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Cover Page Footnote

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THE CASE OF THE MISSING DEVICE PATENTS, OR: WHY DEVICE PATENTS MATTER

Erika Lietzan,* Kristina M.L. Acri,** and Evan Weidner***

A company that earns premarket approval of its medical device is entitled to an extension of one patent claiming the device, to make up for some of the time it spent doing premarket research. Yet, surprisingly, a mere thirteen percent of those eligible for this extension (also known as patent term "restoration") ask for one. In contrast, most drug companies entitled to this same patent extension ask for one. In this Article, we attribute the imbalance largely to differences between the two regulatory frameworks. In brief, because the FDA classifies and regulates devices based on what they do and how they do it, rather than by their composition, and because the device framework, unlike the drug framework, does not offer a regulatory advantage to companies that make exact copies, the most important moment in the lifecycle of a new medical device is the moment a competitor designs an alternative device that accomplishes the same

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end result. This can happen within a few short years. By way of contrast, for drug innovators the critical lifecycle moment is generally no earlier than expiry of the active ingredient patent, which generally happens later. In other words, medical devices have much shorter commercial lifecycles. While some suggest that medical device patents are therefore less important than drug patents, our explanation indicates only that the length of the patents is less important. Recent empirical research (Graham 2009, Simon 2020) describes the role that medical device patents play early in the product lifecycle—often before regulatory approval—focusing on the foundation they provide for efficient exchanges of information and market transactions. Our paper builds on their work by (1) offering a description, grounded in reflection on the essential nature of the two regulatory frameworks, of the differing roles play by drug and device patents, and (2) offering an additional supportive data point in that, although device patenting is steadily increasing, eligible device companies generally do not bother seeking patent extensions. It also illustrates the role that regulatory design can play in dictating the value of patent length, which should be important for policy planners.

INTRODUCTION

In the United States, federal law requires that many medical products undergo extensive premarket safety and effectiveness testing, as well as a premarket review by a federal regulator before commercialization.[1] At the same time, U.S. patent law steers these product developers into securing patent protection as early as possible in the premarket research and development period.[2] The result, predictably, is that a significant portion of the patent term lapses before the invention can be commercialized.

In 1984, Congress amended the Patent Act so a company marketing a medical product subject to premarket approval could receive back a portion of one patent term that had lapsed during the premarket research and regulatory review period.[3] Some call this patent term "restoration," others patent term "extension." An earlier article considered every grant of patent term restoration for a new drug between September 1984 and April 2018 and found, among

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1 *See infra* Part I-A.

2 *See infra* notes 18–19 and accompanying text.

3 *See infra* Part I-B; Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.).

other things, that longer clinical programs lead to shorter effective patent life, even after patent term restoration.[4] The results were strongly statistically significant and contributed to a growing body of literature suggesting that the U.S. legal system may be systematically skewing drug research incentives away from the kinds of problems that require longer clinical programs.[5]

Like new drugs, the highest risk medical devices are subject to a premarket approval requirement and eligible for patent term restoration.[6] But only a small fraction of preapproved medical devices are associated with requests for patent term restoration. In the nearly 35 years since enactment of patent term restoration covered by this Article, the Food and Drug Administration (FDA) approved 1152 premarket approval applications (PMAs) for new medical devices, but of these only 149 (13%) led to requests for patent term restoration. In contrast, nearly every new drug applicant eligible for patent term restoration pursues this benefit.[7]

There are three possible explanations for the lack of patent term restoration requests from eligible medical device innovators. First, some preapproved devices might not be covered by patents. Second, some medical device innovators, despite owning patents, may not know about the option to apply for patent term restoration. Third, some medical device innovators that own patents may choose not to incur the expense of preparing a patent term restoration application.

Based on a comparative analysis of the drug and device regulatory frameworks, we propose that most of the missingness reflects the third explanation. The "device" category at the FDA is broad and wildly heterogeneous; the products that fall within the category have very little in common other than a medical purpose and not functioning the way a drug does (i.e., through chemical or metabolic action). The regulatory framework in turn reflects this heterogeneity. The nature and degree of federal oversight vary tremendously across devices. Moreover, for purposes of determining the applicable

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4 *See* Erika Lietzan & Kristina M.L. Acri née Lybecker, *Distorted Drug Patents*, 95 WASH. L. REV. 1317, 1364 (2020).

5 *Id.*

6 *See infra* Part II-A.

7 *See infra* Part II-C.

regulatory requirements, devices are sorted more by what they do and how they do it (their function) than by what they are made of (their constituent parts). In part as a result, there is no such thing as an "abbreviated" device application, at least not in the sense that there is for drugs—an application in which one company shows that its product *is* the same as another, in order to justify extrapolating safety and effectiveness from the testing of the other. Put another way, the device approval framework offers no particular commercial advantage to a second company seeking to make an exact copy—a potentially infringing duplicate—of another device. Instead, it rewards the second company that makes another device that does roughly the same thing in roughly the same way; as the agency gains familiarity with new technologies, it permits smaller applications.

Device innovators face uncertainty about the regulatory paradigm that will apply to their products. The applicable pathway to market may not be obvious at first, and it will depend in part on whether there are already similar devices on the market. Even if premarket approval is clearly required, the data requirements may be uncertain; there is no standard or conventional testing program for devices, which vary too much. The regulatory uncertainty for device inventors contributes to a first mover *dis*advantage, while by contrast, drug innovators generally experience a first mover *ad*vantage.

Because devices are sorted within the regulatory framework by what they do, because the device regulatory framework does not offer commercial advantage to companies that make exact copies, and because of the first mover disadvantage, the most important moment in the lifecycle of a preapproved medical device is the moment a competitor designs an alternative device that accomplishes the same end result (i.e., another device of the same type). By way of contrast, for drug innovators the critical lifecycle moment is no earlier than expiration of the active ingredient patent, which happens later.

The earlier critical moment for medical devices means a shorter commercial lifecycle. The shorter commercial lifecycle for medical devices in turn leads some to suggest that patent protection is less important for device inventors than it is for drug inventors. But our explanation of the regulatory basis for this shortened lifecycle suggests a more limited conclusion: that the *end* of the patent term

should be less important for device inventors than for drug inventors.

The device patent may nevertheless play a role even if its precise expiry date is immaterial. The primary theoretical view of the patent in the United States today holds that it serves a utilitarian (instrumental) role, encouraging inventive activity through the promise of a period of supra-competitive pricing enabled by the right to exclude. Drug patents have long been viewed as paradigmatic examples, as the connection between drug patents (and patent term) and drug innovation is well established. This basic theory can also account for medical device patents, if the incentive for innovative activity includes economic benefits in the short and intermediate term. Specifically, broad patent protection may facilitate efficient transactions early in the device lifecycle, including the transfer of assets, licensing, and collaborations, which may be especially important when innovation emerges from user-innovators and small inexperienced companies, as it often does in the medical device industry.

In short, we suggest a role for the device patent that squares with the traditional utilitarian theory of the patent but that places less emphasis on the patent's ability to exclude over a period of time. We tie this role in part to the design of the regulatory framework. By implication, Congress and executive branch policymakers may be able to affect the value of patent length through the regulatory frameworks they design.

This Article proceeds as follows. Part I explains the patent term distortion faced by developers of medical products in the United States, the experience of drug companies with patent term restoration, and the fact that medical device innovators are similarly eligible for patent term restoration. Part II describes our study of medical device patent term restoration and our findings, including the finding that most medical device innovators eligible for term restoration do not seek it. Part III considers the possibilities that some preapproved medical devices lack patent protection and that some device applicants are unaware of patent term restoration. Part IV explores the third possibility, that medical device applicants elect not to pursue patent term restoration. It explains why, in view of the design of the medical device regulatory framework, the precise *length* of the medical device patent may not matter, even if securing a patent was

itself vitally important. It thus illustrates how regulatory design can affect the value of patent term length, while articulating a role for medical device patents that remains fully consistent with prevailing patent theory. Part V concludes by considering the implications of the connection between regulatory design and the value of patent length for the broader medical device innovation landscape, which includes many regulated devices that are not subject to premarket approval.

I. DISTORTED MEDICAL PRODUCT PATENTS

A. Patent Protection and Premarket Review

An inventor in the United States may file an application with the U.S. Patent and Trademark Office (PTO), asking the federal government not only to recognize the invention but to enforce the inventor's right to prevent others from making, using, and selling the invention. If the inventor satisfies the criteria for a patent laid out in title 35 of the U.S. Code,[8] the PTO will issue a patent that lasts for 20 years from the date of the inventor's application (or in some cases, the date of an earlier related application).[9] During this term, although a detailed description of the invention is available to the public in the patent itself, the patent owner may use the federal court system to protect its exclusive right, suing those who "practice" the invention without permission, obtaining damages and, in most cases, a court order enjoining further "infringement" until the patent expires.[10]

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[8] Federal law permits a utility patent to issue for any new, useful, non-obvious invention. 35 U.S.C. §§ 101–103. To be patentable, the invention must be a "process, machine, manufacture, or composition of matter" or an "improvement thereof." *Id.* § 101. Various other conditions also must be satisfied, for the patent to issue. *See e.g.*, *id.* § 112 (requiring written description).

[9] *See id.* § 154(a)(2). For most of the 20th century, however, a patent lasted for 17 years from issuance. *E.g.*, 35 U.S.C. § 154 (amended 1994). This changed with enactment of the Uruguay Rounds Agreement Act (URAA), Pub. L. No. 103-465, § 532, 108 Stat. 4809 (1994).

[10] Once PTO issues a patent to an inventor, no one else may—without the permission of the patent owner—make, use, offer to sell, or sell the patented invention in the United States until that patent expires. *See* 35 U.S.C. § 271(a).

A vast body of literature explores the theoretical nature of and basis for patent protection as well as its normative justifications. Most relevant here, Thomas Jefferson's observation in 1813 that "the exclusive right to invention"—the "embarrassment of an exclusive patent"—was "given not of natural right, but for the benefit of society," forms the foundation of the prevailing view that the patent "privilege" serves a utilitarian (instrumental) role.[11] Traditionally, the "benefit" for society was seen as the resulting inventive activity: the inventions themselves and the forward momentum ("progress") in the "useful arts" that disclosure of the invention—including through the patent document itself—engendered. That is, the issued patent allows the patent owner to exclude (or demand a license from) certain competitors, which in turn enables the patent owner to avoid price competition from substitutes. This permits pricing above competitive rates. The prospect of the resulting profits, the theory holds, encourages activity that might lead to patentable inventions.[12] The "embarrassment" of which Jefferson wrote—the loss of consumer purchases that would have occurred at the price set in a competitive market but that were lost due to supra-competitive pricing—is the price we choose to pay for the behavior stimulated by the prospect of above-market profits: activity directed to invention.[13]

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[11] Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), *in* 6 THE WRITINGS OF THOMAS JEFFERSON 175, 181 (Washington, ed., 1854); *ee also* U.S. CONST. ART. I, § 8, cl. 8 (authorizing Congress to "promote the progress of . . . useful arts, by securing for limited times to . . . inventors the exclusive right to their . . . discoveries"). Although this instrumental theory of the patent prevails in U.S. scholarship and jurisprudence, serious questions have been raised about its accuracy as a historical matter. For instance, Professor Mossoff has argued that the "conventional wisdom . . . that American patents have always been grants of special monopoly privileges lacking any justification in natural rights philosophy" is a historical myth and that instead patent rights were "defined and enforced using the social contract doctrine and the labor theory of property of natural rights philosophy." Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent "Privilege" in Historical Context*, 92 CORNELL L. REV. 953, 953 (2007).

[12] *See* Ted Sichelman, *Patents, Prizes, and Property*, 30 HARV. J. L. & TECH. 279, 279 (2017) (citing Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 357–58 (2010); John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 439 (2004); Mark A. Lemley, Ex Ante *Versus* Ex Post *Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 129 (2004)).

[13] *See* Letter from Thomas Jefferson to Isaac McPherson, *supra* note 11. A growing body of literature explores other ways to stimulate inventive activity. *See, e.g.*, Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 122 (2003) (arguing that a

Pharmaceutical patent protection is viewed as the classic example of patent protection playing precisely this role. Research and development directed to discovery of new molecular entities with medical potential is generally understood to be highly motivated by the prospect of patent protection; the connection between patent protection and pharmaceutical research spending is robust and clearly established.[14] Further, there may be correlation between the length of the pharmaceutical patent term and the strength of the research

prize system could eliminate deadweight loss and thus increase social welfare and offering design principles for an effective prize system); Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1078 (2014) (arguing that prize systems can be implemented *with* intellectual property systems, i.e., that the two are not radical alternatives but can complement each other, and that intellectual property may in some cases be superior); Kristina M. Lybecker & Robert A. Freeman, *Funding Pharmaceutical Innovation Through Direct Tax Credits*, 2 HEALTH ECON. POL'Y & L. 267, 270–71 (2007) (proposing as an alternative to the current patent system an approach of rewarding innovators with direct tax credits in exchange for marginal cost pricing); Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J. L. & TECH. 153, 201–08 (2016) (proposing a change to the government health insurance program for low-income individuals, Medicaid, to reward innovators who bring to market drugs for diseases primarily affecting low-income populations).

[14] Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 508 (2009) ("Although the public suffers from high prices for drugs while they are covered by a patent, most of those drugs probably would not have been developed without that protection. As a result, it is widely thought that the benefits of drug patents far outweigh their costs."); F.M. Scherer, *The Pharmaceutical Industry–Prices and Progress*, 351 NEW ENG. J. MED. 927, 927 (2004) ("Numerous cross-industry surveys have shown that managers of pharmaceutical research and development assign unusually great importance to patent protection as a means of recouping their investment in research, development, and testing.").

In addition to patents, protection of the data submitted to support premarket approval also plays an important role in stimulating drug research and development. During the "data exclusivity" period, the FDA may not disclose a drug company's research data—the data generated and submitted to substantiate the safety and effectiveness of its drug product—to the company's competitors or use the data to approve competing products. *E.g.*, 21 U.S.C. § 355(j)(5)(F)(ii) (providing that generic applications cannot be submitted until five years after approval of a new drug with a new active ingredient); Erika Lietzan, *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. REV. 91, 96–99, 110–120 (2016) (explaining how data exclusivity works). Both patents and data protection provide some degree of exclusivity in the marketplace, giving the inventor an opportunity to charge higher prices while they are in effect. Federal law also includes special regulatory incentives to encourage specific types of research, such as additional market protection for drugs and devices intended to treat rare diseases. *E.g.*, 21 U.S.C. §§ 360aa-360cc (governing exclusivity for drugs for rare diseases and conditions).

incentive, such that additional years of protection translate to the development of additional medicines for patients.[15]

Although pharmaceutical innovation is reportedly inspired by the prospect of patent-derived exclusivity in the market and the resulting profits, there is a catch for pharmaceutical innovators. The medicines that embody these inventions cannot be sold without permission from the federal government. Federal law requires that new drugs be shown "safe" and "effective" for their proposed uses and, in fact, bars their sale until the Food and Drug Administration finds them to be so.[16] Generating the testing data and other information needed to satisfy the agency is time consuming; the average drug containing a novel molecule spends ten to twelve years in testing before FDA approval, beginning with laboratory and animal testing, followed by several rounds of clinical (human) trials.[17] Yet various doctrines of patent law push inventors to file their applications as early as possible.[18] The patents then often issue before the FDA has

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[15] *See* Heidi L. Williams, *How Do Patents Affect Research Investments?*, 9 ANN. REV. ECON. 441, 448–56 (2017) (reviewing empirical literature on this question). Professor Williams finds little evidence from patent law changes that stronger patent rights encourage investment but argues the "changes are underpowered to detect those effects." *Id.* at 456. Further, she and two collaborators examined the association between clinical trial length and research, finding the evidence "consistent with patent length having a quantitatively important impact on research investments." *Id.* (citing Eric Budish et al., *Patents and Research Investments: Assessing the Empirical Evidence*, 106 AM. ECON. REV. 183 (2016)). *See also* Dana P. Goldman et al., *The Benefits from Giving Makers of Conventional "Small Molecule" Drugs Longer Exclusivity Over Clinical Trial Data*, 30 HEALTH AFFS. 84, 87 (2011) (showing that precluding the submission of generic applications for twelve years, instead of five years as in current law, would result in 228 additional new drug approvals between 2020 and 2060); Fabian Gaessler & Stefan Wagner, *Patents, Data Exclusivity, and the Development of New Drugs*, 104 REV. ECON. STATS. 571, 572 (2022) ("Our . . . regression results indicate that a reduction in the duration of market exclusivity significantly affects project outcomes. We find that the loss of one year of market exclusivity lowers the likelihood of drug approval by about 4.9 percentage points relative to an unconditional approval rate of 30.8%.").

[16] *See* 21 U.S.C. § 355(b)-(d).

[17] *See generally* Lietzan & Acri née Lybecker, *supra* note 4, at 1327–29; Joseph A. Dimasi et al*., Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016) (referencing a mean time from synthesis to clinical trials of 37.9 months in Note 21 and showing a mean time in clinical trials of 116.1 in Table 4. That comes to 12.8 years. This is a fairly conventional number.).

[18] For example, a patent will generally be denied if the invention was in public use for more than a year before the patent application was filed. *See* 35 U.S.C. § 102(b). The earliest patent filing for a new drug—usually a broad active ingredient patent—often

granted approval to market the commercial products embodying those inventions.

In short, the patent term runs while federal law prohibits drug inventors from commercializing their inventions. This shortens the period during which the inventor may both commercialize the invention and exclude others from doing so, a period known in the literature as the invention's "effective patent life." The Supreme Court has called this effect patent term "distortion."[19]

B. Patent Term Restoration

Prompted mostly by concerns that declining effective patent life for new drugs was responsible for slowing innovation rates, and at the urging of the brand pharmaceutical industry, Congress took steps to address patent term distortion in 1984. As part of legislation that also created a statutory pathway for approval of generic drug applications, it amended the Patent Act to provide that the PTO will, on request, extend (add more days to) the term of one patent for each approved drug product with a new (never before approved) active ingredient.[20]

The PTO does not, however, restore all days lost to premarket research and development. Several limitations apply, the most significant of which follow.[21] First, it will not restore any patent life that lapses during the animal and laboratory testing required to secure FDA permission for human trials, even if these studies involve far more than would be needed to secure a patent.[22] Second,

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occurs well before the first human trials. Lietzan & Acri née Lybecker, *supra* note 4, at 1331–32.

19 Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 669 (1990).

20 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 201, 98 Stat. 1585. The statute directs the PTO to extend a patent claiming a drug, a method of using the drug, or a method of manufacturing the drug, if the drug was subject to a "regulatory review period"—clinical testing with the FDA's permission and regulatory review of a marketing application—before its commercial marketing or use. 35 U.S.C. § 156(a), (g).

21 In addition to those noted in the text that follows, the PTO does not restore any portion of the regulatory review period before patent issuance, and it does not restore any portion during which the applicant did not act with due diligence. 35 U.S.C. § 156(c)–(c)(1).

22 *See* 35 U.S.C. § 156(g)(1)(B). A company that seeks a patent for a new chemical compound that could become a new medicine must satisfy patent law's utility requirement; this means establishing desirable biological activity, which can generally be done with a

although the PTO restores every day during which the company's marketing application was pending before the FDA, it restores only half the time the drug spent in clinical testing.[23] Third, it restores no more than five years.[24] Fourth, the effective patent life after restoration may not exceed fourteen years.[25] Put another way, the expiry date of the restored patent must be no later than fourteen years after FDA approval of the drug.

The nature and length of the premarket testing program required by the FDA to support approval of a new drug depends on a variety of factors outside the control of the inventor and drug developer.[26] Because some types of drugs consistently take longer in premarket research and development than others, and because patent term

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modest amount of preclinical evidence. *See* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) § 2107.03 (9th ed. 2020) (requiring evidence "that reasonably supports" pharmacological or therapeutic utility and noting that data from *in vitro* or animal testing "is generally sufficient"); Nelson v. Bowler, 626 F.2d 853, 856 (C.C.P.A. 1980) (finding utility on the basis of data demonstrating pharmacodynamic activity in animals, specifically, stimulating smooth muscle tissue in gerbils and modulating blood pressure in rats); Cross v. Iizuka, 753 F.2d 1040, 1052 (Fed. Cir. 1985) (finding utility on basis of *in vitro* demonstration of the claimed biological activity, that is, preventing aggregation of platelets). In contrast, the preclinical evidence required by the FDA to justify the start of a clinical program must persuade the agency that it is safe to start testing in humans and that the trials will not expose subjects to unnecessary risks. In addition to manufacturing information, the inventor needs to generate and submit data about the drug's pharmacological effects, mechanism of action, absorption, distribution, metabolism, excretion, and toxicity (e.g., data relating to acute, subacute, chronic, developmental, and reproductive toxicology as well as carcinogenicity). *See* 21 C.F.R. § 312.23(a)(8) (describing what must be submitted in the request to begin clinical trials); FDA, GUIDANCE: CONTENT AND FORMAT OF INVESTIGATIONAL NEW DRUG APPLICATIONS (INDS) FOR PHASE 1 STUDIES OF DRUGS, INCLUDING WELL-CHARACTERIZED, THERAPEUTIC, BIOTECHNOLOGY-DERIVED PRODUCTS (Nov. 1995) (similarly laying out the required submissions ments), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-and-format-investigational-new-drug-applications-inds-phase-1-studies-drugs-including-well [https://perma.cc/DX9J-UXWV]; *see generally* Amy M. Avila et al., *An FDA/CDER Perspective on Nonclinical Testing Strategies: Classical Toxicology Approaches and New Approach Methodologies (NAMs)*, 114 REG. TOX. & PHARMACOLOGY, 104662 (2020) (describing what the FDA expects in a preclinical program).

23 35 U.S.C. § 156(c)(2).

24 *Id.* § 156(g)(6)(C). There is a different cap for a patent issued before the enactment on September 24, 1984, if the product was already in clinical trials—but not approved—on that date. For these products, the PTO restores no more than two years. *Id.*

25 *Id.* § 156(c)(3).

26 *See* Erika Lietzan, *The Drug Innovation Paradox*, 83 MO. L. REV. 39, 62 (2018).

restoration does not fully restore the time spent in research, an earlier Article explored whether the U.S. legal system might be systematically under-encouraging particular areas of new drug research.[27] We examined every grant of patent term restoration for a new drug (including the biological products that are new drugs) from the scheme's 1984 enactment to April 1, 2018. Among other things, we found that longer clinical testing programs lead to shorter effective patent life, even after the PTO has granted patent term restoration.[28] The findings contributed to a growing body of literature raising the alarm that the U.S. legal system may be systematically skewing drug research incentives away from problems that require longer clinical programs, such as a cure for Alzheimer's Disease and interventions at the early stages of cancers.[29]

C. The Question of Distorted Medical Device Patents

This Article was originally conceived as a companion piece. Like new drugs, medical devices are intended for treatment or prevention of diseases and other health conditions, and many require preapproval from the FDA on the basis of marketing applications that establish their safety and effectiveness. Devices subject to premarket approval, like new drugs, require lengthy premarket testing programs. Medical device inventors thus face the same prospect of patent term distortion as new drug inventors, with *both* eligible for patent term restoration under the same provision of the Patent Act.

1. Premarket Approval of Medical Devices

The Medical Device Amendments Act of 1976 established the framework that applies to devices today, requiring premarket submissions to the FDA for many devices.[30] The centerpiece of this framework is classification of device types by the level of risk they present to patients, from Class I (lowest risk) to Class III (highest risk).[31] Both the amount and type of federal regulatory oversight

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27 Lietzan & Acri née Lybecker, *supra* note 4, at 1323.

28 *See id.* at 1349–52.

29 *See id.* at 1353–57 (discussing policy implications of the findings).

30 *See generally* Medical Device Amendments Act of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976).

31 *See id.* § 513.

depends mostly on the risk associated with the type of device, with the highest risk types and new device types requiring premarket approval on the basis of safety and effectiveness.

Today, most medical devices that fall into Class III require premarket approval. To be approved, the device "premarket approval application" (PMA) must provide a "reasonable assurance" that the proposed device is safe and effective under the conditions of use described in its labeling.[32] Like the safety and effectiveness standard for new drugs, the safety and effectiveness standard for devices is understood to require that the product's benefits outweigh its risks, although for devices the statute expressly confirms this meaning.[33] Unlike the statutory provisions governing new drug applications, however, the statutory provisions governing medical device applications do not require human testing, let alone data from an "adequate and well-controlled" clinical trial.[34] That said, the FDA usually expects device premarket approval applications to include a range of nonclinical and clinical safety and effectiveness data.[35]

The approach to premarket device testing differs, however, from the approach to premarket drug testing. Testing a new drug in humans involves introducing a novel chemical compound into the human body. By their nature, active drug ingredients have a physiological effect in the body; the body interacts with the drug (absorbing it, distributing it, metabolizing it, and excreting it, i.e., pharmacokinetics), and the drug acts on the body (pharmacodynamics).[36]

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[32] 21 U.S.C. § 360e(d)(2)(A)-(B).

[33] *Id.* § 360c(a)(2)(C) ("[The] safety and effectiveness of a device are to be determined . . . weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.").

[34] *Compare* 21 U.S.C. § 355(d) (requiring refusal of new drug application that lacks "substantial evidence" of effectiveness, meaning "evidence consisting of adequate and well-controlled investigations, including clinical investigations."), *with id.* § 360e(d)(2) (requiring refusal of device premarket approval application "if there is a lack of a showing of reasonable assurance" that the device is safe and effective under the conditions of use in its labeling), and Jonathan S. Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSM. L. J. 510, 512 (1984) ("Unlike the statutory provisions relating to new drug approvals, the Medical Device Amendments do not require adequate and well-controlled investigations for proof of effectiveness.").

[35] *See infra* Part IV-A.

[36] *See generally Impact Story*, FDA (Feb. 22, 2019), https://www.fda.gov/drugs/regulatory-science-action/impact-story-supporting-drug-

Laboratory and animal testing is meant to rule out significant toxicity issues,[37] but a full understanding of the interaction between new chemical compounds and the human body can take years. As a scientific matter, and as an ethical matter, a drug company cannot start with a large clinical trial at a randomly selected dosage in thousands of actual patients. The process for a new drug is iterative: working from very small safety tests in healthy volunteers; then proceeding to medium-size trials in patients that start to shape the company's understanding of the drug's effect on the body and the body's effect on the drug, helping to refine the dosage needed for treatment; and only then proceeding to the large "pivotal" trials designed to vet the drug's safety and provide statistical proof of effectiveness.[38]

There is—and could be—nothing comparable to this stepwise approach for, say, a new pacemaker or replacement heart valve. Instead, depending on the device, a device developer may start with a "feasibility" study, to determine whether proceeding further (into additional clinical testing) is warranted.[39] A feasibility study could, for instance, confirm the design and operating specifications of the device, provide initial safety data, and generate information to establish parameters (such as sample size and clinical endpoints) for the pivotal study.[40] After this, the developer will conduct a pivotal clinical study to collect the safety and effectiveness data needed to

development-through-physiologically-based-pharmacokinetic-modeling [https://perma.cc/F8S5-GN2N].

37 Avila, *supra* note 22, at 4–5.

38 PETER B. HUTT ET AL., FOOD & DRUG LAW (5th ed.) at 870.

39 *See e.g.*, Aaron V. Kaplan et al., *Medical Device Development from Prototype to Regulatory Approval*, 109 CIRCULATION 3068, 3070 (2004) (referring to a two-step process, beginning with a pilot phase for first clinical use to establish the safety of the device and to help design the pivotal trial).

40 Just as the first test of a new drug in humans requires an effective investigational new drug application (IND), this first test of a medical device in humans usually requires an effective investigational device exemption (IDE). *See* 21 U.S.C. § 360j(g) (allowing the FDA to grant an exemption from misbranding and establishment registration and listing for investigational devices); 21 C.F.R. § 812.1 (regulation creating the IDE exemption). But the IDE framework differs from the IND framework. In some very low risk situations, an IDE is not required. *See id.* § 812.2(c)(3)(ii). In addition, unlike the IND, the IDE may not need to be submitted for FDA review. Specifically, if the device is not a "significant risk" device, the person testing the device may simply submit the IDE to an investigational review board (IRB) for approval. *Id.* § 812.2(b)(1)(ii).

support approval of the device.[41] The FDA may require a randomized, controlled clinical trial, as it does for new drugs, but it is less likely to do so, and these trials are typically comparatively smaller for medical devices.[42]

After completing its clinical trials, the device manufacturer submits a premarket approval application (PMA) to the agency, with the appropriate user fee.[43] The agency's review, supported in part by that fee, involves scientific and regulatory personnel from a range of disciplines (including statisticians, clinicians, and as applicable, engineers and the like) across a range of offices.[44] It may also include a meeting with a panel of external subject matter experts.[45] The agency assigns a target date for its final action on the application, and on completing its review—generally by that target date, extended if necessary on account of amendments during PMA review—the FDA will issue an approval order or, conversely, choose not to approve.[46] The company may not market the device described in the application until the FDA has approved the PMA.[47]

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41 Kaplan, *supra* note 39, at 3070.

42 *See e.g.*, *id.* at 3070 ("[D]evices that require randomized data for approval are the exception rather than the rule."); Jonathan Darrow et al., *FDA Regulation and Approval of Medical Devices: 1976-2020*, 326 JAMA 420, 425 (2021) (finding that 27% of trials supporting approval of cardiovascular devices from 2000 to 2007 were randomized and 14% blinded, while a comparable study of drugs approved from 2005 to 2012 found that 89% of trials were randomized and 80% double blinded).

43 *See* 21 U.S.C. §§ 360e(c), 379j (describing the application for premarket approval, authority to assess and use device fees, respectively); FDA, GUIDANCE: USER FEES AND REFUNDS FOR PREMARKET APPROVAL APPLICATIONS AND DEVICE BIOLOGICS LICENSE APPLICATIONS (Oct. 2022), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-premarket-approval-applications-and-device-biologics-license-applications [https://perma.cc/6XBE-24YJ].

44 *See generally* Donna Headlee, *Introduction to the Premarket Approval Application (PMA) Program*, FDA 11, https://www.fda.gov/media/131254/download [https://perma.cc/KP8P-5HAM]; FDA, PMA REVIEW PROCESS, https://www.fda.gov/medical-devices/premarket-approval-pma/pma-review-process [https://perma.cc/9DFG-3PWT].

45 FDA, PROCEDURES FOR MEETINGS OF THE MEDICAL DEVICES ADVISORY COMMITTEE 3 (Sept. 2017), https://www.fda.gov/advisory-committees/medical-devices/medical-devices-advisory-committee [https://perma.cc/7P7N-QR8W].

46 FDA, PMA REVIEW PROCESS, *supra* note 44.

47 *See* 21 U.S.C. § 351(f). *See also* FDA, PREMARKET APPROVAL (PMA) (May 16, 2019), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma [https://perma.cc/5Q28-SFYP].

Like the premarket research and development process for new drugs, the premarket process for medical devices is time consuming, risky, and expensive.[48] In absolute terms, though, the numbers are smaller. For instance, in 2010, the medical device industry reported that the average cost of developing a new device from concept through approval was $94 million, having risen from $30 to $40 million in the early 1990s.[49] For comparison, in 2016, the cost of developing new drugs was estimated at hundreds of millions to well over one billion dollars.[50] It is nevertheless a substantial sum of money, especially for the smaller companies that turn out to dominate the medical device industry.[51]

2. Patent Term Restoration

Like clinical trials of new drugs, clinical trials of new medical devices usually begin after at least some relevant patent applications have been filed.[52] The subsequent clinical program and premarket application review mean that some of the patent's term passes before the FDA approves the product for commercial marketing. Section 156 of the Patent Act addresses this patent term distortion, offering patent term restoration for medical devices subject to the premarket approval requirement, just as it does new drugs.[53]

Section 156 permits extension of a patent claiming a device, a method of using the device, or a method of manufacturing the

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48 *See* Kaplan, *supra* note 39, at 3072 (describing premarket approval as a "long, arduous, and expensive development path.").

49 *See* Josh Makower, FDA, IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION: A SURVEY OF OVER 200 MEDICAL TECHNOLOGY COMPANIES 7, 38 (2010), https://www.medtecheurope.org/wp-content/uploads/2015/07/01112010_FDA-impact-on-US-medical-technology-innovation_Backgrounder.pdf [https://perma.cc/35FH-38SQ].

50 *See* Darrow, *supra* note 42, at 428 ("Average total costs to bring a device from concept through PMA . . . were estimated in 2010 to be $94 million . . . compared with estimates of hundreds of millions or more for approval of new drugs, likely reflecting devices' shorter development timelines and reduced clinical data requirements."); Joseph DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 26 (2016) (estimating average out-of-pocket cost per approved compound of $1.4 billion and total preapproval cost of $2.56 billion).

51 *See infra* Part III(B).

52 *See* Kaplan, *supra* note 36, at 3068–69 ("Typically, a physician and/or engineer inventor conceives of a device solution to an unmet clinical challenge, initiates the patent process, and builds preliminary device prototypes.").

53 35 U.S.C. § 156.

device, if the device went through a "regulatory review period," meaning clinical testing and FDA review of a marketing application.[54] Again, various conditions apply, analogous to those applicable to new drugs. *First*, patent term restoration is available only if this was the FDA's first ever approval of the medical device.[55] *Second*, the PTO may extend only one patent for each regulatory review period for a particular product.[56] For the most part, this means one patent per premarket application. But in rare situations, the PTO will extend a patent when the FDA approves a modification to another device, *even if* there is no new PMA. If a device company wants to make changes that affect a device's safety or effectiveness, it must supplement its application and usually wait for FDA approval.[57] In some cases, the resulting device—though not the subject of a separate PMA filing—is treated as a new product, and the PTO restores a new patent in connection with the new regulatory review period.[58] *Third*, the PTO may extend a patent only if it has not already extended that same patent previously—for instance in connection with a different device.[59]

As is true for drugs, any patent life that passes before human trials—for instance, during bench tests and animal testing—is not recoverable. The PTO restores half of the *testing* period, which begins on the date that clinical trials actually begin and ends on the date an application for premarket approval is submitted to the FDA under section 515 of the FDCA.[60] It restores the complete *review*

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54 *See id.* § 156(a).

55 *Id.* § 156(a)(5)(A). In other words, the question is whether the specific medical device has been approved in the past. This contrasts with the relevant inquiry for a new drug: whether the active ingredient has been approved in the past pursuant to another new drug application. *See* Lietzan & Acri née Lybecker, *supra* note 4, at 1334, 1334 n.87.

56 *See* 35 U.S.C. § 156(c)(4) ("[I]n no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.").

57 *See* 21 C.F.R. § 314.71(e).

58 *See, e.g.*, *infra* note 68. Although drug companies make changes to their products by supplementing their new applications, the PTO and the FDA do not treat the resulting product as a new product that could entitle the company to another patent extension.

59 *See* 35 U.S.C. § 156(a)(2).

60 35 U.S.C. § 156(g)(3)(B)(i). This contrasts with the testing period for new drugs, which begins on the date that the FDA's permission to start clinical trials—an investigational new drug application (IND)—takes effect. *Id.* § 156(g)(1)(B)(i). The PTO relies on the FDA to identify the start date for drugs and relies on the company to identify

period, which begins when the company submits its application for premarket approval and ends when the FDA approves that application.[61] The same caps apply to device restoration as to drug restoration; for instance, PTO will restore no more than five years.[62]

3. Eligibility of Humanitarian Use Devices

Patent term restoration is also available for devices that are the subject of approved "humanitarian device exemptions" (HDEs). These are devices intended to treat rare disease.[63] Their eligibility for patent term restoration is an artifact of how the humanitarian device provision was conceived and drafted in 1990. Though it appears in a different provision of the FDCA, section 520, the provision authorizes the FDA to grant "an exemption from the effectiveness requirement" of section 515, i.e., the PMA provision.[64] The agency gives these applications a different numerical designator—PMAs begin with P, while HDEs begin with H—and there are some important differences between review of HDEs and review of PMAs, as well as important differences in how the devices are regulated after approval.[65] But as a practical matter, the HDE simply provides an exemption from one part of the PMA standard; it is not an alternative pathway to the market so much as an alternative standard for certain devices. Section 515 authorizes the actual approval decision made. As a result, the patent term extension provision—which defines a medical device's regulatory review period in terms of

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the start date for devices. The difference in approach means that a company that tests its device outside the United States may recover (a portion of) its clinical testing period, but a company that tests its drug outside the United States without an effective IND may not.

61 *See* 35 U.S.C. § 156(g)(3)(B).

62 *See id.* § 156(c)(2), (g)(6). If the patent was issued before enactment of Section 156 and the product was already in clinical trials at that time, the cap is two years. *See id.* § 156(g)(6)(C).

63 Safe Medical Devices Act of 1990, Pub. L. 101-629, § 104 Stat. 4511, 4524 (adding § 520(m) to the FDCA, codified at 21 U.S.C. § 360j(m)). Originally a device was eligible for this pathway if the disease or condition affected fewer than 4,000 individuals in the United States per year. *See id.* Congress revised the threshold to 8,000 individuals in 2016. *See* 21st Century Cures Act, Pub. L. No. 114-255, § 3052, 130 Stat. 1033, 1124–25.

64 *See* 21 U.S.C. § 360j(m)(2).

65 For examples of similarities and differences, see, *e.g.*, FDA, GUIDANCE: HUMANITARIAN DEVICE EXEMPTION (HDE) PROGRAM (Sept. 6, 2019), https://www.fda.gov/media/74307/download [https://perma.cc/TZ9H-E8CV].

submission and approval of an application under section 515—applies to humanitarian use devices.

II. MEDICAL DEVICE PATENTS: DATASET AND FINDINGS

For this Article, we examined the medical devices that go through premarket approval and patent term restoration. The process through which the PTO and the FDA collaborate to implement the patent term extension provisions of the Patent Act produces publicly available information about the approved devices, their premarket testing programs, and—as to each—the one patent each company thought worth extending.

The scope of this exercise was inherently narrow. Only Class III medical devices are subject to the premarket approval requirement, and *most* medical devices in the market—including many that are important, innovative, patented, and expensive—are not in Class III and thus not subject to premarket approval, not eligible for patent term extension, and not included. We discuss these devices and the significance of this scope limitation in Part V. The devices subject to premarket approval requirements and thus at issue here are mostly orthopedic devices, obstetrical and gynecological devices, neurological devices, dental devices, and cardiovascular devices, but they do not even make up the majority of those devices.[66]

A. Dataset

The dataset was assembled as follows. *First*, the PTO provided a spreadsheet of all patent term restoration applications received

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[66] For instance, the cardiovascular devices that currently require PMAs are the catheter balloon repair kit, trace microsphere, intra-aortic balloon and control system (in some situations), ventricular bypass (assist) device, implantable pacemaker pulse generator, cardiovascular permanent pacemaker electrode, pacemaker programmer, pacemaker repair or replacement material, carotid sinus nerve stimulator, replacement heart valve, cardiopulmonary bypass pulsatile flow generator, nonroller-type temporary ventricular support blood pump, cutting/scoring percutaneous transluminal coronary angioplasty (PTCA) catheter, external counter-pulsating device, high energy DC-defibrillator, and automated external defibrillator system. *See* 21 C.F.R. Pt. 870, B. Many more cardiovascular devices—dozens of other types—fall in Class I or Class II and do not require PMAs.

between September 28, 1984, and December 31, 2019.[67] The PTO also maintains a table of patent term restoration grants on its website.[68] Neither list is complete, so the lists were combined, and duplicates removed. Although some PTR applications could have been omitted from both sources, the Federal Register was used to confirm that the PTO restored no other medical device patent in the interval studied.[69]

Second, we categorized the products in the spreadsheet manually based on the regulatory review provisions—new drug approval, biologics license approval, medical device approval or clearance, new animal drug approval, or food additive petition—that would have been applied by the FDA. Medical devices were then extracted for analysis. Between September 28, 1984, and December 31, 2019, the PTO received 257 requests for device patent term restoration, associated with 193 discrete medical devices. (The PTO allows a company to submit applications for multiple patents on the same product and select one for restoration after the Office has performed its analysis and calculated the restoration owed.)

Third, using PTO's Public Patent Application Information Retrieval (PAIR) system, we determined the outcome of the patent term restoration process for each medical device, finishing our data collection on December 31, 2020.[70] If PAIR was missing the relevant documents, we relied on other sources of information, such as the PTO list of patent terms extended, Westlaw, or hyperlinks in a PTO list of notices mailed after November 1, 1996, and before January 1, 2005.[71] We identified 110 grants of patent term restoration

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67 Authors' dataset (on file with authors).

68 *Patent Terms Extended Under 35 U.S.C. § 156*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156 [https://perma.cc/R7HS-THP2].

69 *See* 35 U.S.C. 156(d)(2)(ii); *see also* 21 C.F.R. 60.20 and MPEP 2757. The PTO cannot restore a patent until the FDA has published the regulatory review period in the Federal Register.

70 The PTO retired Public PAIR on July 31, 2022. *See Public Pair To Be Retired*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/public-pair-be-retired [https://perma.cc/DQZ7-SUJ3].

71 *Patent Term Extension (Restoration) Under 35 U.S.C. § 156 Decisions—Commissioner for Patents*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/laws/patent-terms-extended [https://perma.cc/YV26-578J].

between September 28, 1984, and December 31, 2020.[72] When we ended data collection, a decision was still pending for 26 discrete devices. Patent term restoration was denied by PTO or abandoned by the applicant for the remaining 57 devices.[73]

This left 110 medical devices that received patent term restoration. Three were the subject of humanitarian device exemptions, and the remaining 107 were the subject of premarket approval applications (102 devices) or supplements to already approved applications (five devices). In one instance, a manufacturer obtained patent term restoration for both its original PMA and a supplement to the same PMA.[74] We collected regulatory information about the 102 medical devices that were the subject of full PMAs including the types of

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[72] This includes two for which interim extensions totaled the amount of restoration requested: U.S. Patent Nos. 7419696 and 5454779. It does not include a third for which interim extensions totaled the amount of restoration requested—U.S. Patent No. 7555346—because the FDA did not calculate the regulatory review period for this medical device. It also does not include one that was granted before enactment of the URAA and then mooted by the URAA extension which caused the patent to expire even later. Interim extensions, which were added to the statute in 2003, permit successive one-year interim extensions while the FDA reviews the device premarket application and one-year interim extensions and the PTO considers the full request for patent term extension. They prevent the patent from expiring while the process completes. *See* 35 U.S.C. § 156(d)(5), (e)(2); 37 C.F.R. § 1.760, 1.790(a).

[73] These 57 also include a medical device for which interim extensions totaled the amount of restoration requested—U.S. Patent No. 7555346—but for which the FDA did not calculate the regulatory review period. The reasons for denial vary, and in some instances the PTO had more than one reason to deny restoration. The most common explanation was that the device was not approved pursuant to a PM—either because it was never approved (the applicant had just been asking for an interim extension) or, more often, because it was cleared pursuant to the 510(k) premarket notification process. This is a different pathway to market. In other words, companies with devices that did not go through premarket approval had asked for patent term extension, but they were not eligible for it. The next most common explanations for denial were that the request was not timely filed and that marketing under the identified PMA did not constitute the first commercial marketing of the product.

[74] Our dataset shows that Abbott Vascular received 543 days in connection with the XIENCE PRIME and XIENCE PRIME LL Everolimus Eluting Corronary Stent System (P110019) and, one year later, 178 days associated with the Xience Xpedition Everolimus Eluting Coronary Stent System (P110019 S025).

devices at issue and the length of their clinical testing programs.[75] We also collected information about the restored patents.[76]

B. Findings

Devices. We sorted the devices by field of medicine.[77] Of the 102 medical devices, 44 (43%) are cardiovascular—including three

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[75] We collected: (1) the device's intended use, generally taken from the approval letter or, barring this, the FDA's Federal Register notice; (2) the generic name for the device type, the name of the PMA holder, and the name of company to whom the initial approval letter was sent, generally taken from the agency's database of PMA approvals; (3) the classification regulation, if one existed, and the device type's definition in the Code of Federal Regulations; (4) the product code assigned to the device, and whether the device was the first in its product code, found in the agency's PMA database, and; (5) information about the length of each component of the regulatory review period taken from the FDA's Federal Register notice.

[76] We recorded (1) the date on which the inventor filed the patent application that led to issuance of the patent; (2) the date on which the patent issued; (3) the original patent expiry date (after patent term adjustment) without patent term restoration; (4) the patent owner, who requested patent term restoration; (5) whether the PTO applied the five-year (or two-year) cap and fourteen-year limit; (6) the number of days restored; (7) the final patent expiry date after restoration, and; (8) whether the patent owner paid the maintenance fees required during the remainder of the patent term. For the issue date, we recorded the date on which the original patent issued in the case of a reissued patent. A patent may be reissued to correct certain types of error; in this case the patent number changes (and now begins with "RE") but the term remains the same. *See* 35 U.S.C. § 251. For the most part, we took this information from documents available through PAIR.

[77] When it implemented the Medical Device Amendments, the FDA divided devices by field of medicine; one example would be "cardiovascular devices." It divided each general field into subfields; for instance, cardiovascular devices became cardiovascular diagnostic devices, cardiovascular monitoring devices, cardiovascular prosthetic devices, cardiovascular surgical devices, and cardiovascular therapeutic devices. *See* 21 C.F.R. 870, B–F. The agency then classified the devices within each subfield, and each device type received its own regulation. For instance, within cardiovascular prosthetic devices, the FDA published a regulation for implantable pacemaker pulse generators, 21 C.F.R. § 870.3610, assigning these devices to Class III. The FDA also assigns medical devices to three-letter product codes, and this is a separate and more detailed system. It uses product codes to distinguish technology and indication subgroups within a regulation. For instance, the implantable pacemaker pulse generator regulation includes three product codes: DSZ (pacemaker battery), DXY (implantable pacemaker pulse-generator) and PNJ (leadless pacemaker). A device that falls in any of these codes would have the generic name "implantable pacemaker pulse generators," but the product code provides additional distinguishing details. But the FDA also uses product codes to categorize devices that do not fall into existing regulations. *See* FDA, GUIDANCE: MEDICAL DEVICE CLASSIFICATION PRODUCT CODES § 2(C) (Apr. 11, 2013), https://www.fda.gov/media/82781/download [https://perma.cc/RY4W-PPGZ]. To classify the devices by field of medicine, we relied on the regulation into which the device was placed, which is identified in FDA's PMA

mechanical heart valves, six implantable defibrillators, three coronary stents, seven drug-eluting coronary stents, and four prosthetic aortic valves. Another 12 (12%) are ophthalmic devices, including two intraocular lenses and two corneal implants. Another 11 (11%) are orthopedic devices, including three intervertebral infusion devices meant for the lumbar spine, two intervertebral disc prostheses, and a prosthetic knee. The remaining third of the devices are more varied and include several neurological implants, several diagnostic devices (not only reagents for *in vitro* diagnostics but also a magnetic resonance imaging system), sutures, biological wound dressings, a contraceptive device, and an infusion pump. The results appear in Table 1.

Table 1
Approved Devices For Which Patent Term Restoration Was Granted:
Field of Medicine

Field	Number of Devices (%)
Anesthesiology	3 (2.94%)
Cardiovascular	44 (43.14%)
Clinical chemistry and toxicology	1 (1%)
Dental	1 (1%)
Gastroenterology and urology	8 (7.84%)
General and plastic surgery	10 (9.80%)
Hematology and pathology	2 (2%)
Immunology and microbiology	1 (1%)
Neurology	5 (5%)

database. If no regulation is identified, we relied on the device's product code and, specifically, on the identity of review panel (or, if necessary, premarket review office) associated with products falling in that code. These can be found in the FDA's product classification database. *See* FDA, PRODUCT CLASSIFICATION DATABASE, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm [https://perma.cc/55VA-Q3B9].

Obstetrics and gynecology	1 (1%)
Ophthalmology	12 (12%)
Orthopedic	11 (11%)
Radiology	3 (3%)
Total	**102 (100%)**

Patent Owners and FDA Applicants. For any particular patent term restoration, our dataset might identify several entities: the inventor, the person requesting patent term restoration, the FDA applicant, and indeed the current owner of the FDA license. Only the patent owner, or their agent, may submit a request for patent term restoration.[78] The patent owner is typically the inventor or inventors (if there were more than one), although for patents filed after September 16, 2012, it can be an assignee (or someone else with a proprietary interest in the matter) so long as the inventor is identified.[79] Most patent term restoration requests are filed by companies—here, medical device companies—rather than individuals. The PTO requires that the person requesting patent term extension be the one that undertook premarket research and development and sought FDA approval or, in the alternative, that there was an agency relationship between the two parties while that process was underway.[80] But at any time, including after approval, another company might acquire an interest—in the patent, in the company that sought patent term restoration, in the company that sought FDA permission to market, or simply in the regulatory approval itself (the license to market the product).

Today, Medtronic (including Medtronic Ireland, Medtronic Vascular, Medtronic Inc., and so forth) holds 16 of the FDA approvals, Boston Scientific holds another 7, and Abbott companies (Abbott Laboratories, Abbott Medical, Abbott Vascular, and so forth) another 6; these three companies account for 29 (28%) of the approved PMAs. Some other companies (such as Edwards

78 *See* 35 U.S.C. § 156(d)(1); 37 C.F.R. § 1.730.
79 *See* MPEP § 2109 (9th ed. 2020); *cf.* 37 C.F.R. §§ 1.41, 1.42 (amended 2011).
80 *See* MPEP § 2752 (9th ed. 2020); 37 C.F.R. § 1.730.

Lifesciences) hold two or three of the device approvals, but most companies in the dataset—such as Aspire Bariatrics, Endoloix, Guidant, Organogenesis, and Uroplasty LLC—hold only one device approval with a restored patent. But the companies that requested the patent term restoration that was granted—i.e., those involved with the invention at the earliest stages, meaning agents of the inventor or assigned the patent by the inventor—seem to be a more diverse group. At this stage, Medtronic sought 10 of the patent extensions (versus the 16 it holds), Boston Scientific sought 2 (versus 7), and Abbott sought 4 (instead of 6); they accounted for 16% of the requests.[81] This indicates the larger companies acquired their interests after patent term restoration was sought and thus (because it must happen first) after FDA approval was earned.

Clinical Testing Period. The 102 medical devices in our dataset averaged 1,624 days (4.45 years) in clinical testing, but the clinical programs varied.[82] The clinical programs ranged from 6,909 days (18.93 years) for a device indicated to prepare apheresis platelet components in order to reduce the risk of transfusion-transmitted infections to 208 days (less than one year) for an implantable cardioverter defibrillator. Twelve devices spent more than eight years in clinical trials, while nineteen spent less than two years. Table 2 presents our findings on the length of the clinical period.

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[81] We were unable to identify the PTR applicant for five approved medical devices, because the patents were not available on PAIR. A Medtronic company holds the PMA for one of these, and Boston Scientific holds another.

[82] We found no studies in academic literature of comparable scope with which to compare our findings. A 2019 paper considering stents purchased by hospitals from 2004 to 2013 found, on the basis of publicly available clinical trial information from a variety of sources, that "on average" these devices spent over 28 months in clinical testing. Matthew Grennan & Robert J. Town, *Regulating Innovation with Uncertain Quality: Information, Risk, and Access in Medical Devices* 13 (Nat'l Bureau of Econ. Rsch., Working Paper No. 20981, 2019). Another paper co-authored by a former FDA official responsible for medical devices reports that a first-in-class Class III medical device could require two years for its pivotal trial plus a year of follow-up data. Kaplan, *supra* note 39, at 3069–70.

Table 2 **Length of Clinical Testing Period** **Approved Medical Devices with Restored Patents**			
Clinical Testing Period	**Number of Devices**	**Percentage of Total**	**Cumulative Percentage**
0 ≤ years < 1	4	3.92%	3.92%
1 ≤ years < 2	15	14.70%	18.63%
2 ≤ years < 3	21	20.59%	39.22%
3 ≤ years < 4	13	12.75%	51.96%
4 ≤ years < 5	17	16.67%	68.63%
5 ≤ years < 6	10	9.80%	78.43%
6 ≤ years < 7	6	5.89%	84.31%
7 ≤ years < 8	4	3.92%	88.24%
8 ≤ years < 9	6	5.89%	94.12%
9 ≤ years < 10	1	0.98%	95.10%
10 ≤ years < 11	2	1.96%	97.06%
11 ≤ years < 12	0	0	97.06%
12 ≤ years < 13	0	0	97.06%
13 ≤ years < 14	0	0	97.06%
14 ≤ years < 15	1	0.98%	98.04%
15 ≤ years < 16	0	0	98.04%
16 ≤ years < 17	1	0.98%	99.02%
17 ≤ years < 18	0	0	99.02%
18 ≤ years < 19	1	0.98%	100%
Total	**102**	**100%**	

FDA Review of PMAs. The FDA spent an average of 672 days reviewing the marketing applications for the 102 medical devices in

our dataset.[83] The shortest review period was 124 days, for an exercise-responsive cardiac pacemaker approved in 1988, and the longest review period was 3,891 days (10.66 years) for a mechanical heart valve approved in 1997. Eighteen of the 102 devices applications were pending before the FDA for more than three years. Medical device user fees—paid by applicants, with the funds supporting the device center and in exchange for the agency's commitment to more efficient application review subject to agreed deadlines—were first collected in Fiscal Year 2003, i.e., on October 1, 2002. Of the 102 devices applications in our dataset, 53 were submitted before October 1, 2002, and these applications averaged 760 days before the FDA. The remaining 49 were submitted under the user fee paradigm, and they averaged 577 days before the FDA—i.e., about a 24% reduction in time pending.

Time to Market. For the 102 approved medical devices in our dataset, the total regulatory review period—clinical testing plus regulatory review—averaged 2,296 days (6.29 years).[84] Again, this figure does not include time the company may have spent doing the bench testing and other pre-clinical work necessary to justify proceeding into human trials as a regulatory matter. Before

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[83] Various other calculations appear in the literature. For example, in 2021, Professor Darrow presented the results of an exhaustive review of PMA approvals from 1976 through 2021, reporting that the average time from submission to approval has varied from 300 days to 1000 days, and finding no obvious trends. Darrow, *supra* note 42, at 425, 428. Professor Stern examined the length of FDA review for PMA approvals beginning in 1997, through calendar year 2007, finding an overall average of 18.1 months—around 550 days. Ariel Dora Stern, *Innovation under Regulatory Uncertainty: Evidence from Medical Technology*, 145 J. PUB. ECON. 181, 185 (2017).

[84] We found no comparable empirical studies in the academic literature with which to compare our results. A survey of 100 medical device companies published in 2010 indicated that those whose products received premarket approval indicated "it took an average of 54 months to work with the FDA from first communication to being approved to market the device." MAKOWER, *supra* note 49, at 6. Several papers report an average of three to seven years, but this does not appear to be grounded in empirical research. *See, e.g.*, Gail Van Norman, *Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices*, 1 JACC: BASIC TO TRANSLATIONAL SCI. 277, 277 (2016) ("Bringing a new medical device to market takes on average from three to seven years.") (citing K. M. Fargen et al., *The FDA Approval Process for Medical Devices: An Inherently Flawed System or a Valuable Pathway for Innovation?*, 5 J. NEUROINTERV. SURG. 269, 270 (2013) ("It has been estimated that the time from concept to market for medical devices is 3-7 years, although no concrete data could be identified in the literature regarding time or cost.").

implementation of user fees this was 2,189 days (5.98 years) and After implementation of user fees, this time period averaged 2,412 days (6.61 years), which, because the FDA review period grew shorter, indicates that premarket clinical programs have grown longer.[85] Indeed, medical device applications submitted beginning in FY2003 have averaged 1,836 days in trials (5.03 years) compared to 1,429 days (3.92 years) in clinical trials before then.

Effective Patent Life. When initially approved by the FDA, the devices in our dataset had an average of 7.73 years of life remaining on the patents that the companies selected for restoration. These patents received an average of 1,022 days (2.8 years) of restoration, and with this time added they expired on average 10.51 years after medical device approval. Seven were subject to the 2-year cap on restoration, and 20 were subject to the 5-year cap on restoration. Twenty-nine (28%) hit the 14-year limit on effective patent life.

In short, between September 24, 1984, and December 31, 2020, the PTO restored 102 patents associated with Class III medical devices that had gone through premarket approval at the FDA, three of which had benefited from the humanitarian device exemption from effectiveness testing. More than half completed their clinical trials in under four years, and nearly seventy percent were done within five years, but premarket clinical programs may be getting somewhat longer. Enactment of user fees for medical device applications in 2002—meant in part to shorten the time device applications remain under review at the FDA—seems to have worked. Three large companies currently hold nearly one third of the device approvals in question, and they seem to have acquired some of their interests *after* FDA approval; that is, another entity invented and developed the device initially.

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[85] *See also* MAKOWER, *supra* note 49, at 14 (noting in 2010 that the "FDA's clinical data requirements continue to rise" and the agency is "increasingly demanding . . . large-scale clinical data" before approval).

C. The Missing Data

Table 3
Number of PMAs for Which PTR Requests Were Submitted

Calendar Year of PMA Approval	Number of Original PMAs Approved by FDA	Number of Original PMAs for Which PTR Requests Were Filed
1984	9	1 (11%)
1985	22	5 (23%)
1986	42	4 (10%)
1987	13	1 (8%)
1988	28	3 (11%)
1989	37	1 (3%)
1990	23	0
1991	24	4 (17%)
1992	8	1 (13%)
1993	17	4 (24%)
1994	21	3 (14%)
1995	27	3 (11%)
1996	37	4 (11%)
1997	46	7 (15%)
1998	42	5 (12%)
1999	37	3 (8%)
2000	49	3 (6%)
2001	60	5 (8%)
2002	33	2 (6%)
2003	35	3 (9%)
2004	48	2 (4%)
2005	32	3 (9%)

2006	42	3 (7%)
2007	28	0
2008	26	4 (15%)
2009	16	2 (13%)
2010	22	4 (18%)
2011	38	4 (11%)
2012	41	10 (24%)
2013	23	5 (22%)
2014	29	7 (24%)
2015	46	12 (26%)
2016	40	9 (23%)
2017	47	8 (17%)
2018	32	7 (22%)
2019	32	8 (25%)
Total	**1152**	**149 (13%)**

Although these findings could be of interest to policymakers, it is not clear that these 102 medical devices are representative of all medical devices that have gone through premarket approval in the last thirty years. It turns out that only 13% of the PMA approvals during the study window led to requests for patent term restoration in the first instance.[86] In other words, as illustrated in Table 3, nearly

[86] The window runs from 60 days before September 24, 1984, to 60 days before December 3, 2019. We opened the window 60 days before enactment of section 156, because requests are due within 60 days of approval and these pre-enactment devices were therefore eligible. We closed the window 60 days before December 31, 1990, because PMAs approved in the final 60 days could have been the subject of requests for PTR after the last entry in the dataset we received from the PTO. For the numerator (number of original PMAs approved during this window for which a patent term restoration request was filed), we began with all 257 requests for patent term restoration for medical devices and deleted (1) the requests associated with humanitarian device exemptions, 510(k)s; and *de novo* classification; (2) the requests associated with devices that were not approved; (3) requests that were parallel applications for additional patents on devices that were already represented in the dataset; (4) requests stemming from approval of supplements to already

90% of medical device approvals that would in theory allow extension of a patent do not result in a request for an extension. And although the share of approvals resulting in a request has been increasing in recent years, in no single year has it ever exceeded 26 percent.

This stands in stark contrast to the patent term restoration for new drugs; the overwhelming majority of eligible drug approvals—likely at least 75 percent—*do* result in a patent term restoration request.[87] There are at least three possible explanations for the missing patent term restoration requests. *First*, for some of the remaining PMAs, perhaps there were no patents to extend: no patents claiming the device, a method of using the device, or a method of manufacturing the device. *Second*, for some perhaps there were patents to extend, but at the time of FDA approval, the patent owner was not aware of the option to obtain patent term restoration. *Third*, for the rest, perhaps there were patents to extend, but the patent owner chose not to seek an extension. We explore these first two explanations in the next part and the third in part IV.

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approved PMAs, and: (5) a second request relating to a device that was filed by a different, ineligible, patent holder. This left us with 149 PMAs that were the basis of patent term restoration requests. For the denominator (number of original PMAs approved during the window), we searched the FDA's database of PMA approvals by decision date.

[87] Every medical device subject to PMA approval is eligible for patent term extension, which made it easy to calculate the number of missing medical devices. It would be harder to calculate the corresponding number for new drugs, because the eligible new drugs are a subset of those approved via new drug application. An approved new drug is eligible only if the FDA has not previously approved the active ingredient (or its salt or ester) pursuant to another new drug application; the PTO's interpretation of this language has evolved over time (and been the subject of litigation); and there is sometimes disagreement about the identity of a drug's active ingredient. *See* Lietzan & Acri née Lybecker, *Distorted Drug Patents*, *supra* note 4, at 1334 n.87. That said, most NDAs that earn "new chemical entity" exclusivity are likely eligible for patent term extension, which provides a reasonable basis for a prediction. One of us (Lietzan) identified all new drug applications approved in the first eleven months of 2009 (picked randomly) with this exclusivity (n=22) and determined that of these, 18 (82%) were the subject of patent term extension requests. The other four—which contained benzyl alcohol (1); capsaicin (1); and pancrelipase (2)—may not have been eligible for extensions in the first place. Our estimate in the text that at least 75 percent of the eligible new drug applications are associated with patent term extension applications is conservative. The true percentage is likely much higher.

III. DISCUSSION

A. Explanation One: No Patents

One possibility is that some devices lacked any patent to be restored. The extent to which this is true is an empirical question that we did not try to answer. That said, we gathered information about the full set of PMAs approved by the FDA during the study window.[88] The full set of approved PMAs looks somewhat different from the subset of 102 devices for which patents were extended. Table 4 compares the devices for which patents were restored with the full set of PMAs approved during the same period.

Two disparities are striking. *First*, cardiovascular devices are disproportionately represented in the group with extended patents: 43.14 percent of the approved devices with restored patents, compared with 30.42 percent in the larger population. *Second*, devices relating to hematology, pathology, immunology, microbiology, and molecular genetics together comprise nearly 19.81 percent of the approved PMAs, but only 3 percent of the devices with restored patents. These are *in vitro* diagnostic devices and related products, i.e., devices used in the laboratory to diagnose diseases and other conditions, as well as devices used to detect genetic mutations. They include, for instance, 42 hepatitis B tests, 24 HIV tests, six test kits for detecting alpha-fetoprotein (in indicator of neural tube defects in the embryo), and six human papillomavirus DNA tests. Companies obtaining approval of diagnostic tests, in other words, generally do not seek patent term restoration.

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[88] For each PMA, we gathered the generic name (e.g., "replacement heart valve"), the product code assigned by the FDA, the field of medicine, the name of the company that received initial FDA approval, and the name of the company that currently holds the approved PMA. We retrieved this information by looking up the PMAs by their numbers in the FDA's Premarket Approvals database. *See* FDA, PREMARKET APPROVALS DATABASE, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm [https://perma.cc/CC8R-CBRS].

Table 4 **PMAs by Field of Medicine**		
Field of Medicine	**Devices with PMAs That Received PTR**	**All Approved PMAs (That We Could Classify)**
Anesthesiology	3 (2.94%)	11 (0.97%)
Cardiovascular	44 (43.14%)	344 (30.42%)
Clinical chemistry and toxicology	1 (1%)	27 (2.38%)
Dental	1 (1%)	13 (1.15%)
Ear nose & throat	0	16 (1.41%)
Gastroenterology and urology	8 (7.84%)	61 (5.39%)
General and plastic surgery	10 (9.80%)	73 (6.45%)
General hospital and personal use	0	16 (1.41%)
Hematology and pathology	2 (2%)	47 (4.16%)
Immunology and microbiology	1 (1%)	169 (14.94%)
Molecular genetics	0	8 (0.71%)
Neurology	5 (5%)	29 (2.56%)
Obstetrics and gynecology	1 (1%)	38 (3.36%)
Ophthalmology	12 (12%)	150 (13.26%)
Orthopedic	11 (11%)	88 (7.78%)
Physical medicine	0	2 (0.18%)
Radiology	3 (3%)	39 (3.44%)
Total	**102 (100%)**	**1131 (100%)**[89]

[89] We were unable to classify 21 devices.

Nearly 20 percent of the missing devices are *in vitro* diagnostics, and recent cases raise questions about the availability of robust patent protection for this type of invention.[90] It is possible some of these devices were not associated with patents (either because the inventor did not bother seeking a patent or because the patent was rejected). Again, though, we did not investigate whether any of the missing devices was covered by a patent that could have been extended.

In addition, there are reasons to suspect that this explanation—the absence of any patent to extend—would not be generally true of preapproved medical devices, which include devices in a range of fields of medicine.

First, studies have shown that the number of medical device patents has been growing steadily since the 1970s. One study found a nearly fifty percent increase in the number of medical device patent filings from 2007 to 2018.[91] Another reported that the USPTO issued more than 17,000 medical device patents in 2015, nearly three times the number it issued ten years earlier.[92] That said, these reports

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[90] *See, e.g.*, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 77, 80 (2012) (finding unpatentable processes for determining the appropriate dosage of thiopurine for patients based on measuring its metabolite in their drug, which was the basis for diagnostic tests purchased and used by Mayo).

[91] KILPATRICK TOWNSEND, INDUSTRY-FOCUSED PATENTING TRENDS 71–72 (2019) (reporting an upward trend in medical device patenting from 2007 (22,382 filings) to 2018 (33,405 filings) and concluding that innovation and patent filings were "on the rise" in the medical device industry).

[92] Brenda M. Simon, *Patents, Information, and Innovation*, 85 BROOK. L. REV. 729, 750 (2020) (reporting that the PTO granted 6,603 medical device patents in 2005 and 17,596 medical device patents in 2015). Earlier studies noted the beginnings of this trend. *See, e.g.*, OFFICE OF TECHNOLOGY ASSESSMENT OF THE U.S. CONGRESS, FEDERAL POLICIES AND THE MEDICAL DEVICES INDUSTRY, 31 (1984) [hereinafter "OTA REPORT"] (noting that the number of device patents grew modestly through the 1970s while the total number of patents remained essentially constant; further, from 1968 to 1979, "almost 22,000 applications were filed for medical device patents that were subsequently issued, representing 2 percent of all patents"); Susan Bartlett Foote, *The Impact of Public Policy on Medical Device Innovation: A Case of Polyintervention*, *in* THE CHANGING ECONOMICS OF MEDICAL TECHNOLOGY 69, 70–71 (Annetine C. Gelijns & Ethan A. Halm eds., 1991) (noting the total number of patents issued to device innovators had increased); Candace L. Littell, *Innovation in Medical Technology: Reading the Indicators*, 13 HEALTH AFFAIRS 226, 230 (1994) ("Since 1980 medical devices have been patented in the United States at an increasing rate, reaching a total of 4,871 patents granted in 1993."); Aaron K. Chatterji, *Spawned with a Silver Spoon? Entrepreneurial Performance and Innovation in the*

of an increase in the number of patent filing and patents issued might reflect an increase in the number of medical devices rather than an increase in the percentage of devices for which patents are sought. Or they could reflect an increase in the number of patents sought for each medical device for which *any* are sought. Moreover, these studies did not focus exclusively on devices that went through premarket approval; the increased filings and patents could be associated with innovative devices that reach the market through other premarket pathways.[93]

Second, some recent studies show that most medical device companies hold patents and, indeed, that most hold multiple patents. Professor Stuart Graham and colleagues found, in a 2008 survey of more than 1000 U.S.-based startup companies, including medical device and biotechnology companies, that 76% of the surveyed medical device startup companies held patents and that they held, on average, 15 patents.[94] More recently, Professor Brenda Simon's examination of publicly available information about acquisitions of smaller medical device companies by the three largest medical device companies from June 2012 to July 2018 revealed that the vast majority of targets held at least one issued patent before acquisition.[95] Although these studies focused on small start-up medical device companies, we also know that the larger device companies in fact hold most of the issued device patents.[96]

As a result, although some approved devices for which no patent term restoration application was filed may have lacked patent

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Medical Device Industry, 30 STRATEGIC MGMT. J. 185, 189 (2009) ("[P]atenting is crucial in the medical device industry with over 9,000 patents issued by 2003.").

93 *See, e.g.*, Zachary E. Shapiro et al., *Nothing Generic About It: Promoting Therapeutic Access by Overcoming Regulatory and Legal Barriers to a Robust Generic Medical Device Market*, 98 N.C.L. REV. 595, 598 (2020) ("Patented devices make up a substantial portion of the U.S. medical device market.").

94 Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1277 tbl.1 (2009).

95 Simon, *supra* note 92, at 761.

96 On the basis of patent applications filed through 2018, Kilpatrick Townsend reported that the "top 5 patent holders" in the medical device technology field are Boston Scientific, Covidien, Medtronic, Olympus Corporation, and Philips—all large companies. KILPATRICK TOWNSEND, *supra* note 91, at 6.

protection, we think it unlikely this explains all of the missing patent term restoration requests.

B. Explanation Two: No Knowledge

A second possibility is that the inventors, and the associated companies that obtain premarket approval, are largely unaware of patent term restoration. Conventional wisdom holds that breakthrough medical device innovation stems mainly from individual inventors and small (start-up) companies.[97] Inventions emerge from user innovators in the clinic, for instance, and from academic medical centers or university innovation incubators.[98] Physician (user) entrepreneurs invent technologies to solve problems they encounter and remain in the lead through patenting and prototype development, after which the process spins off a start-up company.[99]

Most device companies are on the smaller side, and most medical device approvals are held by smaller firms. An industry-sponsored survey in 2010 reported, for instance, that more than 80

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[97] Simon, *supra* note 92, at 733 ("Truly groundbreaking medical devices often originate with small companies."); Chatterji, *supra* note 92, at 189 ("With industry giants like Medtronic and Johnson & Johnson largely focusing on incremental innovations to their existing products, disruptive innovation has been largely left to physician-entrepreneurs . . . former employees of industry incumbents . . . serial entrepreneurs who found multiple companies, and individuals from outside the industry who develop promising ideas.").

[98] *See supra* Part III(B); *see also* Kaplan, *supra* note 39, at 3069 ("A small percentage of device ideas are conceived in academic medical centers using federal or other grant funding. Few academic centers have the intrinsic capabilities to develop the device beyond the early prototype stage. Intellectual property is typically out-licensed to an existing company or startup for further development."); Chatterji, *supra* note 92, at 189 ("Furthermore, academic research is a key component of product development. In many cases, advances in the academic literature spur product development and company formation.").

[99] *See* Aaron K. Chatterji et al., *Physician-Industry Cooperation in the Medical Device Industry*, 27 HEALTH AFFS. 1532, 1532 (2008) (finding that innovative activity by physician users accounted for almost 20 percent of the approximately 26,000 medical device patent applications filed from 1990 to 1996); *id.* at 1533 (explaining that clinicians are well positioned to engage in medical device innovation, because they know the most about unmet needs and feasible solutions); Kaplan, *supra* note 39, at 3069 ("Few academic centers have the intrinsic capabilities to develop the device beyond the early prototype stage. Intellectual property is typically out-licensed to an existing company or startup for further development.").

percent of medical device companies have fewer than 50 employees.[100] These "start-up" companies, it added, "are the engine that fuels the development of innovative new devices."[101] The primary trade association for the medical device industry today, AdvaMed, reports 6500 companies, "which are mostly small- and medium-sized enterprises," most with "fewer than 100 employees."[102] The predominance of entrepreneurial inventors and start-up companies has been well documented since the beginning of the modern medical device age.[103]

Although device inventors and entrepreneurial small firms pursue patent protection, they are less likely to have experience developing commercial products and they may have never interacted with the FDA before, let alone pursued premarket approval. They may simply be unaware that the Patent Act offers an extension for patents claiming medical devices subject to premarket approval. We did not investigate this possibility, but we did find that the 57 denied requests for patent term extension included 17 that had been filed for moderate risk devices that were "cleared" by the FDA; these are not "approved" by the FDA and are not eligible for patent term

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100 MAKOWER, *supra* note 49, at 12.

101 *Id.*; *see also* Kaplan, *supra* note 39, at 3068 ("Although large medical device companies typically develop successive iterations of existing devices, most new device categories are typically developed by venture-backed start-up companies.").

102 *Medical Device Industry Facts*, ADVAMED, https://www.advamed.org/medical-device-industry-facts/ [https://perma.cc/TL3D-NP6S]. The medical device industry has always been predominantly small companies. *See, e.g.*, OTA REPORT, *supra* note 92, at 17 ("[M]ore than in many other U.S. industries, small firms are particularly important in developing and producing medical devices."); Gelijns & Halm, *supra* note 92, at 8 ("The device industry is younger, less concentrated, and comprises mostly smaller firms."); Foote, *supra* note 92, at 73 (estimating that 7,000 medical device firms together produced over 1,700 different types of devices, with the firms themselves ranging from "single product firms" to "giants in computers and electronics" to "billion-dollar pharmaceutical firms"); Simon, *supra* note 92 (citing a 2014 study).

103 *See, e.g.*, Alan Kahn, *The Dynamics of Medical Device Innovation: An Innovator's Perspective, in* THE CHANGING ECONOMICS OF MEDICAL TECHNOLOGY 89, 91 (Geljins & Halm, eds., 1991) (noting in 1991 that with some exceptions such as the medical imaging area, in which new devices are costly and complex, larger companies generally do not develop and introduce truly innovative medical devices); Adam Lewin, *Medical Device Innovation in America: Tensions Between Food and Drug Law and Patent Law*, 26 HARV. J.L. & TECH. 403, 414 (2012) ("[S]mall, venture-backed startups often drive innovation in the industry.").

extension. These requests for patent term extension suggest some confusion about the scheme.

We were unable to determine the initial PMA holder, i.e., the company that obtained initially obtained approval from the FDA, for more than one third of the PMAs in the full dataset. The FDA approval letters were not posted on the agency website. We are not, therefore, in a position to determine whether larger and perhaps more experienced companies are disproportionately represented in the subset that seeks patent term restoration, though this would be a useful analysis to perform. Larger companies do seem represented among the remaining 735 observations in the dataset; for instance, Medtronic (and related companies) held 48 approvals, Abbott (and related companies) held 36, and Boston Scientific held another 24. But there also seem to be several hundred companies that hold one or two PMAs at most, at least *suggesting* the possibility that inexperience could play a role.

IV. EXPLANATION THREE: NO INTEREST

The most interesting explanation for the missing patent term restoration requests, however, is the possibility that FDA approvals were held by medical device innovators that elected not to seek patent term extension. Perhaps for these firms the benefit of patent extension was not worth the cost incurred in preparing the submissions. This could be because very few days would be added to the patent term; some reports suggest that most premarket testing of medical devices is nonclinical (bench testing) rather than clinical (in humans), and patent life lost to nonclinical testing is not restored.[104] Or, more intriguingly, it could be because additional days at the *end* of the patent term are worth less than the current and near-term days of patent life. In this Part, we explain why this might be true. In brief, the additional days at the end may have reduced value because the

[104] *See, e.g.*, Makower, *supra* note 49, at 29–30 figs.8, 11 (finding that more than 55 months on average are spent on concept development, proof of concept, and clinical unit development, before clinical trials, which take 40 months on average); Kaplan, *supra* note 39, at 3069 (estimating two to three years for preclinical testing and another three to six months securing permission for clinical trials, as compared to one to two years of clinical trials and up to one year of follow up).

device regulatory paradigm favors second-in-class alternatives while the drug paradigm favors exact copies, and patent protection in the immediate term may be of critical importance to the small and inexperienced start-up companies who drive disruptive device innovation and then seek investors, collaborators, and purchasers.

As to the first point: devices are sorted within the regulatory framework (for purposes of determining the requirements that apply both before and after market entry) by what they do, not by what they are composed of. And the device regulatory framework does not offer any advantages to companies that make exact copies. If anything, it privileges the second entrant who does not have to explain a new technology to FDA staff. As a result, the most important moment in the lifecycle of a preapproved medical device may be the moment a competitor designs an alternative device that accomplishes the same end result. That device, which may not infringe any patents held by the first company, may also enjoy a second mover *advantage* now that the agency has experience with the first mover's technology. By way of contrast, for drug innovators the critical lifecycle moment is usually no earlier than expiry of the active ingredient patent and can be even later. This happens later in time than the moment a device innovator's competitors figure out how to make a competing device without infringing its patents, and it can be pushed even later with patent term restoration. This makes patent term restoration vital for drug innovators.

A. Regulatory Design and the End of the Patent Term

The new drug approval paradigm is straightforward and well understood. In essence, any compound intended to prevent, treat, or cure disease (or intended to affect the structure or function of the body) that is not generally recognized as safe and effective is deemed a "new drug" and requires premarket approval of a new drug application.[105] New drug applications have been required since 1938, and new drugs have been subject to preapproval for more than

[105] 21 U.S.C. §§ 321(p), 355(a) (identifying the definition of new drug, and requirement of an approved new drug application, respectively).

sixty years.[106] Each application must show the drug is safe and effective and, in particular, must contain substantial evidence of effectiveness from trials in humans (presumptively, two randomized, controlled, blinded clinical trials).[107] Although the premarket research and development process varies in length and difficulty, and the outcome is highly uncertain, every new drug goes through essentially the same type of premarket research and development program, and although the FDA exercises some flexibility in practice every new drug is subject to the same approval standard.[108] And as a conceptual category, drugs do not vary all that much; they vary in their route of administration—for instance, some are ingested, some are injected, and some are applied topically—but they all achieve their purposes in the human body through chemical action or metabolism. Some companies are smaller and newer, especially those developing new drugs through biotechnology, but it is impossible to take a compound through the new drug testing and approval process without substantial resources, and thus much of the industry comprises sophisticated large companies with histories tracing to the early 20th or even late 19th century.[109]

The device paradigm, which is newer and continues to evolve, contrasts with this straightforward and predictable paradigm in three fundamental ways. First, the category that comprises "devices" itself is wildly heterogeneous, leading to a regulatory paradigm that varies almost as much. Second, although the premarket pathway and requirements depend on the riskiness of the device type, devices are sorted for regulatory purposes based mostly on what they *do*, from a clinical perspective. Third, there is no paradigmatic approach to premarket research and development for a new medical device, and a medical device innovator may face considerable uncertainty about even the basic question whether premarket approval will be required, not to mention the data requirements. We elaborate further below, and in the next subsection we explain the implications.

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106 Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 201(p), 52 Stat. 1040, 1041–42 (1938); Drug Amendments of 1962, Pub. L. No. 87-781, §§ 505, 103, 76 Stat. 780, 783 (1962).

107 21 U.S.C. § 355(d) (requiring and defining "substantial evidence").

108 Federal Food, Drug, and Cosmetic Act § 201(p).

109 *See generally* Lietzan, *Innovation Paradox*, *supra* note 26.

1. Heterogeneity and Taxonomy Based on Medical Function

The Federal Food, Drug, and Cosmetic Act of June 1938 gave the FDA regulatory authority over "devices" for the first time.[110] For this purpose, a device was any instrument, apparatus, or contrivance intended either (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or (2) to affect the structure or any function of the body.[111] In 1938, this would have included stethoscopes and scalpels, as well as ultraviolet lights, orthopedic shoes, surgical instruments, and prosthetic devices, among other things.[112] Then, as now, any other item intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease was considered a "drug," as was any other item (other than food) intended to affect the structure or any function of the body.[113] The definition of "device" has evolved since, most importantly with the caveat that a device does not achieve its primary intended purposes through chemical action or metabolism in the body. But this basic approach—a list of article types (which now includes a catch-all "or other similar or related article") plus certain intended uses—has not changed.

The 1938 statute did not give the FDA authority to review medical devices before they were marketed, as it did new drugs at the time. Nor did the 1962 statute, which created the modern new drug preapproval framework.[114] Premarket review of medical devices was not enacted until the late 1970s, by which time the device landscape had evolved considerably. More sophisticated devices had come along in the 1950s and 1960s, with advances in electronics, plastics, and engineering.[115] By the time the policymaking process

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110 Federal Food, Drug, and Cosmetic Act, § 201(h).

111 *Id.*

112 Larry R. Pilot, *Remarks on Medical Devices*, 25 FOOD DRUG COSM. L.J. 266, 467 (1970); *Hearing on the Implementation of the Food and Drug Modernization Act of 1997 Before the Subcomm. on Health & Env't of the Comm. on Commerce, H.R.*, 105th Cong. 10 (1997) (prepared statement of Michael Friedman, Lead Deputy Commissioner, Food and Drug Administration).

113 Federal Food, Drug, and Cosmetic Act, § 201(g).

114 Drug Amendments of 1962, Pub. L. No. 87-781, § 103, 76 Stat. 780, 782 (1962).

115 Friedman, *supra* note 112, at 10. The National Aeronautics and Space Administration (NASA) and Department of Defense (DoD) poured resources into medical device innovation during these decades, and NIH funded much of the basic science. Foote, *supra* note 92, at 75 (noting the "heyday" of medical device innovation in the 1950s and early 1960s); *see also* Bruce J. Hillman, *Government Health Policy and the Diffusion of New*

completed, the market included a wide range of high-risk devices, such as artificial heart valves, cardiac pacemakers, intrauterine contraceptive devices, prosthetic and orthopedic implants, cardiac defibrillators, incubators, plastic tracheotomy tubes, and valves on emergency oxygen respirators.[116]

Medical devices have in common only the fact that they are made by humans, intended for medical purposes, and neither metabolized nor dependent on chemical action.[117] The definition is broad enough to capture the toothbrush, a bandage for a paper cut, a condom, a dentist's drill, the dentist's chair, a hip implant, the equipment used to perform the surgery that implants the hip implant, hospital gowns, chemical reagents used by laboratories that test tissue samples, splints, crutches, systems for measuring compounds (such as cholesterol) in blood, and clips for aneurysms. A mobile x-ray system, a nuclear whole body scanner, an electric heating pad, and a pen for writing on a patient's skin are all devices, but they are more dissimilar than similar. Devices are made of different things, and they work in differing ways; some are simple to design, make, and use, and cheap to produce and purchase, while others are sophisticated and complex, took years to develop, and are expensive to manufacture, purchase, and operate. The risks that these differing devices present to patients vary, and how one would establish their safety and effectiveness—the testing that one could do, and the testing that might need to be done—varies as much as the device types themselves.

The sheer diversity of products fitting the definition of "medical device"—from the toothbrush to the heart valve—led policymakers away from a simple "new device approval" paradigm that replicated the new drug approval paradigm. Instead, a committee convened by

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Medical Devices, 21 HEALTH SERVS. RSCH. 681, 681–82 (1986) (describing significant pace of medical technology development from the end of World War Two through the mid-1980s).

116 OTA REPORT, *supra* note 92, at 97–98; Pilot, *supra* note 112, at 467; David A. Kessler et al., *The Federal Regulation of Medical Devices*, 317 NEW ENG. J. MED. 357, 357 (1987) ("Spurred by the increased technological complexity of devices and mounting disclosures of shortcomings involving pacemakers, intrauterine devices, and intraocular lenses, Congress enacted the comprehensive Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act.").

117 21 U.S.C. § 321(h).

the Department of Health, Education, and Welfare recommended classifying devices according to their level of risk, with some subject to premarket review, some subject to tailored safety and performance standards, and some exempt from standards and premarket review.[118] Although classification and risk-based regulation would be a new approach for the FDA to implement, the committee noted the "variety of medical devices already in use," produced from "an equally wide variety of materials," with scientific support ranging "from almost pure empiricism to reasonably well systematized information."[119] It concluded that "a new regulatory plan . . . specifically adapted to the needs of devices" was needed.[120]

Congress embraced the recommendation, creating a regulatory paradigm that tailors both premarket requirements and subsequent government oversight to the risk associated with each device type. The types, in turn, are functional categories; devices are sorted by *what they do* (as a medical matter), not what they are. For example, the general field of cardiovascular devices comprises five subfields, such as cardiovascular *monitoring* devices, on the one hand, and cardiovascular *surgical* devices, on the other hand. The regulation for each device type also identifies the type by describing what it *does*. A cardiopulmonary bypass defoamer, for instance, "is a device used in conjunction with an oxygenator during cardiopulmonary bypass

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[118] David M. Link, *Current Medical Device Regulation Activities*, 27 FOOD DRUG COSM. L.J. 552, 552–53 (1972); Joseph R. Radzius, *Medical Devices and Judicial Legislation*, 27 FOOD DRUG COSM. L.J. 639, 640 (1972); OTA REPORT, *supra* note 92, at 98; *see also* STUDY GROUP ON MEDICAL DEVICES, MEDICAL DEVICES: A LEGISLATIVE PLAN 11 (Sept. 1970) [hereinafter COOPER REPORT] ("The Secretary should promptly enlist the assistance of appropriate organizations to: a) complete an inventory and review of medical devices on the market and b) undertake an initial classification of devices to identify: A. Those that can be exempt from standards or pre-clearance; B. Those for which adequate existing standards or data permit certification of old or establishment of new safety and performance standards, together with compliance tests for design, manufacture, installation, and operation; C. Those devices that should be made subject to performance review prior to clinical application and marketing because the data do not yet permit development of standards.").

[119] COOPER REPORT, *supra* note 118, at 10.

[120] *Id.* Others shared this view. Bills introduced before the Cooper Committee released its report had already suggested that differing levels of regulation would be appropriate. *See, e.g.*, Medical Device Safety Act of 1967, H.R. 10726, 90th Cong. (1967); 113 CONG. REC. 15228-29, 15233 (describing this act as dividing medical devices into three classes, one of which would going through premarket review).

surgery to remove gas bubbles from the blood."[121] The actual devices (products) that fall under a particular regulation may vary considerably in their technological characteristics and the wording of their indications for use.

The FDA classifies each device type based on the risk it presents.[122] For instance, a device (type) falls in class I if the "general controls" of the FDCA suffice to provide a "reasonable assurance" of the device's safety and effectiveness.[123] The general controls are the basic federal regulatory requirements that apply across the board to devices, such as the prohibitions on misbranding and adulteration and the obligation to comply with current good manufacturing practices unless exempt.[124] Low risk device types include enema kits, non-electric wheelchairs, manual stethoscopes, and bedpans.[125] A device (type) falls in Class II if the general controls are not enough but "special controls" will, when added, provide the required assurance of safety and effectiveness.[126] Special controls could mean performance standards, postmarket surveillance requirements, or even a request for clinical data before market entry.[127] Examples of moderate risk device types include powered wheelchairs, acupuncture needles, blood pressure cuffs, and soft contact lenses.[128] Finally, a device (type) falls in Class III if general controls and special controls are insufficient, and it is "purported or represented to be 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 it

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121 21 C.F.R. § 870.4230(a) (2021).

122 *Classify Your Medical Device*, FDA (Feb. 7, 2020), https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device [https://perma.cc/RK6E-UE2A]; *Regulatory Controls*, FDA (Mar. 27, 2018), https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls [https://perma.cc/YS7N-DMYW].

123 21 U.S.C. § 360c(a)(1)(A)(i).

124 *Id.* (citing 21 U.S.C. §§ 351, 352 (adulteration, including good manufacturing practice requirement, misbranding, respectively)).

125 21 C.F.R. §§ 876.5210, 890.3850, 870.1875, 880.6800 (enema kit, mechanical wheelchair, manual stethoscope, bedpan, respectively).

126 21 U.S.C. § 360c(a)(1)(B).

127 *Id.*

128 21 C.F.R. §§ 890.3860, 880.5580, 870.1120, 886.5925 (powered wheelchair, acupuncture needle, blood pressure cuff, soft contact lens for daily wear, respectively).

"presents a potential unreasonable risk of illness or injury."[129] Examples include implantable pacemakers, breast implants, coronary stents, knee prostheses, and replacement heart valves.[130]

2. Uncertainty About Pathway and Burden

Broadly speaking, as Congress intended, premarket requirements and subsequent oversight depend on the risk a device (type) presents. But reality is more complex than this. A company that plans to develop a new drug understands from the outset what lies ahead: that it must follow a well-established iterative process of testing that new drug for safety and effectiveness, culminating in pivotal trials that establish the drug's effectiveness in achieving a recognized clinical outcome, and followed by a new drug application. A device inventor, by way of contrast, faces uncertainty about the class into which its device falls, the premarket pathway that will then apply, and the data (if any) that the FDA will require to support market entry.[131]

Some medical devices are exempt from premarket review altogether; the companies introducing these devices must register their facilities with the FDA and list the marketed devices with the agency, but they do not make premarket submissions.[132] Other pathways to market involve premarket submissions to the FDA and, in many cases, premarket clinical testing. The possible premarket submissions are the premarket approval application (PMA) and its variations,[133] the modular PMA[134] and the product development protocol (PDP);[135] the humanitarian device exemption (HDE), which

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129 21 U.S.C. § 360c(a)(1)(C).

130 21 C.F.R. §§ 870.3610, 878.3540, 888.3480, 870.3925 (implantable pacemaker, silicone gel breast implant, knee prosthesis, replacement heart valve).

131 The uncertainty faced by device innovators is well established in the literature. *See, e.g.*, Mitchell W. Krucoff et al., *Medical Device Innovation: Prospective Solutions for an Ecosystem in Crisis*, 5 JACC 790, 790 (2012) (discussing barriers facing device innovation: constrained financial resources, rising research costs, concerns with the predictability of regulatory process).

132 21 C.F.R. § 880.5075 (elastic bandage).

133 21 U.S.C. § 360e(c).

134 *Id*.

135 21 U.S.C. § 360c(f).

contains safety data but not necessarily effectiveness data;[136] the premarket notification, or 510(k) notification, which might contain some safety and effectiveness data;[137] and the *de novo* classification petition, which may contain as much testing information as a PMA.[138]

A company developing a device of a type that has already been placed, by regulation, in Class III—say, a heart valve—understands that its product requires premarket approval, and it can examine precedents to understand the data expected. But the regulations were drafted to classify devices on the market before 1976, and a novel device might not fall within one. (Of the 102 approved devices in our PMA dataset, 84 (82%) did not fall within a preexisting regulation.) Even if a regulation seems to apply and classify a company's device type, the pathway to market for any *particular* device (product) depends also on the features of the device itself as well as on the other devices in the market. As a result some low and moderate risk devices can, surprisingly, require premarket approval.

The result is uncertainty, which creates risks that deter investment. Consider the perspective of a small firm, perhaps a start-up founded by a clinical entrepreneur. To classify its proposed device, it might begin by identifying a similar device on the market, i.e., one that is similar in intended use and technology, and determining how that device reached the market.[139] The company would then verify that the device description in the governing regulation seemed applicable to its own device. This would allow it to draw a preliminary conclusion about the class and premarket pathway applicable to its device.[140]

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136 21 U.S.C. § 360(j)(m).

137 21 U.S.C. § 360(k).

138 21 U.S.C. § 360c(f)(2).

139 The FDA's website includes separate databases identifying all devices cleared through the 510(k) process, all devices approved through the PMA process, and all devices that reached the market under de novo classification orders. These databases would allow the company to identify that (similar) device's classification name and classification regulation.

140 This is not the only way to start; another approach would be to review the classification regulations directly to find a device type (based on the description) that seems applicable. Then one could search a different FDA database by the regulation number (or the product code) to find all medical devices associated with that regulation or code.

But a conclusion reached at this stage would be preliminary. If the regulation suggested the company's device might be exempt from premarket notification, for instance, the company would be required to find a suitable predicate, such as an exempt device with the same intended use, operating with the same fundamental scientific technology.[141] Even if the device type is exempt, a premarket notification will be required if the particular device is for a new intended use, as compared to legally marketed devices of that type, or operates using a different fundamental scientific technology than legally marketed devices of that type. The company must find a suitable device on the market to confirm that its own device is exempt. And if the company cannot find a predicate that works, its device will not be exempt; instead, the device would be placed in Class III and require premarket approval.

If instead the regulation suggested the device required premarket notification, the company would need to identify a marketed device to cite in its submission. The essence of the premarket notification is a showing of "substantial equivalence" to another device, lawfully on the market, that itself did not need premarket approval.[142] Substantial equivalence is a term of art and a tricky standard; it does not mean identity (sameness), and in fact substantial differences, e.g., competitively important differences and differences reflecting patentable innovations, are possible. To be substantially equivalent, two devices must have the same intended use.[143] This is *not* the same as having the same indication; the devices can have differing indications.[144] Differing technological characteristics are also permitted, so long as the new device does not raise a different *type* of safety or

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[141] Each subpart of the agency's classification regulations includes a regulation stating that any exemption listed for a particular generic device type applies to a new product so long as the new product has "existing or reasonable foreseeable characteristics of commercially distributed devices within that generic type." *E.g.*, 21 C.F.R. § 876.9.

[142] 21 U.S.C. § 360c(i).

[143] *Id.*

[144] The "intended use" is the "general purpose of the device or its function." FDA, THE 510(K) PROGRAM: EVALUATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 16 (2014), https://www.fda.gov/media/82395/download [https://perma.cc/44R2-ZT7Y]. In contrast, a device's "indications for use" describe the "disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended." *Id.* The intended use includes its indications for use.

effectiveness issue, and so long as it is at least as safe and effective as the first device.[145] The flexibility inherent in this standard means the premarket notification process allows evolution and variation, but this complicates the task for a firm seeking to use this pathway and contributes to the uncertainty it faces.

If the company could not find a suitable predicate, or if it found it could not make a compelling comparison, the company's device would default into Class III and require premarket approval. Indeed, a company might think it had succeeded with the comparison, only to find that the FDA disagreed, similarly leading to Class III status and a premarket approval requirement. In this case, the company has another option if it believes the device is truly moderate or low risk. It can, at its option, instead file a *de novo* classification petition.[146]

The goal of a *de novo* petition is to persuade the FDA that Class III status is not warranted. The petition is therefore a considerable undertaking and generally must be supported by extensive safety and effectiveness information. If the FDA grants the petition, the letter granting the petition is an order that licenses the petitioner to market its product immediately. The FDA also issues a classification regulation that defines the device type, classifies it (usually in Class II), and describes any applicable special controls. This means that subsequent manufacturers of devices of that type may file premarket notifications themselves.[147] In other words, a device marketed on the basis of a reclassification petition may serve as the predicate for another manufacturer's 510(k) notification.

If the regulation itself indicated the type of device is Class III, the company will have to prepare a premarket approval application (PMA).[148] But the device premarket approval provisions contain no concept equivalent to the "substantial evidence" concept, which at least in theory imposes some uniformity on premarket clinical trial

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145 21 U.S.C. § 360c(i).

146 *Id.* § 360c(f)(2).

147 *Id.* § 360c(f)(2)(B)(i).

148 There is one exception: if the device type was marketed before 1976, and the agency has not yet called for PMAs. Only two Class III devices remain subject to this exception. *See* 21 C.F.R. §§ 864.4020, 864.9205. A company wanting to market a device falling in one of these regulations may file a premarket notification citing a predicate on the market to which its device is substantially equivalent.

design for new drugs. The statutory device provision is written only in general terms, and the variability of medical devices means there is no single well-understood paradigm to follow. The FDA's device regulations thus explain the range of "valid scientific evidence" that can be used to substantiate safety and effectiveness. Further, the agency adds, the evidence required to support approval "may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use."[149] Generally, the agency prefers well-controlled trials, but in some cases those might not be feasible or necessary.[150] In other cases approval may rely on partially controlled studies, on studies without controls, on case histories, and even on reports from marketed devices.[151] As a recent empirical study found, "the types of trials that can constitute a pivotal study for a new high-risk medical device are highly heterogeneous."[152] Moreover, some believe the agency has become less predictable and transparent in recent years about premarket testing requirements.[153]

Finally, device manufacturers face a risk that drug innovators do not: that a device's classification—and therefore its pathway to market—will shift under the firm's feet. A company could be in the middle of premarket clinical trials to support a PMA—trials that it has discussed with FDA staff, to support a PMA that it has also discussed with FDA staff—when the FDA reclassifies the device type, perhaps at the instigation of one of the company's competitors.[154] In

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[149] *Id.* § 860.7(c)(2).

[150] A controlled investigation might not be suitable—and as an ethical matter, a placebo-controlled trial would never be suitable—for an implantable device meant to sustain human life, for instance.

[151] *Id.* § 860.7.

[152] Stern, *supra* note 83, at 185; *see also* Darrow, *supra* note 42, at 425 (reporting a variety of designs for trials included in PMAs for cardiovascular devices approved from 2000 to 2007, of which for instance only 27% were randomized and 14% blinded); *id.* at 428 ("Even when a PMA is required, evidence requirements for device approval tend to be highly flexible.").

[153] *See, e.g.*, MAKOWER, *supra* note 49, at 11; *see also* Krucoff et al, *supra* note 131, at 790 (citing concerns in 2012 about rising research costs and the predictability of the research process).

[154] The FDA may reclassify an older device type using Section 513(e) at its own request or the request of a regulated company, and it may reclassify a newer device type using Section 513(f) at the request of a regulated company. *See* 21 C.F.R. § 860.130(b)(3).

this situation, its device would be "cleared," rather than "approved" pursuant to a PMA, despite its investment in premarket clinical trials, which its competitors would now not need to do. (This happened to one company in our dataset.)[155]

In sum, medical device innovators, as well as the investors who fund them, are plagued by uncertainty about the regulatory landscape in which they operate.[156] This stems from the complexity of the medical device regulatory framework and the fact that there is no single conventional pathway to market; there is no conventional (default) pathway of preclinical testing followed by three phases of clinical trials, the last satisfying a well-understood standard. It stems from the inherent heterogeneity of medical devices and the fact that a novel medical device type is more likely to be disruptive (especially from a regulatory perspective) than a new chemical entity. And the uncertainty may be exacerbated by the relative inexperience of most medical device companies. In other words, much of the time a device company will have no experience and will have invented something utterly new, it will not be clear even to a regulatory expert how the thing should be classified, and there will be no *ex ante* transparency about the premarket testing requirements because the FDA will not have thought them up yet.

3. The First Mover Disadvantage

The regulatory uncertainty for medical device innovators contributes to a first mover disadvantage. There are at least two reasons for this. First, the first firm to invent and develop a novel type of device needs to educate itself and agency medical and scientific staff

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155 Our dataset includes one patent term extension denial that resulted from the FDA's reclassification of a device two years after the company had started the clinical trials required for its PMA. The history can be pieced together by reviewing the patent term restoration application for U.S. Patent No. 4621638, which PTO dismissed, and PTO's rejection of the patent owner's petition for reconsideration, available in the Image File Wrapper. *See also* Reclassification and Codification of Nonabsorbable Poly (Ethylene Terephthalate) Surgical Suture, Nonabsorbable Polypropylene Surgical Suture, and Nonabsorbable Polyamide Surgical Suture 56 Fed. Reg. 24684 (May 31, 1991) (to be codified at C.F.R. § 878) (reclassifying ophthalmic suture into Class II).

156 *See also* Stern, *supra* note 83, at 185 ("[T]he lack of *ex ante* specificity about the design and execution of clinical trials is largely the result of product and delivery-method heterogeneity . . . .").

about the device and its operating principles. This can involve not only establishing that the device is safe and effective but also establishing how one would test its safety and effectiveness in the first place. Subsequent entrants have the advantage of working with agency personnel who are now familiar with the basic concept. Second, the first entrant may face more rigorous clinical testing requirements, as the FDA learns about the safety and effectiveness of the new technology.[157] The agency may reluctant to require testing from subsequent entrants that arguably replicates testing performed by the pioneer, and the flexibility of the device statute permits it to simply require a smaller data package. The statute now explicitly accommodates this evolution by allowing the FDA to rely on the data in one PMA to support approval of another, if six years have passed since the first device's approval.[158]

Recent empirical evidence confirms a first mover disadvantage with respect to the time that the PMA spends under review at the agency, and our dataset hints that this might be true for the length of clinical programs as well. Professor Stern's examination of PMA approvals from 1977 to 2007 found that pioneer entrant applications (meaning the first in a product code) spend 34% (7.2 months) longer than subsequent entrants under FDA review.[159] Further, he found, "approval time for subsequent entrants falls by approximately 40% (6.1 months) after application content and evaluation procedures are made explicit through formal guidance."[160] In our dataset of 102 medical devices that received patent term restoration, 40 devices were the first in their product code, and these averaged 1785 days in clinical testing, compared to the 1521 days for the entire dataset.

4. Lack of Regulatory Advantage for Infringing Products

Not only does the subsequent entrant in the product code have a regulatory advantage because the first entrant paid most of the cost of the uncertainty in the framework, but unlike a drug company's

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157 *See* Kaplan et al, *supra* note 39, at 3070 ("For first-in-class devices, [e.g.], drug-eluting stents, where there are few data regarding short- or long-term outcomes, FDA/CDRH requires prospective randomized controlled studies.").

158 *See* 21 U.S.C. § 360(j)(h)(4)(A)(i).

159 *See* Stern, *supra* note 83, at 189.

160 *See id.* at 183.

generic competitor, this second device company also has no particular regulatory incentive to make a perfect copy and thus, no particular reason to wait for patent expiry. The drug statute offers a significant incentive for an innovating drug company's competitor to practice the innovator's invention. It provides an alternative pathway to the market that is much faster and less expensive than the one inventors use. And it makes this pathway available if the competitor has copied the inventor's product closely enough that, as a scientific matter, the inventor's research can be understood to apply equally to the competitor's own product. In addition, the drug statute reinforces the very same patents by tying submission and approval of the competitor's application to patent expiry. The device regulatory scheme has none of this.

A drug containing a new chemical entity must be supported by a full marketing application containing extensive safety and effectiveness data.[161] The active ingredient is likely to be patented, and other aspects of the finished product may also be protected by patent. Later in time, other companies may file abbreviated applications that rely on these full applications and omit the testing data.[162] For instance, a conventional generic drug application, known as an "abbreviated new drug application" (ANDA), must propose a product with the same active ingredient, route of administration, dosage form, strength, and labeling as the corresponding brand product, and it must show that the two are "bioequivalent."[163] It may be possible to vary the route of administration, dosage form, and strength, but the product at the heart of an ANDA must have the same active ingredient.[164] On the basis of this showing, the generic applicant relies on the safety and effectiveness data in the first company's application. Indeed, it is this copying that, as a scientific matter, justifies reliance on the innovator's testing.

In a sense, though, the essence of a new drug product is its active ingredient. This is the component that furnishes the product's pharmacological effect, which in turn makes it a regulated drug in the

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161 21 U.S.C. § 355(a).

162 *See generally id.* § 355(j)(2)(A). Federal law provides a period of exclusivity for the drug innovator, before this reliance may occur. *See supra* note 14 and accompanying text.

163 *See* 21 U.S.C. § 355(j)(2)(A)(iv).

164 *Id.* § 355(j)(4).

first instance when combined with therapeutic claims.[165] This is the component largely responsible for the product's commercial value. A new formulation or other features can similarly make this formulated active ingredient a new drug subject to regulatory approval, and it can contribute profoundly to its commercial value, but the essence of a drug product is its active ingredient. And a utility patent on the active ingredient thus covers the essence of the regulated product.

Another company that copies this active ingredient for its own product has, then, appropriated the very essence of the innovator's product, i.e., the *value-conferring* invention in that product. And it necessarily practices the active ingredient patent held by the innovator. For this reason, the active ingredient patent, until it expires, excludes the most significant and robust competition the innovator will ever face: others marketing the same active ingredient for the same use. While other inventions embodied in the brand product may be important, and a competitor may need to wait for some or all of these to expire, or may choose to do so for competitive purposes, the competitor *cannot* use the ANDA pathway without using the very same active ingredient.[166] As a matter of regulatory design, expiry of this patent is necessary—though in some cases not sufficient—for a generic drug (one approved without its own safety and effectiveness data) to be marketed.

Indeed, the drug statute also ties approval of the competitor's drug to expiry of the inventor's patents, so that the regulatory framework reinforces the exclusivity-conferring properties of the patent. Each new drug applicant must identify the patents that claim its drug or a method of using its drug and with respect to which a claim of patent infringement could reasonably be asserted if another person manufactured, used, or sold the drug, without permission.[167] A

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165 21 C.F.R. § 314.3(b).

166 21 U.S.C. § 355(j)(2)(A)(i)–(iv). It is possible to make changes to the active ingredient and file an abbreviated application under a different provision of the FDCA—not the ANDA provision. *See id.* § 355(b)(2). Although this application could rely on the brand company's research, it would also need to contain safety and effectiveness data relating to the changes proposed by the competitor.

167 *See id.* § 355(b)(1).

generic applicant must then address these patents in its application.[168] In the case of an unexpired patent, the generic applicant has two choices. It can note the date that the patent will expire, in which case final approval of its drug may not take effect until the patent expires.[169] Or it can assert that the patent is invalid or will not be infringed by its product. In this case, if the patent owner (or brand company) brings suit within 45 days, final approval of the generic drug is stayed for thirty months.[170] Moreover, if a court finds the patent valid and infringed, it must order the effective date of final generic drug approval to be no sooner than patent expiry.[171]

The device framework has none of this. The device category does not have anything equivalent to the "active ingredient" that is the essence of every medical device; medical devices—the toothbrush and the MRI machine—are more unalike than they are alike. Although a device innovator may well own numerous patents, including a patent claiming the central invention embodied in its product, the regulatory framework does not offer any particular advantage to a company that seeks to market the very same invention. There is nothing comparable to the abbreviated application: the paradigm in which one company performs extensive foundational research (establishing safety and effectiveness) and subsequent entrants perform comparative studies (establishing a bridge to the first product).[172] Instead, within Class III, every applicant—whether first

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168 *See id.* § 355(j)(2)(A)(vii). With respect to a patent claiming a method of using the reference drug, a generic applicant may instead decline to seek approval of the use in question. *See id.* § 355(j)(2)(A)(viii).

169 *See id.* § 355(j)(5)(B)(ii).

170 *See id*. § 355(j)(2)(A)(vii)(III)-(IV). At the end of the thirty months, assuming the approval standard has been met, the FDA must approve the generic drug unless another generic applicant is eligible for 180-day exclusivity because it was the first to file a paragraph IV challenge to the innovator's patent(s). *See id.* § 355(j)(5)(B)(iv).

171 *See* 35 U.S.C. § 271(e)(4)(A). It may separately enjoin the generic applicant from commercial manufacture, sale, and use of the product. *Id.* § 271(e)(4)(B). The drug statute also states that FDA approval may not take effect until the date specified by the court. 21 U.S.C. § 355(j)(5)(B)(iii)(II)(bb); *see* also C.F.R. § 314.107(b)(3)(B)(iii)(A).

172 The closest equivalent to the paradigm of full applications followed by abbreviated applications occurs when one company submits a *de novo* classification petition, after which others may submit premarket clearances. But the theory is different in the device framework. The company submitting the premarket notification does not propose a copy in order to establish a bridge and rely on the first company's safety and effectiveness research.

or tenth in class—files a full PMA. There is some possibility of reliance on data in earlier applications, but the FDA's authority to rely on earlier submitted data is not tied to the second applicant's omission of testing data (as is the case for new drugs), nor is it tied to the second applicant's making a precise copy (as is the case for new drugs).

5. The Critical Moment: A Shorter Lifecycle

In the drug context, a generic applicant may enjoy the enormous commercial advantage of filing an abbreviated application *if* the applicant creates an exact copy of the innovator's drug. But if the patents are valid and infringed, the generic drug will not be approved until patent expiry. Once generic copies reach the market, they quickly take over the market.[173] This makes the length of the brand company's patents critical for the innovator. It also means expiry of the active ingredient patent is the most important moment in the innovative drug's lifecycle. Although the drug innovator may have other patents, the active ingredient patent imposes the first and most basic obstacle to approval of a generic drug, and the FDA statute ensures that a competitor hoping to market such a drug on the basis of an abbreviated application *must* wait for its expiry, if not also the expiry of other patents.

Again, though, devices are sorted within the regulatory framework (for purposes of determining the applicable rules) by their clinical function. And the FDA statute offers no particular advantage (comparable to an abbreviated application) to device companies that seek to make exact copies. The first mover disadvantage means that a second company seeking to market a device with the same basic function may benefit from the agency's new familiarity with the device concept. But nothing in the FDA statute or regulatory paradigm

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[173] *See, e.g.*, Henry Grabowski et al., *Recent Trends in Brand-Name and Generic Drug Competition*, 17 J. MED. ECON. 207, 213 (2014) (finding that the average brand new molecular entity product experiencing initial generic entry in 2011 and 2012 retained only 16% of the market after one year); Murray L. Aitken et al., *The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity* 250 (Nat'l Bureau of Econ. Rsch, Working Paper No. 19487, 2013) (finding that six drugs losing exclusivity between 2009 and 2013 lost 60% of their market share within, on average, three months of generic entry).

even nudges this subsequent applicant, the aspiring competitor, into making an exact copy. One might argue, not unreasonably, that a subsequent applicant may be able to avoid (design around) the *kinds* of patents that claim pioneer devices and thus present a "substitute" in the economic sense—an acceptable alternative for consumers that competes on the basis of price—before expiry of whatever patents the device pioneer *does* have. In simpler language, there can be more than one way to build an item that does the same thing.

As a result, the critical moment in the lifecycle of a new medical device may not be any particular patent expiry; it may be sooner, that is, as soon as a second company can design a non-infringing competing device and reach the market through the same pathway as the first company. And, indeed, conventional wisdom holds that Class III devices tend to become "obsolete" due to competing and sometimes better alternatives (generally other devices within the same "product code" at the FDA) within 18 to 24 months of market entry.[174] In his study, for instance, Professor Stern found that the first entrant into a product code "has an average of 3.8 years as the sole product with regulatory approval (before the second product is approved for market entry—that is, the pioneer can expect an average of 3.8 years of *de facto* market exclusivity)."[175] This period was shorter (2.8 years) for high risk cardiovascular devices.[176] This lifecycle is meaningfully shorter than the typical drug lifecycle; most new chemical entities enjoy 11 to 12 years before generic entry.[177]

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[174] *See, e.g.*, Simon, *supra* note 92, at 771 ("Typically, a new version replaces an existing medical device every eighteen to twenty-four months—resulting in a relatively short lifecycle compared with pharmaceuticals."); Gelijns & Halm, *supra* note 92, at 9 (noting that the product life of devices is shorter than that of drugs and that competitors rapidly introduce slightly modified versions); Kahn, *supra* note 103, at 93 ("The continuous product changes that devices undergo eventually render the product obsolete, often within 2 years or less. Device manufacturers must bring products to market more rapidly than drug manufacturers in order to keep up with this high rate of product obsolescence."); Chatterji, *supra* note 99, at 1533 (noting that the "leading medical device companies derive the majority of their revenues from products that are less than two years old, as a result of competition from fast imitators."); *id.* (citing a "lifecycle" of "about eighteen months").

[175] Stern, *supra* note 83, at 189.

[176] *Id.*

[177] *See, e.g.*, Erika Lietzan & Kristina M.L. Acri nee Lybecker, *Evidence Based Pharmaceutical Policymaking*, 33 FORDHAM INTELL. PROP. MEDIA & ENT. L. J.

B. A Role for the Medical Device Patent

The shorter commercial lifecycle leads some to suggest that patent protection is less important for medical device innovators than it is for drug innovators.[178] More accurately, though, the shorter commercial lifecycle for medical devices may make the final years and ultimate expiry date of device patents less important.[179] The

(forthcoming 2023) (manuscript at 39) (on file with author) (examining the 224 new drug applications for which the FDA has listed first generic launch dates on its website and finding an average of 11.3 years, with the new chemical entity subset averaging 13.34 years); Lietzan & Acri née Lybecker, *supra* note 4, at 1363 (finding a mean of 12.62 years and a median of 13.28 years for 227 new drugs that received an award of patent term restoration under § 156 between 1984 and 2018, using generic market launch dates purchased from IQVIA); Reed F. Beall et al., *Patent Term Restoration for Top-Selling Drugs in the United States*, 24 DRUG DISCOVERY TODAY 20, 20 (2019) (reporting average exclusivity in the market—time to generic market entry—as 13.75 years for eighty-three top-selling drugs, and identifying the quarter of generic market entry as the one in which a prescription for a therapeutically equivalent generic drug appeared in Medicaid prescription data aggregated by the Centers for Medicare and Medicaid data); Bo Wang et al., *Research Letter: Variations in Time of Market Exclusivity Among Top-Selling Prescription Drugs in the United States*, 175 JAMA INTERNAL MED. 635, 635–36 (2015) (finding median market exclusivity period of 12.5 years for the 175 drugs that experienced generic competition by the end of 2012, out of the 437 top-selling drugs by sales in the United States between 2000 and 2011, also using Medicaid prescription data as proof of generic competition); Henry Grabowski et al., *Updated Trends in US Brand-Name and Generic Drug Competition*, 19 J. MED. ECON. 836, 839 (2016) (finding that non-biologic drugs experiencing initial generic entry in 2011–2012 had enjoyed 12.9 years of actual exclusivity in the market, using IQVIA data to confirm generic launch); Henry Grabowski et al., *Continuing Trends in U.S. Brand Name and Generic Drug Competition*, 24 J. MED. ECON. 908, 908 (2021) (finding that new molecular entities experiencing initial generic entry in 2017-2019 had enjoyed 14.1 years of actual exclusivity in the market, and those with sales over $250 million in 2008 dollars the year before generic entry had enjoyed 13.0 years, using IQVIA data to confirm generic launch).

[178] *See, e.g.*, Halm & Gelijns, *supra* note 91, at 9 ("Because a device for a specific application often can be designed in a number of different ways, patents are less significant for device than for drug innovation."); Kahn, *supra* note 103, at 89 ("Drug patents tend to be more useful, for it is difficult to design a drug that simulates all the efficacies and side effects of another drug."); *id*. at 90 ("Patents appear to be of relatively less importance in many segments of the device industry" that is, "once a product is introduced, competition usually follows quickly."); Darrow, *supra* note 42, at 427 ("Patents and nonpatent exclusivities tend to be less important for devices than for drugs.").

[179] When combined with the first mover disadvantage, it could also explain the relatively high rate of incremental (rather than disruptive) innovation that is reported in the medical device field. *See, e.g.*, Halm & Gelijns, *supra* note 91, at 9 (noting "high level of incremental innovation"); Simon, *supra* note 92, at 751–52 ("Large companies engaging

critical moment in a novel medical device's commercial lifecycle—the effective loss of exclusivity in the market—occurs when a similar, but non-infringing, medical device enters the market. This, then, provides our third proposed explanation for the missing medical device patents in PTO's spreadsheet of patent term restoration requests: in many cases the end of the patent term may not be important. The loss of a device's patent protection ten years after FDA approval may not matter, if the device has already become obsolete in the market.[180]

And yet device inventors seek patents. Moreover, some whose devices are subject to preapproval also seek patent term restoration, suggesting that additional days at the end of the term sometimes have value—or at least that these additional days at the end of the term have value during the first sixty days after FDA approval, when the inventor must apply for patent term restoration. But many others—most—do not seek patent term restoration, suggesting the patent's value to these inventors derives from something other than the length of time during which it confers a right to exclude. As explained in this part, the value of the patent, to these inventors and perhaps to society, may derive from other properties of the patent.

Understanding this requires returning to the nature of device innovation and the role of individual user-inventors and academic clinicians in generating disruptive change. These entities will generally lack the resources or sophistication to navigate the FDA regulatory process, particularly if premarket approval on the basis of safety and effectiveness trials will be required.[181] A smaller company might plan to seek approval itself with the support of investors, or it might intend to partner with (or license to, or indeed simply sell to) a larger

in R&D often focus on making incremental improvements to devices already in existence, as opposed to discovering and developing new technologies.").

[180] *See, e.g.*, Simon, *supra* note 92, at 771 ("[A device] may become obsolete long before its underlying patent expires."). This hypothesis could be explored further by determining whether medical device patent owners are more or less likely to pay maintenance fees than other patent owners. We did determine that the companies who obtain patent term restoration for their medical devices generally pay maintenance fees until expiry—suggesting that the term continues to matter for these companies.

[181] *See e.g.*, Kahn, *supra* note 103, at 90 (noting that small entrepreneurial companies do the initial research and development, but larger companies buy and introduce the invention or their own modified version).

firm that will seek approval or continue development and introduce a modified version. In either case, a meaningful patent portfolio can play a significant role in furthering the goals of the small inventor.

The issuance and protection of patents can support activities that are crucial to medical device startups. In particular, the presence of a patent can improve the chances of securing investments. For at least some prospective investors, issued patents and pending patent applications communicate something about the value of the idea and, perhaps, the viability of the product.[182] Across fields of technology, the signaling role of patents to prospective investors—or at least venture capital investors—is well established.[183] Indeed, small device firms have confirmed that venture capital investors look to them for patents.[184]

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[182] *See, e.g.*, Simon, *supra* note 92, at 771; Kahn, *supra* note 103, at 90; Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 647–49 (2002) (discussing the signaling role of patents); Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA. L. REV. 1, 20–22 (2005); Timothy R. Holbrook, *The Expressive Impact of Patents*, 84 WASH. U. L. REV. 573, 573 (2006); *see also* Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 142–4 (2000) (noting that over 150,000 patents issue every year but the vast majority go "missing," i.e., are never enforced, and offering several reasons these patentees might nevertheless have invested in patent prosecution, e.g., as "financing tools" to attract "venture capitalists").

[183] *See, e.g.*, Pierre Nadeau, *Venture Capital Investment Selection: Do Patents Attract Investors?*, 19 STRAT. CHANGE 325, 338 (2010) (empirical study of patenting activity of successful venture-capital-backed technology firms from 1980 to 2000, showing that "patenting activity by technology firms helps venture capital investors overcome investment selection risks."); Sebastian Hoenen et al., *Do Patents Increase Venture Capital Investments Between Rounds of Financing?* 34 (manuscript presented to Patent Statistics for Decision Makers 2012 Knowledge Assets and Economic Growth, OECD, Paris) (Nov. 28–29, 2012) (finding that patents acquired before the first round of funding by a firm receive more investments); Iain Cockburn & Genia Long, *The Importance of Patents to Innovation: Updated Cross-Industry Comparisons with Biopharmaceuticals*, 25 EXP. OPINION ON THERAPEUTIC PATENTS 739, 740 (2015) (finding that patents are of particular importance to the biopharmaceutical industry and mentioning that patents function as a "signal" to potential investors); Christopher A. Cotropia, *Patents as Signals of Quality in Crowdfunding*, 2021 U. ILL. L. REV. 193, 193 (2021) (finding that, for crowdfunded projects, patented projects are not more likely to obtain funding than non-patented ones, but that patent-pending projects are more successful in getting funded).

[184] *See, e.g.*, Graham, *supra* note 94, at 1307 (noting that 85% of medical device companies reported that venture capital investors considered patents important); *see also* Simon, *supra* note 92, at 757–58 ("For devices that must go through the PMA process, patent protection is often essential to securing the investment necessary to undertake the costs associated with that process.").

The protective function of the patent—the fact that it permits disclosure of, and open discussion of, an invention, without risk of expropriation—may be especially important for the inventors of medical devices that are inherently self-revealing.[185] This may be critical for discussion with potential investors, and it can facilitate a variety of additional transactions in the marketplace that inure to the benefit of the firm. For instance, it can allow outsourcing of development and marketing to a larger medical device firm, leading more quickly and efficiently to an approvable medical device.[186] Indeed, recent empirical research confirms that the first mover disadvantage contributes to the reluctance of smaller companies to attempt the approval process themselves.[187]

In short, medical device patents may be critical to support the small start-up companies that dominate the medical device innovation landscape, by providing a foundation for investments, by increasing the likelihood of and improving the efficiency of licensing arrangements and collaborative development agreements, perhaps by increasing the likelihood that a breakthrough invention will make its way to physicians and patients, and perhaps by increasing the likelihood of an eventual company acquisition or other liquidity event. These activities, however, generally occur before FDA approval or, given the short commercial lifecycle of medical devices, in the first year or two after approval.

Medical device patents thus conceived continue to play an utilitarian (instrumental) role and, indeed, continue to fit with what some call the "reward" theory of the patent.[188] As a descriptive matter,

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185 Simon, *supra* note 92, at 763–65.

186 *See, e.g.*, *id.*, at 744–45.

187 *See, e.g.*, Stern, *supra* note 83, at 192–93. Professor Stern found that smaller firms were less likely to be the first to introduce a device in a particular product code (category), meaning they were less likely to be the actual applicant for premarket approval at the end of the day. A "small" company for his purposes is one that (1) is not publicly listed; (2) has revenue that does not exceed $500 million per year; and (3) is not a subsidiary of another that *is* publicly listed or *has* revenue exceeding that threshold. *Id.*

188 DANIEL F. SPULBER, THE CASE FOR PATENTS 30–32 (2021) (contrasting his "market foundation view" with the "'rewards' view" of patents); *see also* Dan L. Burk, *On the Sociology of Patenting*, 101 MINN. L. REV. 421, 425–26 (2016) (arguing that the signaling rationale for patenting is still "for the most part based on some sort of utility maximization.").

drug patents provide the better fit for this theory: that the prospect of above-competitive pricing stemming from the right to exclude copies provides the motivation to engage in activities that lead to patent-eligible inventions, and indeed that the duration of this pricing period may dictate the power of that motivation. But the idea is that the transaction enhancing qualities of the medical device patent provide an important incentive for inventive activities despite the shorter life cycle of medical devices. And it should not be taken to diminish the exclusivity conferring value of the medical device patent in the short term.[189] It just suggests that much of the value of a medical device patent, at least to a small company inventor of a breakthrough technology, lies more in the fact that the patent provides a foundation for efficient transactions in the market.[190] This value does not turn on the length of the patent term (the duration of the exclusion right) and may, instead, turn more on the scope of the patent (the breadth of the claims).

In a significant recent contribution to the theoretical literature, Professor Daniel Spulber laid out another—still consequentialist—theory of the patent, which works from the same empirical observations about the role played by the patent, but turns away from the motivation provided to inventors.[191] Instead, he argues, the patent provides the foundation for an efficient market in inventions themselves. Under his theory, the medical device patent would thus "separate" the inventor from the invention,[192] which would in turn allow subsequent innovation and commercialization by third parties. The fact of the patent itself—for instance, through the combination of disclosure (which can, for instance, reduce information costs) and

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189 Medical device patentees enforce their patents. *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1592 (2003) ("[O]ne study found that patentees in the medical device and software industries are far more likely to bring suit than patentees in other industries, such as chemistry or semiconductors."); Graham, *supra* note 94, at 1302 (noting that medical device firms list prevention of copying as "very important").

190 For arguments that patents reduce transaction costs in technology licensing, see Michael J. Burstein, *Exchanging Information without Intellectual Property*, 91 TEX. L. REV. 227, 276–79 (2012); Paul J. Heald, *A Transaction Costs Theory of Patent Law*, 66 OHIO ST. L.J. 473, 473 (2005).

191 *See generally* Spulber, *supra* note 188.

192 *See, e.g.*, *id.* at 26 ("By separating inventions from inventors, patents also facilitate the financing of commercialization and innovation.").

exclusion—increases the efficiency of a variety of transactions such as transfers and licensing of discoveries, as well as collaborations involving discoveries made by multiple parties.[193] The transferability and exclusionary aspects of the patent can also promote the financing of not only the inventive activity but subsequent commercialization activities.[194] The medical device patent, like other patents, promotes the "progress of . . . useful arts" *not* by encouraging inventive activity, but instead by providing the foundation for a market in inventions.[195] The view that the patent does its work (and is meant by the Constitution to do its work) by providing a foundation for market transactions, rather than by ensuring a steady stream of invention, is not widely held. But academic interest in the "transactional role" of patents in "economic" activity is growing, even within the more conventional "reward" theory.[196] And the medical device industry may offer an interesting area for further study of this role, with its combination of start-up companies, significant regulatory barriers, and exceptionally short commercial lifecycles.

C. Post Script

This Article has focused only on devices that go through formal premarket approval at the FDA, as these, and the devices subject to a humanitarian device exemption, are the only ones eligible for patent term restoration. But Class III devices make up only around 10 percent of the medical devices in the market.[197] Nearly half the devices in the market fall in Class II, and although some are exempt from any premarket submission, the vast majority of these will have been the subject of a premarket notification or a *de novo* classification petition.[198] These devices can embody innovations that are the

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193 *See, e.g.*, *id.* at 8–14.

194 *See id.* at 25–30.

195 *See id.* at 2.

196 *See* Robert P. Merges, *Philosophical Foundations of IP Law: The Law and Economics Paradigm*, *in* RESEARCH HANDBOOK ON THE ECONOMICS OF IP LAW 72, 81–82 (Menell et al. eds., 2016) (describing a "new branch of literature" that focuses on the "transactional role" that patent rights "play in economic activity;" that is, patents facilitate the disclosure, exchange, and licensure of information).

197 *See, e.g.*, FDA, LEARN IF A MEDICAL DEVICE HAS BEEN CLEARED BY FDA FOR MARKETING, https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda [https://perma.cc/V7F6-WABL].

198 *See id.*

subject of patent protection, and they cannot be marketed without a submission to a federal regulator and satisfaction of federal regulation expectations.[199] The role of the patent for these innovators could be the subject of additional research and reflection.

The basic policy of section 156 of the Patent Act was to restore a portion of the patent term that lapsed—on account of federally imposed premarket testing requirements and delay while the FDA application is pending—before a company subject to those requirements could market commercial embodiments of its invention. In the drug paradigm, these testing requirements flow inherently from the NDA requirement, and there is no other pathway to market for a new drug. But the device paradigm is more complex, and novel (patentable) devices may reach the market more than one way. The point of patent term restoration is simply to restore patent term lost due to distortion on account of a barrier to entry imposed by the federal government, there may be no compelling reason to distinguish medical device PMAs from *de novo* classification petitions for devices automatically placed in Class III, on the one hand, and device clearances supported by clinical data, on the other hand.[200] Indeed, restoration is already available for not only new drugs and preapproved medical devices, but food additives, color additives, and

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[199] For instance, the FDA estimates that it requests clinical data in less than approximately 10% of 510(k) submissions. FDA, *supra* note 144, at 23 (2014).

[200] In both cases, a subsequent entrant's application is comparative. A company citing a *de novo* petition may file a premarket notification instead, and a company citing a premarket notification files its own premarket notification. But it would be a mistake to assume that substantial equivalence establishes infringement. As already noted, the standard permits meaningful technological differences. *See also*, 42 Fed. Reg. 42520, 42525 (1977) ("The Commissioner notes . . . that a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act . . . is not intended to have any bearing whatever on the resolution of patent infringement suits."); Innovative Therapies, Inc. v. Kinetic Concepts, Inc., 599 F.3d 1377, 1383–84 (Fed. Cir. 2010) (holding that a premarket notification was not an admission of infringement); *see also* Lewin, *supra* note 103. To be sure, though, in some cases depending on the predicate device and the FDA's requirements for subsequent devices citing that predicate, establishing substantial equivalence could require infringement. *See, e.g.*, Mateo Aboy & Jacob S. Sherkow, *IP and FDA Regulation of De Novo Medical Devices*, FUTURE MED. DEVICE REG.: INNOVATION & PROT. 117, 122 (Cohen et al., eds., 2022) (arguing that, depending on the content of the special controls imposed by the FDA when granting the *de novo* petition, a subsequent entrant might be forced to infringe the first entrant's patent or lose the substantial equivalence pathway).

animal drugs, all regulated by the FDA, as well as veterinary biologics regulated by USDA.[201] Further consideration of these issues would be warranted.

V. CONCLUSION

This Article suggests that many small start-up companies engaged in disruptive innovation that leads to devices needing premarket approval seek patent protection primarily to encourage investors and facilitate information exchange and related commercial transactions, rather than because the patents will provide a particular period of exclusivity in the market. It supplements recent empirical papers exploring this alternative role for the medical device patent, making two contributions: (1) noting the lack of patent term restoration requests as further evidence that medical device patents are valued for something other than the length of the exclusivity rights they confer, and (2) offering an explanation, grounded in device regulatory concepts and a careful contrast with the drug regulatory system, *why* the terminal years of device patents and drug patents might be valued differently. It thus illustrates an important point: that regulatory concepts and design—choices made by the administrative state relating to oversight of products and services in the market—can profoundly affect the role that patents play and the timing of that role.

By regulatory design, drug patents play the critical role in postponing the loss of exclusivity for drug innovators to generic competitors; consequently, their duration after drug approval—and thus patent term restoration—is vitally important. But the fact that devices are sorted and regulated mostly on the basis of their medical purpose and broad principles of operation, the (to some extent resulting) lack of an abbreviated pathway for premarket approval of medical devices, and the resulting short commercial lifecycle for disruptive (class III) medical devices eliminates this role for medical

[201] As initially enacted, Section 156 required patent term restoration for new drugs, biological products, preapproved devices, food additives, and color additives. Congress later enacted patent term restoration for animal drugs and veterinary biologics in the Generic Animal Drug and Patent Term Restoration Act. *See generally* Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988).

device patents. At the same time, because the innovative process often emerges from inventors and entrepreneurs ill equipped to risk the medical device regulatory process, the medical device patent has an opportunity to play a different role, earlier in its term: that of furthering a market in new technologies and technology companies. Rather than incentivizing innovation by offering a period to recoup investment, device patents may make it possible for medical device inventors to engage in early collaborations, secure financial support, and engage in commercial transactions that increase competition and ensure inventions can be realized in the market for the benefit of healthcare professionals and patients.

The notion that regulatory requirements can bolster or undermine patent protection is not new. But this Article suggests that more basic regulatory design choices can profoundly affect the role that product patents play and, indeed, dictate whether their value derives from the length of the exclusivity they confer, from their breadth and their features that facilitate market transactions, or both. This has implications for policymakers not only considering products within the FDA's jurisdiction, but considering other products and services subject to federal regulation.