, GAO reported that numerous Class III devices — including some, like implantable hip joints, that have seen recalls — remain marketable through 510(k).¹¹⁷

In response to this study, FDA decided to review the 510(k) process internally and commissioned the Institute of Medicine ("IOM") to do the same in parallel.¹¹⁸ In its report, revealed in early 2011, FDA announced that it would implement 25 new mecha-

¹¹³ *Id.*

¹¹⁴ Pub. L. No. 110-85, 121 Stat. 823.

¹¹⁵ GAO 2009, *supra* note 18, at 27–28.

¹¹⁶ *Id.*

¹¹⁷ GAO 2011, *supra* note 102, at 6–8.

¹¹⁸ *FDA offers plans to improve 510(k) device clearance process, punts hard decisions to IOM*, THEHEART.ORG (Jan. 21, 2011), <http://www.theheart.org/article/1175297.do>; see *infra* Part III.D.3.

nisms to improve 510(k), bolstering the program's safety while facilitating innovation in medical devices.¹¹⁹ Among these, FDA promised to streamline the de novo review process and begin communicating with industry more regularly.¹²⁰ It stated it would issue refreshed and clearer guidance on numerous issues, such as what changes to a device require a new 510(k) and when clinical data are needed.¹²¹ To improve safety, FDA pledged to establish a "Science Center Council" of senior FDA experts to ground the 510(k) process (and even interpretation of the statutory and regulatory legal standards) in science.¹²² The agency similarly stated it would begin to avail itself of a network of external experts for similar purposes.¹²³

Although the medical device industry was apprehensive about the possibility of more burdensome premarket regulation for medical devices, FDA's proposals were received as relatively harmless.¹²⁴ The agency largely agreed with industry complaints

¹¹⁹ News Release, U.S. Food & Drug Admin., FDA to improve most common review path for medical devices (Jan. 19, 2011), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm240418.htm>.

¹²⁰ *Plan of Action for Implementation of 510(k) and Science Recommendations*, U.S. FOOD & DRUG ADMIN. (Jan. 21, 2011), <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf>.

¹²¹ *Id.*

¹²² *Id.* FDA, disturbingly, neglected to report how 510(k) is not currently grounded in science.

¹²³ *Id.*

¹²⁴ *Industry reacts to proposed changes to 510(K) program*, MASSDEVICE (Aug. 4, 2010), <http://www.massdevice.com/news/update-industry-reacts-proposed-changes-510k-program>. Some said FDA simply conceded to industry. *Id.*

that the 510(k) process had become “unpredictable, inconsistent, and opaque” as device complexity increased.¹²⁵

On the other hand, FDA did not adopt some of the more disruptive possibilities it had considered. For example, some scientists had suggested bifurcating Class II into Class IIa and Class IIb, the latter requiring clinical data before clearance to market.¹²⁶ Industry argued in reply that special controls and postmarket surveillance were sufficient to ensure the safety of Class II devices, and in any event, FDA lacked the authority to split the statutory class.¹²⁷ FDA declined to adopt the bifurcation proposal, a decision that the industry predictably lauded. Consumer groups like Public Citizen responded that not adopting the Class IIb category represented a failure to remedy what it sees as 510(k)’s inability to protect the public.¹²⁸

3. The IOM Report

In contrast, the concurrent IOM report, released in July 2011, caused an uproar in the industry. IOM, a nonpartisan expert arm of the National Academy of Sciences, became involved at the request of FDA in 2009, in the wake of the Menaflex incident and

¹²⁵ Shuren, *supra* note 34.

¹²⁶ Rita F. Redberg & Sanket S. Dhruva, *Medical Device Recalls*, 171 ARCHIVES INTERNAL MED. 1011, 1012 (2011).

¹²⁷ See *FDA offers plans to improve 510(k) device clearance process*, *supra* note 118.

¹²⁸ *Id.*

the GAO report.¹²⁹ FDA instructed IOM to evaluate whether 510(k) “optimally protect[s] patient[s] and promote[s] innovation in support of public health.”¹³⁰

IOM, unwaveringly, concluded that 510(k) should be abandoned altogether because it is “flawed” and cannot be improved to adequately examine safety and effectiveness.¹³¹ Indeed, in IOM’s view, 510(k) was never meant to play the role of a pre-market gatekeeper for safety, so it is structurally incapable of being fixed to do so. IOM recommended in particular the construction of a new regulatory framework for Class II, “moderate risk” devices.¹³²

Remarkably, industry began criticizing IOM’s report as biased and erroneous before it was even released.¹³³ An attack on a report, sight unseen, was unprecedented for IOM, which considers itself to be a scientific rather than partisan organization. Although industry fully rejected its report, patient groups embraced it.¹³⁴ Meanwhile, FDA — which is under no obligation to adopt anything in the advisory report — was left in disbelief at the breadth and certitude of IOM’s conclusions.¹³⁵

¹²⁹ See Michele L. Buenafe, *FDA Continues Efforts to Reform 510(k) System, but Future Remains Uncertain*, J. HEALTH CARE COMPLIANCE, Nov.–Dec. 2011, at 43, 43.

¹³⁰ *Id.* at 44.

¹³¹ See generally INSTITUTE OF MEDICINE, *supra* note 31. Interestingly for our purposes, IOM concluded that 510(k)’s effect on medical device innovation is indeterminate. *Id.* at 164–72.

¹³² See Buenafe, *supra* note 129, at 44.

¹³³ See Barry Meier, *Fight Over Medical Device Rules, Sight Unseen*, N.Y. TIMES, July 28, 2011, at A1. Industry even released its own reports to demonstrate that increased regulation would curb innovation and harm patients. *Id.*

¹³⁴ Barry Meier, *Medical Device Approval Process Is Called Flawed*, N.Y. TIMES, July 30, 2011, at B1.

¹³⁵ See *id.*

E. Innovation in the Medical Device industry

In spite of all the rhetoric and regulatory complexity, the medical device industry remains a pioneering, dynamic, and hugely lucrative field. Medical devices represent a \$188.8 billion industry in the United States (generating the majority of medical device revenues worldwide).¹³⁶ Within the healthcare sector, medical devices represent a significant market share, and growing rapidly: from 35% in 2004 to 45% in 2007.¹³⁷ The industry has an overall growth rate of 23%, and, at a profit rate of 18%, carries one of the highest margins in the private sector.¹³⁸

Both revenues and innovations are extremely unbalanced in the industry. In the United States, the largest 2% of medical device companies produce more than half of all industry sales.¹³⁹ Interestingly, however, “virtually all *revolutionary* medical device development in the U.S.” is driven by venture capitalists (“VCs”), channeling funds into small startup firms.¹⁴⁰ This is particularly relevant to our discussion of the *introduction* of new medical devices. VCs invest between \$2–4 billion each year in medical devices, although they are extremely sensitive to the regulatory environment because of the ex-

¹³⁶ See INSTITUTE OF MEDICINE, *supra* note 31, at 169; Geire, *supra* note 56, at 247.

¹³⁷ *Id.*

¹³⁸ See *id.*

¹³⁹ See *id.*

¹⁴⁰ Jack W. Lasersohn, Nat’l Venture Capital Ass’n, Interagency Collaboration in support of Medical Device Innovation, Slides from Presentation at FDA Public Workshop: Identifying Unmet Public Health Needs and Facilitating Innovation in Medical Device Development (June 24, 2010), *available at* <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM221031.pdf> (emphasis added).

pense of bringing a new device to market.¹⁴¹ They also demand significant returns for their large upfront investment.¹⁴² Still, the amount of venture capital, which works as rough proxy for the level of innovation in the field at any given time, is large.¹⁴³

One area of innovation that has recently emerged is the use of powerful, hyper-connected mobile phones and tablets to improve healthcare.¹⁴⁴ Because of the FDCA's sweeping definition of medical device, a smartphone application falls within the scope of FDA's authority when used as a medical device within the meaning of the FDCA.¹⁴⁵ The explosion of mobile applications ("apps") calls for an evaluation of the regulatory environment that serves to control their market entry, and some reflection on how well food and drug law responds to new technology.¹⁴⁶ While overregulation could suppress innovation in this promising area, certain apps will need some oversight to ensure their safety and effectiveness.

As an example, the first smartphone app cleared for marketing (on Apple's iPhone platform) is Mobile MIM, an app that allows physicians to review various kinds of

¹⁴¹ See *id.*

¹⁴² D. Clay Ackerly et al., *Fueling Innovation In Medical Devices (And Beyond): Venture Capital In Health Care*, 28 HEALTH AFF. w68, w69 (2008).

¹⁴³ See *id.* at w74.

¹⁴⁴ 81% of physicians are expected to be using a smartphone in 2012. Jessica Wapner *iRegulate: Should Medical Apps Face Government Oversight?*, SCI. AM. (Apr. 12, 2010), <http://www.scientificamerican.com/article.cfm?id=medical-apps-regulation>.

¹⁴⁵ See *id.*

¹⁴⁶ There are over 1,500 medical apps available, many of which are simply pocket-sized reference volumes, but some of which monitor and control important healthcare functionality. See Katherine Harmon, *Your MRI is calling: FDA approves first medical iPhone app*, SCI. AM. BLOGS (Feb. 7, 2011), <http://blogs.scientificamerican.com/observations/2011/02/07/your-mri-is-calling-fda-approves-first-medical-iphone-app>.

imaging — including CT, PET, MRI, and more — immediately on a mobile device, anywhere in the world, without having to wait for film to develop.¹⁴⁷ Though this is not exactly a breakthrough technology, it does substantially improve the process of reviewing images from important scans by applying technology in a novel fashion.

FDA has now cleared several other smartphone-related “devices.” One includes an ultrasound probe that plugs into a smartphone rather than a specialized computer, and allows for its readings to be distributed over the internet worldwide.¹⁴⁸ This solution, created by Mobisante, was cleared in 2011 and allows for patients in more remote areas to have access to greater medical expertise through the internet.¹⁴⁹

Another app, called PracticeRx, promises to improve patient safety by reporting medical errors to a central database, which can observe trends and alert medical professionals to avert future harm.¹⁵⁰ Yet another app automatically alerts doctors to emergency room visits by their patients, which allows an unnecessary visit to be prevented before the expense is incurred.¹⁵¹ Finally, AgaMatrix now produces a blood glucose meter called iBGStar, which allows a diabetic patient to monitor and analyze glucose infor-

¹⁴⁷ Anne Eisenberg, *Those Scan Results Are Just an App Away*, N.Y. TIMES, Oct. 15, 2011, at BU5. It is worth noting that Mobile MIM took over two years to clear. *Id.*

¹⁴⁸ Scott Jung, *Mobisante’s MobiUS Smartphone Ultrasound Receives FDA 510(k) Clearance*, MEDGADGETS (Feb. 7, 2011), http://medgadget.com/2011/02/mobisantes_mobius_smartphone_ultrasound_receives_fda_510k_clearance.html.

¹⁴⁹ *See id.*

¹⁵⁰ Wapner, *supra* note 144.

¹⁵¹ *Id.*

mation in real-time and send data to a physician via email.¹⁵² FDA cleared iBGStar through the 510(k) process.¹⁵³

It is obvious that FDA must regulate medical apps to some extent, especially because some adverse events have already been reported.¹⁵⁴ But the central tension in medical device regulation, between protection and promotion, is equally apparent here because innovation in this area is as easy to observe as refreshing the ever-expanding list of available medical apps. FDA, for its part, acknowledges this tension. It reports that it is working on guidance for apps, which will probably be on a mild but sliding scale of regulation, and through 510(k).¹⁵⁵

III. A PRIMER ON PATENT LAW AND MEDICAL DEVICES

A. The Foundations and Purpose of Patent Law

The usual legal embodiment of innovation policy in the U.S. — and that of most nations worldwide — is patent law. The U.S. Constitution explicitly grants Congress the power to create a patent system with the express purpose of “promot[ing] the Progress

¹⁵² Brian Dolan, *FDA clears AgaMatrix’s iPhone Glucose Meter*, MOBIHEALTHNEWS (Dec. 7, 2011), <http://mobihealthnews.com/15137/fda-clears-agamatrixs-iphone-glucose-meter>.

¹⁵³ *Id.*

¹⁵⁴ A clinical decision support app failed to display allergy-related information in one instance. Wapner, *supra* note 144.

¹⁵⁵ *See id.* (noting that apps that monitor a pulse or an electrocardiogram, for example, will need some regulation, but digital reference books will not). All of these examples are of devices with identical intended use but different technological characteristics as compared to predicate devices. As such, they can be cleared for marketing through 510(k), but FDA will examine how, if at all, differences in technology affect safety or effectiveness. For example, in the case of Mobile MIM, FDA worked with app developers to ensure that the varying screen contrast of a phone, as compared to a traditional light box, did not compromise physicians’ ability to read scans. Harmon, *supra* note 146.

of . . . useful Arts.”¹⁵⁶ A patent is an exclusive right, or a monopoly, on an idea, granted for a limited period of time.¹⁵⁷

Standard economic theory informs us that in ordinary circumstances, free competition is preferable to monopolies, which cause inflated prices and reduced output (or deadweight loss, in economic terms).¹⁵⁸ However, ideas and other forms of intellectual output, which can be very costly to generate through R&D, are what economists refer to as public goods.¹⁵⁹ This means they 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).¹⁶⁰

Innovation is extremely important to economic growth, but in the absence of some form of legal exclusivity over intellectual output, we will witness a market failure.¹⁶¹ Because many types of inventions have a high upfront cost but their resulting intellectual products are public goods, pioneers will not be able to recover their upfront

¹⁵⁶ U.S. CONST. art. I, § 8, cl. 8. Interestingly, this is the only of Congress’s enumerated powers with a purpose given.

¹⁵⁷ See, e.g., Raciti & Clements, *supra* note 51, at 372.

¹⁵⁸ See Kristen Nugent, *Patenting Medical Devices: The Economic Implications of Ethically Motivated Reform*, 17 ANNALS HEALTH L. 135, 139 (2008).

¹⁵⁹ See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1605 (2003).

¹⁶⁰ 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 is non-excludable in its natural form, in the absence of legal or technological protection measures.

¹⁶¹ Nugent, *supra* note 158, at 153.

investment, and free-riders will take advantage of innovators without doing any work of their own.¹⁶² In response, innovators will either reduce their level of R&D to highly suboptimal levels, or refrain from disclosing their inventions to the public, which is problematic because most innovation builds on earlier knowledge.¹⁶³

By means of a limited monopoly, patent law thus seeks to stimulate innovation, generate dissemination of information, encourage development and commercialization, and enable cumulative or follow-on innovation.¹⁶⁴ An exclusive right to an invention for a limited period of time assures an inventor that it can recuperate its upfront investment by charging high monopoly prices, free of competition. The patent system accomplishes exclusivity by giving a patentee the exclusive right to make, use, and sell the patented invention for a finite term.¹⁶⁵ Exclusivity is commonly considered a “bargain,” where the public satisfies itself with a monopoly in exchange for the inventor revealing technological secrets to the public.¹⁶⁶

Patents are a “limited” monopoly because their duration is finite, fixed to 20 years by default.¹⁶⁷ Moreover, the scope of a patent’s legal protection is defined by — and limited to — its claims, which do not necessarily correspond to one product or *em-*

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ Geire, *supra* note 56, at 243.

¹⁶⁵ Nugent, *supra* note 158, at 153.

¹⁶⁶ See generally Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 407 (2010).

¹⁶⁷ See 35 U.S.C. § 154 (2006). Under certain circumstances, the term of a patent can be modified, such as delays caused by the USPTO or FDA. See *infra* Part IV.A.

bodiment of the invention. The claims describe the patentee's proprietary rights "like metes and bounds of property," and patent infringement is not based on the similarity of two products but whether the claims of a plaintiff's patent literally cover the technology of a defendant's product.¹⁶⁸ Because of this, "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.¹⁶⁹ On the other hand, patent law utilizes a "doctrine of equivalents" to deal with the problem of trivial design-around meant for nothing more than evasion of a patent's claim language.¹⁷⁰ In a common formulation, a product nonetheless infringes on patent claims that do not literally cover it if it accomplishes "substantially the same function, in substantially the same way," to achieve substantially the same result.¹⁷¹

Inventions that cover drugs or devices have extremely high upfront costs — for example, due to the need for extensive R&D, clinical trials, and regulatory procedures — but are easily duplicated at relatively low cost once disclosed to the public. Whereas there is some debate about whether patents are needed to encourage innovation in some fields, the patent mechanism is particularly well suited to drugs and device-

¹⁶⁸ See *SUNG*, *supra* note 37, at 73 ("[E]ach and every claim limitation [must] be present in the accused product."); Barron et al., *supra* note 14, at 305.

¹⁶⁹ 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)).

¹⁷⁰ See generally *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997).

¹⁷¹ *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 399 U.S. 605, 608 (1950). This has become known as the triple identity test.

es.¹⁷² Without patent protection in these fields, inventors and investors might flee to other industries.¹⁷³ Yet, because life is often at stake, the deadweight loss produced by monopoly prices is particularly insidious in the medical sector.¹⁷⁴

B. Patentable Subject Matter and Medical Device Patents

Not all ideas are patentable. However, 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,”¹⁷⁵ which courts have interpreted to mean “anything under the sun that is made by man.”¹⁷⁶

Medical devices, and improvements upon medical devices, easily satisfy this requirement.¹⁷⁷ Indeed, patents are of paramount importance to medical device manufac-

¹⁷² See Burk & Lemley, *supra* note 159, at 1616.

¹⁷³ Nugent, *supra* note 158, at 153.

¹⁷⁴ *Id.* at 139.

¹⁷⁵ 35 U.S.C. § 101 (2006).

¹⁷⁶ *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. *E.g., id.* at 309. 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 *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, 1359, *vacated* *Ass’n for Molecular Pathology v. Myriad Genetics*, No. 11-725, 2012 WL 986819 (U.S. Mar. 26, 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, also patentable under current law, may also be in IP jeopardy as software patents have been under fire for some time. See, e.g., Burk & Lemley, *supra* note 159, at 1687–88; Steve Lohr, *Microsoft’s AOL Patent Deal Intensifies Patent Wars*, N.Y. TIMES, Apr. 10, 2012, at B1.

¹⁷⁷ See Nugent, *supra* note 158, at 138.

turers.¹⁷⁸ Because the regulatory barriers — particularly 510(k) — are lower than those applicable to drugs, patents are the primary means by which device manufacturers erect barriers to prevent market entry by competitors.¹⁷⁹ This enables them to realize their profits, for medical devices require great upfront expense to develop.¹⁸⁰

The medical device industry has some unusual features. Unsurprisingly, the most profitable medical device companies also hold the greatest number of patents.¹⁸¹ Interestingly, however, because small, venture-backed startup companies drive innovation in the industry,¹⁸² they are much more likely to own and rely on patents.¹⁸³ Whereas small companies obtain less than one-third of all patents, they obtain more than half of medical device patents.¹⁸⁴

C. The Utility, Novelty, and Non-Obviousness Requirements

Patentable subject matter is a relatively weak threshold requirement for an invention's patentability. More significant are the substantive requirements of utility, novelty, and non-obviousness, without which a patent may not be granted (or, if erroneously granted, is rendered invalid).¹⁸⁵ Most medical device patents easily satisfy the

¹⁷⁸ See Burk & Lemley, *supra* note 158, at 1592 (medical device patentees are far more likely to assert their patents than patentees in other fields).

¹⁷⁹ Raciti & Clements, *supra* note 51, at 371–72.

¹⁸⁰ See Buchanan, *supra* note 17, at 306.

¹⁸¹ Geire, *supra* note 56, at 247.

¹⁸² INSTITUTE OF MEDICINE, *supra* note 31, at 170.

¹⁸³ Ackerly et al., *supra* note 142, at w72; Burk & Lemley, *supra* note 159, at 1591.

¹⁸⁴ John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 VAND. L. REV. 2099, 2128 (2000).

¹⁸⁵ 35 U.S.C. §§ 102, 103, 112 (2006).

utility requirement, which demands only that an invention accomplish the result that the claims purport to achieve.¹⁸⁶

To satisfy the novelty requirement, an invention must not have been “known or used by others . . . or patented or described in a printed publication.”¹⁸⁷ Any document accessible to the public (known as the “prior art” reference), no matter how obscure or hidden, will render a patent claim invalid if all elements of that claim are disclosed within the “four corners” of the document.¹⁸⁸ If that is the case, the patent claim is considered “anticipated” by the prior art.¹⁸⁹

In the United States, an inventor has a one-year grace period to file for a patent. Inventions that are “on sale or in public use” during this year do not bar patentability.¹⁹⁰ Many other countries have an “absolute novelty” rule that renders an invention unpatentable the moment it emerges in public, but patent rights are preserved worldwide upon filing a patent application in the United States by treaty.¹⁹¹ As a matter of practice, therefore, inventors intending to broadly market their products prefer to file patent applications no later than the day products embodying their inventions go to market.¹⁹²

¹⁸⁶ See Nugent, *supra* note 158, 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).

¹⁸⁷ 35 U.S.C. § 102(a) (2006).

¹⁸⁸ See Raciti & Clements, *supra* note 51, at 379.

¹⁸⁹ *Id.*

¹⁹⁰ See 35 U.S.C. § 102(b) (2006).

¹⁹¹ See Raciti & Clements, *supra* note 51, at 372, 381.

¹⁹² *Id.* at 381.

Finally, the non-obviousness requirement holds that the subject matter of a patent must not have been “obvious at the time the invention was made to a person having ordinary skill in the art” (“PHOSITA”).¹⁹³ Whereas a patent claim may be anticipated by only one prior art reference, the obviousness analysis asks whether the leap to the patent from a single prior art reference, or from a combination of multiple prior art references, is too trivial to be deserving of a patent in light of the state of the art.¹⁹⁴ Together, the novelty and non-obviousness requirements prevent material in the public domain from being excised into patent protection.

IV. THE TENSIONS BETWEEN MEDICAL DEVICE REGULATION AND PATENT LAW

Although the patent system is extremely important for medical device manufacturers, the interface of the regulatory environment governing new devices and patent law is “jagged and complicated.”¹⁹⁵ While patent law requires that a technology be new, the majority of medical devices are cleared through a mechanism that requires similarity to a preexisting device. This tension, in light of the central balance between promotion and protection that medical device regulation seeks to achieve, may cause significant distortions in the economics of medical device market introduction.¹⁹⁶ The situation is not helped by the total absence of coordination between the two agencies that serve

¹⁹³ 35 U.S.C. § 103 (2006).

¹⁹⁴ See *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2006).

¹⁹⁵ *Raciti & Clements*, *supra* note 51, at 372.

¹⁹⁶ 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.

as gatekeepers to marketability of medical devices: FDA, in the Department of Health and Human Services, and the United States Patent and Trademark Office (“USPTO”), in the Department of Commerce (not to mention frequent lack of synchronization between companies’ patent attorneys and their counsel for FDA). This Part surveys many of the doctrinal and political pressure points between the two fields and how some (but not all) 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 entirely gone unnoticed. With the passage of the 1984 Hatch-Waxman Act, Congress (inter alia) sought to remedy two distortions related to the duration of the patent term for drugs and devices.¹⁹⁷

First, patentees are normally entitled to begin exclusively marketing products embodying their inventions immediately upon the USPTO’s issuance of a patent. But because premarket regulatory barriers to entry are often so lengthy at FDA, the patent term experiences a de facto *shortening* because the initial phase of the patent term may be consumed by FDA procedures rather than commercialization.¹⁹⁸ Filing for a patent later in the process is disfavored for a number of reasons, most significantly because the

¹⁹⁷ Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 1984 Stat. 1538 (codified as amended in various sections of 21 & 35 U.S.C.).

¹⁹⁸ See Upadhye, *supra* note 27, at 6.

prior art that may anticipate or render a patent obvious, as well as infringement by others, is judged from the time of the patent's filing.

Second, because a patent includes the exclusive rights to *make* and *use* the claimed invention, in addition to the exclusive right to *sell* it, a competitor may not begin even testing a product that is to compete with a patented product upon the patent's expiration, until the day the patent expires. Normally, this is not problematic because the public nature of patented inventions enables competitors to rapidly enter the market soon after the patent expires. In the context of drugs and medical devices, however, a competitor (such as a generic drug manufacturer) may not begin pursuing FDA approval or conducting clinical trials, which usually require making and using the patented product, until the patent expires.¹⁹⁹ Under such a system, a competitor product would not reach the market until long after the patent expired, creating a de facto patent term *extension* for the patent holder.²⁰⁰

1. § 156's Patent Term Extension

Section 201 of the Hatch-Waxman Act, now codified at 35 U.S.C. § 156, is meant to remedy the de facto patent term reduction caused by delays to market resulting from FDA review.²⁰¹ The objective of the extension is to restore the time during which a manufacturer was unable to market its product because FDA review was underway. In the-

¹⁹⁹ See *id.* at 6–7.

²⁰⁰ See *id.*

²⁰¹ See Michelle A. Sherwood, *Medical Devices and Patent Term Extension Under the Hatch-Waxman Act*, LANDSLIDE, July/Aug. 2010, at 38, 39.

ory, the extension provided should exactly offset this lost time, which would unfairly disadvantage drug and device manufacturers as compared to patentees in other industries.²⁰²

The extension is available from the USPTO for patents that claim a product or a method of using or manufacturing a product.²⁰³ 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).²⁰⁴ Facially, the Act applies only to drugs, but the Supreme Court has held that the Hatch-Waxman Act applies equally to medical devices.²⁰⁵ 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.²⁰⁶

This 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. No manufacturer would nonetheless prefer PMA, but the asymmetry does somewhat reduce the appeal of the 510(k) process. A robust patent term, even as measured in months, may be important to manufacturers of devices cleared through 510(k), whose

²⁰² See 35 U.S.C. § 156 (2006).

²⁰³ Sherwood, *supra* note 201, at 39.

²⁰⁴ *Id.* There is an overall limit on the extension of five years. 35 U.S.C. § 156 (2006)

²⁰⁵ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990) (holding that medical device issues also arise under the FDCA).

²⁰⁶ Buchanan, *supra* note 17, at 322; Sherwood, *supra* note 201, at 39.

competitors face relatively low barriers to entry and whose patents may be relatively weak substantively.²⁰⁷

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

Section 202 of the Hatch-Waxman Act, now codified at 35 U.S.C. § 271(e)(1), mitigates the de facto patent term extension caused by FDA regulatory delays to competitor entry upon a patent's expiration.²⁰⁸ § 271(e)(1) provides a "safe harbor" to patent infringement for conduct taken "solely for uses reasonably related to the development and submission of information" to FDA for procuring regulatory approval to market a device or drug. This exception permits companies to engage in activity — making and testing devices covered by a soon-expiring patent — that would be infringing, to prevent a de facto extension of the patent term.

The Supreme Court held in *Eli Lilly* that making and using a patented device in pursuit of a PMA requirement qualified as "reasonably related" to obtaining regulatory approval.²⁰⁹ However, the Court left unanswered the question whether § 271(e)(1) also applied to devices that do not require PMA, such as devices exempt from premarket review or those utilizing 510(k).²¹⁰ For a time, this issue was unsettled because the Court had elsewhere acknowledged the important differences between premarket approval

²⁰⁷ A patent on an improvement or new use for a product is considered weaker than a patent on the product itself as a machine or composition of matter.

²⁰⁸ Upadhye, *supra* note 27, at 3.

²⁰⁹ 496 U.S. 661 (1990); Upadhye, *supra* note 27, at 25.

²¹⁰ Buchanan, *supra* note 17, at 321.

and premarket notification.²¹¹ Nonetheless, the Federal Circuit, applying its nationwide appellate jurisdiction over patent cases, held that the § 271(e)(1) safe harbor applies to all regulated medical devices,²¹² and more recently, that devices not subject to pre-market review are *not* covered.²¹³ These holdings are consistent with the purposes of § 271(e)(1), because exempt devices do not face any FDA-related delay in marketing upon expiry of a relevant patent.²¹⁴ As a result, productions and uses related to advancing a PMA or 510(k) are immunized by § 271(e)(1), but manufacturers must wait until a patent covering an exempt device expires before creating or testing a competing product.

Unlike § 156, the safe harbor in § 271(e)(1) — if properly administered — creates a completely even playing field between medical device patents and all other types of patents. While it is true that the research and development required to manufacture a competing medical device may be more extensive than in other fields, the fact remains that under normal circumstances in most industries, companies may not begin manufacturing competing products (in the absence of a license) until patents covering the original, patented products expire. § 271(e)(1) merely relieves medical device companies of a distortion that emerges from the introduction of the FDA regulatory framework.

²¹¹ *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); Buchanan, *supra* note 17, at 314.

²¹² *See Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1028 (Fed. Cir. 1997).

²¹³ *See Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008).

²¹⁴ *Cf. Buchanan, supra* note 17, 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).

Manufacturers may be nudged into 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 that would enable them to recoup upfront R&D costs. In such circumstances, § 156 would compensate such an inventor for the time involved in the PMA process (although, as discussed above, not a manufacturer that proceeds through 510(k), even when the new device embodies patentable inventions). For the most part, however, the Hatch-Waxman Act restores medical devices to the usual innovation-promotion framework in U.S. patent law, at least insofar as patent term is concerned.

B. Anticipation by 510(k)

A 510(k) becomes a public document, accessible either through a Freedom of Information Act request or by FDA publication.²¹⁵ In theory, therefore, a 510(k) submitted by a patent applicant or by another device manufacturer can be used as a prior art document to demonstrate a patent claim's lack of novelty, thereby rendering that claim invalid.²¹⁶ The risk is particularly salient because, by its nature, a 510(k) claims "equivalence" to an existing device. This promises to render all medical device patents less val-

²¹⁵ Raciti & Clements, *supra* note 51, at 376. Medical Device Reports, which are filed when a manufacturer experiences an adverse event during premarket testing, are also public documents. *Id.* at 384–86.

²¹⁶ See *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1376 (Fed. Cir. 2001). Recall that 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 Regize, *How a 510(k) Submission Can Affect Your Patent*, MED. DEVICE & DIAGNOSTIC INDUSTRY (June 1, 2010), <http://www.mddionline.com/article/how-510k-submission-can-affect-your-patent>.

uable, because each one is at greater risk of invalidity. It also may result in a trap of sorts for companies that accidentally disclose too much in a 510(k).

The underlying problem with such theories is that while a 510(k) discloses some — but not all, and not necessarily all patent-important — technical aspects of a *product*, it does not necessarily disclose all elements of a *patent claim*. Therefore, a 510(k) description often does not amount to anticipation.²¹⁷ Indeed, aware of this, savvy companies may choose predicate devices in their 510(k)s to enable them to claim equivalence in ways oblique to patent eligibility or explicitly disclaim patent issues in their 510(k).²¹⁸

Fortunately for new 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 analysis is to compare the prior art with the patent claims.²¹⁹ With more particularity, 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 to FDA of substantial equivalence rather than a

²¹⁷ Raciti & Clements, *supra* note 51, at 376.

²¹⁸ *See id.* at 376, 378.

²¹⁹ *Arthrocare Corp. v. Smith & Nephew, Inc.*, 310 F. Supp. 2d 638, 667 (D. Del. 2004) (510(k) inadmissible to prove anticipation).

comparison of an older device to newer patent claims.²²⁰ At the end of the day, a 510(k) itself (notwithstanding the product it claims equivalence to) should not prove to be too much of an obstacle to patentability of new devices for careful companies, and so the notion of anticipation by 510(k) is probably not a major distortion to the introduction of medical devices.²²¹

C. 510(k) as Evidence of Infringement

It is easy to see why a manufacturer of a predicate device covered by a patent would be agitated by a new device entering the market that claims to be equivalent to the predicate. While FDA maintains that a determination of substantial equivalence should not have any bearing on a patent suit,²²² parties to patent litigation argued for some time that a 510(k) should be admissible to prove infringement, since it is at least probative of the similarity between two devices.²²³

²²⁰ *Sunrise Medical HHG, Inc. v. AirSep Corp.*, 95 F. Supp. 2d 348, 406 (W.D. Pa. 2000) (510(k) inadmissible to prove anticipation).

²²¹ 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.

²²² *Barron et al.*, *supra* note 14, at 316.

²²³ *See* FED. R. EVID. 401 (relevance); *see also* FED. R. EVID. 801(d)(2) (admissions by party-opponent are non-hearsay and therefore generally admissible); FED. R. EVID. 803(8) (public records exception to hearsay rule).

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. Uncertainty tends to discourage innovation.²²⁴

The Federal Circuit recently weighed in, stating definitively that a 510(k) is not an admission of infringement.²²⁵ It reasoned 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*.²²⁶ This holding was consistent with the trend among some lower courts, which recognized the distinction between what is compared in a 510(k) submission and what is compared in a patent infringement lawsuit.²²⁷ Ultimately, 510(k) represents a completely separate regulatory regime than patent law, with different overall standards but some confusingly similar language.²²⁸ This clarification in the law should remove whatever distortions existed for medical device manufacturers due to fears that a 510(k) might be used against them.

D. Inequitable Conduct

510(k) applicants, especially those who seek 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 assert to the USPTO that their devices are completely new

²²⁴ See Buchanan, *supra* note 17, at 326.

²²⁵ See *Innovative Therapies, Inc. v. Kinetic Concepts, Inc.*, 599 F.3d 1377, 1382 (Fed. Cir. 2010).

²²⁶ See *id.*

²²⁷ See, e.g., *CardioVenton, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 840 (D. Mass. 2007).

²²⁸ See *id.*

and non-obvious, in other words, unlike anything in the prior art.²²⁹ Such incongruous behavior can lead to an inequitable conduct defense if that manufacturer later asserts a patent in litigation.

The judge-made inequitable conduct defense consists of intentional failure to disclose to the USPTO material prior art known to the patent applicant at the time of patent prosecution.²³⁰ If successful, such a defense renders the patent unenforceable and may make attorney fees available to a defendant.²³¹ This can be devastating, especially for an entity like a medical device startup, which may have one or two key patents that represent much or all of the technological value of the company.²³²

Medical device manufacturers are at particular risk for an inequitable conduct defense because, as the Federal Circuit held in *Bruno*, 510(k) filings submitted to FDA can demonstrate what was subjectively known to the manufacturer when it prosecuted its patent.²³³ In that case, Bruno, a device manufacturer, submitted a 510(k) for a stairlift, in which it described similarities to products from another company.²³⁴ Bruno filed its 510(k) after its patent application but before the patent issued, and at no point did Bru-

²²⁹ Raciti & Clements, *supra* note 51, at 388–89.

²³⁰ See, e.g., *Therasense, Inc. v. Becton, Dickson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011); Regize, *supra* note 216.

²³¹ *Id.*

²³² *Id.*

²³³ See *Bruno Indep. Living Aids v. Acorn Mobility Servs.*, 394 F.3d 1348, 1352 (Fed. Cir. 2005) (holding that a substantial equivalence determination can support an inequitable conduct finding).

²³⁴ *Id.* at 1350.

no disclose its 510(k) to FDA.²³⁵ The case arose when Bruno asserted this patent against a competitor. 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.²³⁶ The court held the patent unenforceable and affirmed the lower court's award of attorney fees to the defendant.

Lower courts have not read *Bruno* to mean that nondisclosure to the USPTO of a 510(k) that cites a competing medical device amounts to inequitable conduct.²³⁷ After all, not all claims of substantial equivalence are relevant to patentability; many predicate devices lack the new technology that serves as the basis for a patent and are cited only for their functional equivalence of safety and effectiveness.²³⁸ Still, less shrewd manufacturers must tread carefully when submitting a 510(k) and a patent application close in time.²³⁹ The fear of losing patent protection makes 510(k) a slightly more perilous route to market than a PMA, especially when a company's patent attorneys are unaware of filings by its FDA counsel.

²³⁵ See *id.* at 1350–51.

²³⁶ *Id.*

²³⁷ *E.g.*, *Medtronic Xomed, Inc. v. Gyrus ENT LLC*, 440 F. Supp. 2d 1300 (M.D. Fla. 2006).

²³⁸ See *Regize*, *supra* note 216.

²³⁹ See *id.*

E. 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.²⁴⁰ This means that each and every element of at least one claim applies to the defendant's product or activity.²⁴¹ Sometimes, however, the defendant comes very close to infringement, but somehow avoids the specific language of the claims, often through trivial design-around meant precisely to avoid them. The "doctrine of equivalents" holds that products that do not "read literally on the claims" of a patent may still infringe if the difference is insubstantial.²⁴² A common alternative formulation is that the doctrine of equivalents applies if a product performs "substantially the same function, in substantially the same way, to give . . . substantially the same result" as the patent.²⁴³

The language of substantial equivalence is familiar to us by this point as the standard used to evaluate 510(k) applications. Of course, equivalence for purposes of 510(k) is in terms of functional safety and effectiveness, yet equivalence for purposes of the doctrine of equivalents is in terms of technology. The similarities in language nonetheless raise the possibility of conflict between two concepts of equivalence in distinct areas of law.²⁴⁴ To claim patentability is to claim nonequivalence, and yet a manufactur-

²⁴⁰ Barron et al., *supra* note 14, at 306.

²⁴¹ SUNG, *supra* note 37, at 74.

²⁴² Barron et al., *supra* note 14, at 307.

²⁴³ Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 901–02 (Fed. Cir. 1984).

²⁴⁴ Barron et al., *supra* note 14, at 304, 312.

er explicitly claims equivalency in a 510(k).²⁴⁵ Even if a 510(k) is not admissible to prove anticipation, is a statement of equivalence for purposes of FDA clearance admissible to prove equivalence for purposes of the patent law doctrine of equivalents?

It is possible that the answer is no, because 510(k) involves a comparison between products rather than between a patent and a product.²⁴⁶ On the other hand, the existence of a 510(k) may amount to a presumption of equivalency for purposes of the doctrine of equivalents.²⁴⁷

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 doctrine of equivalents argument.²⁴⁸ The comparison in a 510(k) is holistic; the comparison evaluated in a patent case is piecemeal and rooted in patent claims. However, courts have not definitively held that a 510(k) is categorically inadmissible for doctrine of equivalents purposes, unlike in the context of anticipation. Therefore, it remains true that as compared to other types of inventions, there is some risk that medical devices cleared through 510(k) are more likely to infringe on a patent, because the 510(k) process involves a possible admission of infringement under the doctrine of equivalents. The uncertainty alone may deter innovation in devices that would be cleared through 510(k), which contravenes one of the primary purposes for the premarket notification program. Conversely, this

²⁴⁵ *See id.* at 313.

²⁴⁶ Upadhye, *supra* note 27, at 28.

²⁴⁷ *Id.*

²⁴⁸ *E.g., Cintec Nutrition Co. v. Baxa Corp.*, 988 F. Supp. 1109 (N.D. Ill. 1997).

possibility may strengthen the patent rights of earlier medical device manufacturers, which may result in higher levels of innovative activity in the industry overall.

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

Most plainly, 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 problems. 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, but it is silent on which *types* of devices are encouraged.²⁴⁹ Overall, it is far from clear whether 510(k) and related regulations have a positive or negative effect on innovation because it is too difficult to disentangle device types and how innovation should be measured in this context.²⁵⁰ When it comes to the intersection between 510(k) and the patent system, we should note that only 15% of all 510(k) applications are for devices with new technological characteristics of any kind.²⁵¹ It is to these devices and those subject to PMA that our analysis turns.

A common question in patent law theory is whether the patent system — our legal implementation of innovation policy and the usual mechanism for encouraging innovation — strikes the optimal balance between bringing new technology to the public

²⁴⁹ See Flaherty, *supra* note 4, at 927.

²⁵⁰ See INSTITUTE OF MEDICINE, *supra* note 31, at 164–72. The IOM 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.*

²⁵¹ GAO 2009, *supra* note 18, at 7.

through the promotion of innovation, and ensuring that new technology is widely available at a reasonable price.²⁵² Overbroad patent protection can stifle innovation and dissemination by reducing opportunities for follow-on innovation.²⁵³ This may be particularly hazardous in the area of medical devices, where the vast majority explicitly claim inspiration from an earlier device in their 510(k) applications. Even though improvements to existing devices can themselves be patent-eligible, those patent rights are often subservient to the “blocking patents” covering an earlier product.²⁵⁴ 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 point.²⁵⁵ Despite the fact that the 510(k) system was essentially designed for improvements on existing devices, and that the Special 510(k) mechanism expedites the process of clearing improved devices for marketing,²⁵⁶ the patent system could be harming innovation in this area.²⁵⁷

There is, of course, a difference from a public policy perspective between introducing an improvement and building a wholly new device that solves a new problem.

²⁵² See Nugent, *supra* note 158, at 136.

²⁵³ See *id.* at 154–55.

²⁵⁴ See Barron et al., *supra* note 14, at 306.

²⁵⁵ See Nugent, *supra* note 158, at 139.

²⁵⁶ See *The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, *supra* note 17.

²⁵⁷ The de novo review pathway could ameliorate the situation greatly for new devices that would otherwise require PMA, but it appears to suffer from underutilization. See HUTT ET AL., *supra* note 10, at 992 (“The number of devices initially marketed pursuant to . . . initial classification requests is negligible.”).

While a new device may be marketable without the need to obtain patent licenses from others, it is difficult for new technology to compete in a system in which old technology (or improvements on it) can overcome FDA regulatory barriers much more rapidly.²⁵⁸ Patents typically raise barriers to entry for competitors by erecting monopolies, but in the medical device industry, the need for FDA clearance or approval can create its own kind of barriers that prevent market entry.²⁵⁹ These obstacles, unfortunately, increase as a device's unfamiliarity and novelty increase. Ultimately, manufacturers who wish to engage in disruptive innovation will be deterred by the incentive structure that nudges them toward marginal advances in the art.²⁶⁰ This will remain the case except where revolutionary device pioneers are sufficiently profit-motivated to endure the PMA process.²⁶¹

Venture capital 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.²⁶² This may be the case because venture funding, as a descriptive matter, is three times more effective per dollar in producing patentable in-

²⁵⁸ Black, *supra* note 169, at 417.

²⁵⁹ *Id.*

²⁶⁰ 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 very useful to adapt older devices to new technology (such as in the cases of 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.

²⁶¹ *Id.* The patent system surely helps encourage innovation that results in truly valuable patents. It might help restore balance to the inventor's choice between marginal and revolutionary innovation.

²⁶² Ackerly et al., *supra* note 142, at w74.

ventions than is traditional corporate research and development, patents themselves being a very good proxy for innovation.²⁶³ In addition to Medicare reimbursements, the two legal constraints that VCs care desperately about are the patent landscape and the efficiency of FDA review.²⁶⁴ Patent protection is absolutely essential to acquiring new venture funding in the medical device industry,²⁶⁵ and the form and outcome of FDA review greatly affects a startup company's exit strategy.²⁶⁶ The relationship between patents and 510(k) is therefore of utmost importance to the source of funding for many new medical devices.

The VC community, unsurprisingly, takes the position that FDA review ought to be thinner, particularly for revolutionary devices, most of which are developed by small, venture-backed companies.²⁶⁷ While the 510(k) system is useful for "routine" products (and encouraging of them), truly revolutionary advances are unfairly taxed by the requirement that they undergo PMA.²⁶⁸ VCs perceive FDA's risk aversion to be harmfully impacting innovation and development in medical devices.²⁶⁹ From their per-

²⁶³ *See id.* at w69.

²⁶⁴ *Id.* at w71–w72.

²⁶⁵ Keith D. Lindenbaum & James D. Borchardt, *MX: A Head Start for Medical Device Start-ups*, MED. DEVICE & DIAGNOSTIC INDUSTRY (Jan. 21, 2011), <http://www.mddionline.com/article/mx-head-start-medical-device-startups>.

²⁶⁶ INSTITUTE OF MEDICINE, *supra* note 31, 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 265 (the average medical device company that goes public holds 15 U.S. patents at the time of its IPO).

²⁶⁷ *See* Lasersohn, *supra* note 140.

²⁶⁸ *Id.*

²⁶⁹ *See id.*

spective, the FDA regulatory system is “broken” in its treatment of novel medical devices and a revised process is needed for approval of new technology.²⁷⁰

This take on medical device regulation is in some tension with the need to ensure safety of truly novel devices, even though no one disputes that promoting the development of such devices is generally desirable. Despite the cries of VCs against overregulation by FDA, at least one academic has advanced the argument that vigorous regulation might be in the long-term interest of VCs and innovators.²⁷¹ Even though it may seem that regulation increases costs, it may be that over time, patents and regulation work together to increase and protect profits.²⁷² After all, increased regulatory hurdles, alongside patent protection, also increase barriers to entry for competitors.²⁷³ For truly new devices, then, the existence of PMA as a later barrier to innovation may encourage innovation when feasible for a pioneer. At the same time, a robust regulatory system that ensures safety and effectiveness may increase public and physician confidence in medical devices, lubricating new devices’ general acceptance in the market and increasing revenues for all device manufacturers.

²⁷⁰ *Id.*

²⁷¹ See generally Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 349 (2007).

²⁷² See *id.* at 356.

²⁷³ *Id.*

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 confusion is greatly exacerbated when medical device regulation intersects with the patent system, which is our usual mechanism for promoting innovation. Ultimately, 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 is that the Byzantine regulatory system and the intricate 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.