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Patents, Information, and Innovation

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INTRODUCTION

Patents are often critical to encouraging information exchange during the innovative process, yet their role has not been clearly articulated. Most of the understanding of the function of patents in facilitating the exchange of information during commercialization has focused primarily on entities in two industries—biotechnology and software.[1] This article provides a more complete account of the disclosure-enabling function of patents throughout the innovative process by providing a richer description of an essential, yet often-overlooked area—the medical device industry.[2] The limited analysis of the medical device

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[1] *See, e.g.*, JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE*:* HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 2–28 (2008) (drawing on examples from the software and biotechnology industries); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1675–96 (2003) (describing how policy levers in patent law allow courts to take into account the types of innovation in different industries); Michael J. Burstein, *Exchanging Information Without Intellectual Property*, 91 TEXAS L. REV. 227 (2012) (discussing information exchange through the lens of the biotechnology and software industries).

[2] This oversight is somewhat puzzling, as innovation in medical devices is important to public health as well as to the economy. U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-635R, MEDICAL DEVICE COMPANIES' SALES AND PROFITS 5 (2015); *see also* Joanna Brougher et al., *A Practical Guide to Navigating the Medical Device Industry: Advice from Experts in Industry, Law, Intellectual Property, and Academia*, FDLI MONOGRAPH SERIES, Mar. 2011, at 1, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1850887 [https://perma.cc/4KLL-YCFK] (noting that global sales of medical devices in 2009 totaled over $220 billion, with the United States controlling 41 percent of the market); Ilian Iliev et al., *Emerging Patent Thickets and Standards in the Medical Devices and Telehealth Space* 65, 84–85, 95 (Cambridge IP., Working Paper, Apr. 9, 2011), http://www.caba.org/CABA/DocumentLibrary/Public/IS-2013-79.aspx [https://perma.cc/2PYU-9Y8D] (describing a UK-commissioned report in which Cambridge IP examined patent thickets, standards, and patent pools, based on its case study in the area of Telehealth, in which eight respondents were interviewed); MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS:

industry in the literature has focused on the largest few dozen firms.[3] Of course, as publicly-traded entities, a great deal of data about them is readily available. Because small medical device companies tend to be privately held, information about them is more difficult to obtain. The discussion and analysis set forth here begins to fill that gap. An evaluation of the empirical literature, as well as examples from fourteen semi-structured interviews with medical device professionals from small and medium-sized firms, provides further contextualization.[4] In addition to considering the perspective of inventors, which has often been the focus of scholarship, this article elucidates the viewpoint of investors and commercialization partners, such as manufacturers and distributors.[5] Understanding the role of patents through examples from small and mid-sized companies in the medical device industry can serve as a barometer of how well the patent system in general is functioning in accordance with its historic purpose—to promote progress through innovation.[6]

Patents often serve a very different purpose in the initial stages of discussion with prospective investors than during later attempts to structure commercialization alliances. Numerous factors, such as the nature of the invention and the relationship between the parties, can help mitigate the risks of expropriation that ordinarily would arise in the absence of patent protection.[7] For example, in the medical device industry, innovators seeking to engage in negotiations involving traditional mechanical devices, such as a standard stent, often depend on patents to prevent

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MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 209 (2017), http://www.medpac.gov/docs/default-source/reports/jun17_ch7.pdf?sfvrsn=0 [https://perma.cc/43MS-UPZZ] (stating that U.S. spending on medical devices was estimated at $172 billion in 2013).

[3] *See, e.g.*, Brougher et al., *supra* note 2, at 1 (providing an overview of the medical device industry).

[4] Each of the interviews lasted at least thirty minutes, though several lasted over sixty minutes; ten interviews took place in-person, and four by telephone. I also had informal conversations with many other medical device professionals. The individuals interviewed have requested to remain anonymous. As such, throughout the paper, I use the term "Executives" to refer to Investors, CEOs, Presidents, Vice Presidents, General Counsels, IP Strategists, and outside counsels of medical device companies. The term "Scientists" includes researchers, scientists, CTOs, and product developers. *See infra* Part III and App. B for more information about the interviews as well as methodology. Interview notes are on file with the author. The examples described herein are not intended to provide quantitative evidence as to the regularity or frequency of occurrences.

[5] *See* Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709 (2012) (discussing the issue of near simultaneous invention and its implications); *infra* Part III.

[6] *See* U.S. CONST. art. I, § 8, cl. 8.

[7] *See, e.g.*, Burstein, *supra* note 1, at 271–72; Peter Lee, *Transcending the Tacit Dimension*: *Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CALIF. L. REV. 1503, 1527–30 (2012); *cf.* Jonathan M. Barnett, *Why Is Everyone Afraid of IP Licensing?*, 30 HARV. J.L. & TECH. 123, 133 (2017) ("While repeat-play incentives may sometimes constrain expropriation, those incentives are unobservable in the case of a new supplier and, even in the case of an old supplier, may not be reliable . . . .").

expropriation, given the self-revealing nature of these types of inventions.[8] In contrast, when discussing devices with a strong software or data-generating element, such as an implantable glucose monitor, inventors are more likely to rely on trade secrecy to protect at least some aspects of their technology.[9]

The role of patents in facilitating the exchange of information during the investment-seeking process includes not only encouraging disclosure of information *about* the invention, but also allowing access to information *distinct* from it.[10] As many companies may be experimenting with similar technology at approximately the same time,[11] information about the inventive entity and its track record, for example, may prove more valuable to prospective investors than information about the invention itself.[12] Thus, patents allow for a glimpse into information distinct from the invention that may not be obtainable otherwise, which ultimately facilitates the sharing of information about the invention and increases the likelihood that it will be commercialized.[13] Indeed, signaling theory may help explain why startups in some technology areas continue to spend their limited resources on patents, despite the challenges of obtaining patents of adequate scope that are often too costly to enforce.[14]

Additionally, this article identifies another information-facilitating function of patents that has not been clearly defined. Innovators can use patents as a way to communicate an objective indication[15] of the value of the inventor's idea—a concept I call "viability." As previous empirical research indicates, and the interviews conducted for this article confirm, patents can communicate viability in a number of ways—such as increasing the likelihood that first-mover advantage will be extended and that a product will have a potentially longer period of exclusivity

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[8] *See infra* Section III.E.1.

[9] *See* Brenda M. Simon & Ted Sichelman, *Data-Generating Patents*, 111 NW. U. L. REV. 377, 377 (2017).

[10] *See* Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 647 (2002).

[11] *See* Lemley, *supra* note 5, at 709; Lea Shaver, *Illuminating Innovation: From Patent Racing to Patent War*, 69 WASH. & LEE L. REV. 1891, 1922 (2012).

[12] *See* Long, *supra* note 10, at 655–58.

[13] *See id.* at 647–49.

[14] Signaling theory describes how patents can provide relatively low-cost information about the firm that holds them, such as its research and development skills, executive team, experience, or resource allocation. *See id.* at 645–46. For an excellent description of startups and their motivations, see 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, 1271–75 (2009) (describing startups as companies that are "resource constrained (in money and time)").

[15] *See* Timothy R. Holbrook, *The Expressive Impact of Patents*, 84 WASH. U. L. REV. 573, 596–97 (2006) ("The patent has gone through a review by the government that vests the patent with some level of certainty regarding the credibility of the disclosure.").

in the marketplace, as well as providing an intangible asset that can be licensed or sold if the startup faces financial distress.[16]

Similar to the highly-contextual role of patents in the early-stages of investment seeking, the function of patents in encouraging information exchange during commercialization depends on the transactional setting at issue. Particularly for smaller companies, or more precisely those that are not vertically integrated, patents can provide a mechanism to enable increased scaling and coordination with commercialization partners, allowing greater flexibility in determining organizational structure, and facilitating disclosure by mitigating the risks of expropriation by the partner.[17] And from the perspective of potential commercialization partners, patents can encourage development and information exchange by providing reassurance against expropriation risks by unrelated parties.[18] Without adequate patent protection, prospective manufacturers, distributors, and marketers may be reluctant to enter into agreements with emerging companies, reducing information exchange and ultimately investment, especially for inventions that are costly to implement.[19] By providing leverage against other patent holders and discouraging free-riding, patents can help encourage negotiation, increasing the likelihood of finding partners in the commercialization process.[20] Further, the availability of patent protection can encourage reciprocal exchanges of information among unrelated parties, creating synergies in the development process that might not otherwise exist.[21] Inventors and firms frequently discover and benefit from the work of others through the disclosures that patents make possible.[22]

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[16] The concept of viability assumes that the patent portfolio tracks the development of the product, or at least is sufficiently daunting to provide some deterrence to competition. *See infra* Section I.C.

[17] *See* GARY P. PISANO, SCIENCE BUSINESS: THE PROMISE, THE REALITY, AND THE FUTURE OF BIOTECH 149–53, 163–66 (2006) [hereinafter PISANO, SCIENCE BUSINESS]; David J. Teece, *Capturing Value from Technological Innovation: Integration, Strategic Partnering, and Licensing Decisions*, *in* TECHNOLOGY AND GLOBAL INDUSTRY: COMPANIES AND NATIONS IN THE WORLD ECONOMY 65, 65 (Bruce R. Guile & Harvey Brooks eds., 1987); *see also* Jonathan M. Barnett, *Three Quasi-Fallacies in the Conventional Understanding of Intellectual Property*, 12 J.L. ECON. & POL'Y 1, 8 (2016) (distinguishing between "the unintegrated (and often smaller) firm that primarily undertakes R&D and other innovation activities" and "the integrated (and often larger) firm that independently undertakes the full suite of innovation, production, distribution, and other commercialization activities required to deliver an innovation from lab to market").

[18] *See* Gary P. Pisano, *Can Science Be a Business? Lessons from Biotech*, HARV. BUS. REV., Oct. 2006, at 114, 120 ("[B]iotech start-ups appear to be retreating from the riskiest projects."); Ted Sichelman, *Commercializing Information with Intellectual Property*, 92 TEX. L. REV. SEE ALSO 35, 38 (2014).

[19] *See* Sichelman, *supra* note 18, at 42–43.

[20] *See* Brougher et al., *supra* note 2, at 12; Sichelman, *supra* note 18, at 36–40.

[21] *See infra* Section II.C.

[22] *See* Lemley, *supra* note 5, at 747 (explaining that "the patent does not so much communicate valuable technical information itself as induce the communication of that

The narrative drawn from existing empirical data, and confirmed by interviews I conducted with professionals from small and mid-sized medical device companies, is consistent with the theoretical understanding of the importance of patents to information exchange throughout the innovative process. Truly groundbreaking medical devices often originate with small companies.[23] These emerging companies frequently rely on investment funding as well as alliances with large companies to manufacture and market their products, and their commercialization partners often rely on intellectual property to prevent expropriation by third parties and ensure exclusivity.[24] Small medical device companies typically depend on patents to exchange information about their innovative devices in an industry with a small number of investors where a few dozen large companies dominate.[25]

As an example, consider the experiences described by a founder of a medical device startup.[26] The founder had discovered a pain-free way to measure glucose levels in blood, a vast improvement over existing medical devices.[27] After obtaining an exclusive license of the patents, he built a simple prototype and

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information by other means"); Mark A. Lemley, *The Surprising Resilience of the Patent System*, 95 TEX. L. REV. 1, 54 (2016) (describing how the market might value patents as "markers of innovation or trading chits"); Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 803, 808 n.9 (1988) ("There is a significant amount of evidence showing that inventors in many fields rely on published patents for technical information."); Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 545, 559 (2012) ("[M]any companies . . . advise researchers to avoid reading patents and to look elsewhere for technical information.").

[23] *See* JEFFRY LOO, S&P CAPITAL IQ, INDUSTRY SURVEYS HEALTHCARE: PRODUCTS & SUPPLIES 19–20 (Oct. 2014); D. Clay Ackerly et al., *Fueling Innovation in Medical Devices (and Beyond): Venture Capital in Health Care*, 27 HEALTH AFF.: SUPP. I, Dec. 2, 2008, at w68, https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.28.1.w68 [https://perma.cc/A6U2-XCM8] ("Increasingly, innovation occurs in small, early-stage companies that rely heavily on venture capital.").

[24] MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 209–10 ("83 percent of [medical device] companies had less than $1 million in assets, and 95 percent had less than $10 million in assets . . . . [T]he top 1 percent of firms in the medical device industry accounted for 82 percent of total assets . . . .").

[25] *See infra* Part III; *see also* John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 VAND. L. REV. 2099, 2128 (2000) (finding that, in their sample, small companies "patented more than half of the medical devices . . . , [but] they patented less than 1/3 of every other type of invention"); U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 2, at 5 (finding that although most medical device companies are small and mid-sized, thirty large companies constitute approximately 95 percent of the total sales each year from 2005 through 2014); INST. OF MED., MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA'S 510(K) CLEARANCE PROCESS AT 35 YEARS 170 (2011); MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 209 (citing a 2010 study that found that "73 percent of medical device firms had fewer than 20 employees and . . . 88 percent had fewer than 100 employees").

[26] Interview with Scientist V (Dec. 2017, June 2018) (in-person and telephonic).

[27] *Id.*

sought investment funding.[28] He knew that venture capital investors would expect reassurance about the viability of the technology and the startup's ability to protect against competition—they consider the likelihood of commercialization even in the early stages, given the costly and extensive process required to obtain regulatory approval.[29] Before meeting with investors, he had filed a dozen patent applications to provide a "defensible moat," which would make it difficult for competitors to make "gainful progress."[30] Patents allowed the startup to "fence off a green pasture" that the company could highlight to prospective investors, enabling communication of information both about the invention and apart from it, while at the same time providing an objective assessment of the idea's value by the U.S. Patent and Trademark Office (USPTO).[31] Having patent protection not only makes it difficult for competitors to make "gainful progress," it can also facilitate external communication about the invention to unrelated parties. For example, several companies in related markets have contacted the founder to express interest in licensing the technology.[32] And later in the commercialization process, patents can enable greater flexibility in organizational structuring—they not only provide protection for the startup, but also provide "cover" to manufacturing partners against the risks of expropriation.[33]

Part I describes the role of patents in facilitating early-stage negotiations with potential investors. It focuses on the conditions under which patents may encourage information exchange about an invention and apart from it by studying several factors, such as the nature of the invention itself, the importance of reputation in repeat transactions, and the ability to stage disclosure. It also sets forth the role of patents in providing an objective indication of the invention's viability. Part II elaborates on some of the distinct functions of patents during the commercialization process—from protecting against expropriation by partners and unrelated parties to promoting coordination and synergistic exchanges of information. To provide a more complete description of the information-facilitating role of patents during investment seeking and commercialization in Parts I and II, this article discusses

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[28] *Id.*

[29] *See infra* Part III (describing the premarket approval process for Class III devices); Graham et al., *supra* note 14, at 1269–72 (describing the characteristics of venture-backed startups).

[30] Interview with Scientist V (Dec. 2017, June 2018) (in-person and telephonic).

[31] *Id.*

[32] *Id.*

[33] Telephone Interview with Exec. VII (Aug. 2017).

existing literature in the biotechnology industry to understand how patents encourage information flow in the innovative process.[34] Part III then turns its focus to the medical device industry, examining the functions of patents for small and mid-sized firms in this industry, describing the unique nature of innovation in this area, analyzing data about recent acquisitions by top medical device companies, and contextualizing the discussion with examples drawn from interviews with professionals from medical device industry startups about their experiences with patents both during early-stage investment seeking and later in the commercialization processes. Part IV concludes with the implications of the analysis for patent policy more broadly.

The discussion in this article about the role of patents in small and mid-sized firms in the medical device industry limits the ability to generalize its findings. Its goal is not to provide conclusive evidence of the role of patents in innovation. Given the modest sample size of interviewees, I do not claim that my sample is representative of all medical device professionals, or that the examples discussed provide quantitative evidence of the regularity or frequency of similar occurrences. Rather, the description seeks to provide context to how the role of patents in promoting innovation, understood from a theoretical perspective, can play out in this segment of the medical device industry. By providing a descriptive timeline of the innovative process through a closer examination of the largely-overlooked medical device industry, this article sets forth a more complete account of the ways in which patents may enable information exchange and when they may be less necessary, elucidating the larger narrative of innovation and the role of patents in it.

I. THE ROLE OF PATENTS IN PROMOTING INFORMATION FLOW DURING EARLY-STAGE NEGOTIATIONS WITH INVESTORS

The translation of an intangible asset into a commercial product, even after it has been conceived and reduced to practice, often requires substantial investment.[35] The inventor of a novel idea may lack the resources to fully develop and commercialize it. So, the inventor may need to reach out to investors to bring an idea to market. But, approaching investors can raise several

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[34] Startups in both the biotech and medical device industries are far more likely to hold patents and applications than startups in other industries. *See* Graham et al., *supra* note 14, at 1277–78.

[35] *See, e.g.*, F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 703 (2001).

issues. First, there is a risk that investors will take the idea without compensating the inventor. Second, investors might seek reassurance that if the investment is made, the inventor's team has the ability and means to execute the idea. Finally, both inventors and investors would benefit from being able to rely on an objective indication about the viability of the invention.

A. Encouraging Information Exchange About the Invention

Exchanging information in the initial stages of innovation, particularly when courting prospective investors, can pose challenges because of the expropriation risks involved.[36] To secure funding, an inventor often needs to disclose at least some information about his or her idea to prospective investors, so they can decide whether to proceed. The difficulty occurs because the invention has value while it is secret, but if the inventor fully releases the information without compensation, its value may be lost through expropriation.[37] Nobel laureate Kenneth Arrow first described the information exchange conundrum as the "fundamental paradox."[38]

Patents provide one mechanism for addressing Arrow's paradox, allowing for the exchange of information about an invention by making the information excludable.[39] If prospective investors attempt to make or use an invention protected by a patent without the inventor's consent, they may be subject to an injunction or damages.[40] Patent protection thus discourages prospective partners from making or using an invention without permission, mitigating the risks of disclosure. Intellectual property protection is one of many possible mechanisms that can reduce the likelihood of expropriation, making the discussion of the function of patents in promoting information exchange highly contextual.

Some scholars have noticed ambiguities in the traditional account of the role of patents in enabling the disclosure of

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[36] *See* Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* NAT'L BUREAU OF ECON. RESEARCH, THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 615 (1962).

[37] *See id.*

[38] *Id.* ("[T]here is a fundamental paradox in the . . . demand for information; its value for the purchaser is not known until he has the information, but then he has in effect acquired it without cost.").

[39] *See, e.g.*, Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 277–78 (1977); Jason Rantanen, *Peripheral Disclosure*, 74 U. PITT. L. REV. 1, 33–34 (2012) ("Patents provide an escape from the paradox, allowing inventors to disclose information about the technology in the context of these transactions without losing the ability to monetize the invention.").

[40] *See* eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391–94 (2006).

information about inventions.[41] The long-held assumption had been that information is necessarily nonexcludable, meaning that after information has been disclosed, it is not possible to stop others from using it.[42] However, innovation-related information is more like a shape shifter in some circumstances. Although information can sometimes be sorted into categories of "secret" or "disclosed," it may not fit neatly into either.[43] At one end of the spectrum are inventions that can be maintained entirely as trade secrets, such as a search engine algorithm that cannot be reverse engineered easily. At the other end, "self-disclosing" inventions allow expropriation and competition as soon as the product embodying the invention is disclosed, if the product is not covered by intellectual property or subject to other restrictions.[44] An example of a self-disclosing invention is a simple mechanical device, such as bottle opener, where the invention is easily understood as soon as it becomes available in the marketplace.

Information that is partially excludable permits inventors to retain tacit knowledge to optimize the development and execution of the invention after disclosure, or it simply may be difficult to codify.[45] For instance, inventors may retain knowledge about the precise parameters of how to manufacture a given biologic as a trade secret.[46] The nature of the retained information enables inventors to provide a prospective investor with sufficient information to determine whether to move forward, while some know-how remains undisclosed, protecting against expropriation.

In addition to challenging the conception of nonexcludability, commentators have argued that information need not be homogenous, which means that it is disclosed entirely or not at all.[47] Instead, disclosure does not have to be an all-or-nothing decision that takes place only at one moment in time. Inventors can sometimes disclose information about an invention in stages, as trust develops between the negotiating partners and additional contractual safeguards are in place.[48] Thus, the disclosure of information can be "multilayered."[49] For example, software developers seeking funding need not disclose

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[41] *See, e.g.*, Burstein, *supra* note 1.

[42] *Id.* at 247–57.

[43] *Id.*

[44] Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 105.

[45] *See* Burstein, *supra* note 1, at 252–54.

[46] *See* W. Nicholson Price II, *Regulating Secrecy*, 91 WASH. L. REV. 1769, 1794 (2016) (defining biologics as "large biological macromolecules made by living cells").

[47] *See, e.g.*, Burstein, *supra* note 1, at 255–57.

[48] *Id.*

[49] *Id.* at 255.

source code at the outset of a negotiation; instead, they could describe "what the software can do, what the potential underserved need might be, what the competitive landscape for the application might be," allowing "potential funders and partners to evaluate the business opportunity without appropriating the core information asset."[50] The use of staged disclosure, as well as the importance of industry norms and reputation in repeat-play transactions, may allow for disclosure of information about an invention without the use of patent protection to guard against the risk of expropriation.[51]

Even though startups are sometimes able to use alternative mechanisms to patents to protect against the risk of expropriation, such as retaining tacit knowledge or engaging in staged disclosure, patent protection may provide a more efficient way to reduce the threat of expropriation than the alternatives.[52] For example, reputational incentives can protect against expropriation risks by "repeat-play parties," such as established investors, but they often do not provide a satisfactory deterrent against expropriation by new entrants, who may have not invested heavily in building a reputation.[53] Additionally, if the projected benefits of diverging from anti-expropriation norms are sufficiently large and the negative consequences are minimal, even repeat players may decide to deviate from industry norms.[54] And time and resource constraints may make such alternative mechanisms impracticable for certain transactions.[55]

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[50] *Id.* at 256.

[51] *Id.* at 256–57; *cf.* Barnett, *supra* note 17, at 8.

[52] *See* ASHISH ARORA ET AL., MARKETS FOR TECHNOLOGY: THE ECONOMICS OF INNOVATION AND CORPORATE STRATEGY 139–40 (2001) ("[A] benefit . . . of stronger intellectual property rights would be a more efficient flow of tacit knowledge from the technology sources to unaffiliated technology users."); Barnett, *supra* note 17, at 18; Henry E. Smith, *Exclusion and Property Rules in the Law of Nuisance*, 90 VA. L. REV. 965, 971 (2004) ("[G]iving owners a right to exclude from a thing good against the world is a rough but low-cost method of generating information that is easy for the rest of the world to understand.").

[53] Barnett, *supra* note 17, at 11 ("[R]epeat-play parties may have reputational incentives to forego the short-term gains from expropriating an innovator's idea in order to maximize the long-term stream of future opportunities that can be sourced from the same innovator plus all other innovators.").

[54] *Id.*

[55] One of the main alternatives to patent protection, nondisclosure agreements, may not be a realistic option. *See* Rantanen, *supra* note 39, at 34, 34 n.145. In addition to the difficulties of establishing a breach of a nondisclosure agreement, investors or other negotiating partners may refuse to sign nondisclosure agreements. *See id.*; Stuart J.H. Graham & Ted Sichelman, *Why Do Start-Ups Patent?*, 23 BERKELEY TECH. L.J. 1063, 1082 (2008). Additionally, third parties are not bound by NDAs they have not signed, while patents may protect against infringing activity by these types of actors. *See* Rantanen, *supra* note 39, at 34, 34 n.145.

B. The Biotechnology Industry as an Innovative Template for Information Sharing

Existing scholarship from the biotechnology industry provides a useful model to describe how patents facilitate information exchange in the innovative process more broadly. Similar to inventions in the medical device industry, which will be discussed in Part III, biotechnology-related inventions must undergo an extensive regulatory process to bring an idea to market.[56] Additionally, startups in both of these industries are far more likely to hold patents or patent applications than startups in other industries.[57]

Technology in the biotechnology industry often begins with universities that spin off new startups, investors then provide funding,[58] and ultimately the startups exchange their intellectual property with established pharmaceutical companies to obtain further investment.[59] Professor Gary Pisano describes the "fragmented nature" of the biotechnology industry as comprising a multitude of small startups in "islands of expertise."[60] He notes that the ways in which companies are funded sometimes "conflicts with the long R&D timetable needed to create new drugs."[61]

Developing new drugs comes with considerable risk. The process of evaluating drug candidates and engaging in discovery prior to clinical trials can take three to six years.[62] After that point, if the U.S. Food and Drug Administration (FDA) permits the Investigational New Drug (IND) application to go into effect, clinical trials take place over the next six to seven years.[63] If the clinical trials are successful, the FDA then reviews the New Drug Application (NDA), which adds another six months to two

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[56] *See infra* Part III; Burstein, *supra* note 1, at 232 ("Biotechnology companies (biotechs) specialize in early-stage research and development of pharmaceuticals.").

[57] *See* Graham et al., *supra* note 14, at 1277–78 (finding that 75 percent of biotechnology and 76 percent of medical device startups that responded to the survey hold U.S. patents or patent applications, compared to 39 percent of all startups that responded).

[58] Ackerly et al., *supra* note 23, at w69 (finding venture capital "play[s] a critical role in providing early-stage financing to bring technologies past the financial 'valley of death'").

[59] *See* Pisano, *supra* note 18, at 116–17 ("[V]irtually every new biotech firm has formed at least one contractual relationship with an established pharmaceutical or chemical company, and most have formed several.").

[60] *Id.* at 116.

[61] *Id.*

[62] Ronald J. Gilson, *Locating Innovation: The Endogeneity of Technology, Organizational Structure, and Financial Contracting*, 110 COLUM. L. REV. 885, 910 (2010) (noting that "the number of compounds examined runs from 5,000 to 10,000").

[63] *Id.*

years.[64] A recent estimate of the costs of new drug development, from research to FDA approval, is approximately $2.6 billion.[65] For funding, biotech startups often rely on equity financing through venture capital when they are in the early stages of conducting research, given the challenges of measuring performance at that time.[66] Later in the drug development process, however, obtaining financing through entering into a joint venture is more closely aligned with the technological landscape and organizational structure of the industry, given the large expense and extended timeframe associated with obtaining FDA approval.[67]

Commentators from the biotechnology industry have questioned whether alternative structures for mitigating expropriation risks, such as staging disclosure or relying on reputational or industry norms, are best-suited for addressing the disclosure paradox, at least when seeking early-stage investment.[68] The difficulty of obtaining patent protection[69] and increasing reliance on trade secrets in some circumstances can be problematic in this industry, given the time constraints investors and companies operate under and the importance of information exchange for development.[70] In particular, emerging companies "have limited financial resources, and investors aren't willing to give them the time to perfect their craft."[71] So, the disclosure paradox at the early venture-financing stage may remain a challenge where patent protection is difficult to obtain.

Although the information exchange dilemma might be addressed in part by such mechanisms as staged disclosure or

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[64] *Id.*

[65] Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 31 (2016).

[66] *See* Gilson, *supra* note 62, at 914 ("Equity financing through venture capital provides a sensible form of financial contracting for early-stage biotech companies while research efforts identify drug candidates. At that stage, uncertainty makes it difficult to base payment to the biotech company largely on performance.").

[67] *See id.* ("[T]he FDA approval process, especially regarding human testing, involves levels of costs and time that are inconsistent with the venture capital funding structure.").

[68] In Burstein's discussion, the main biotech example focuses on later-stage alliance formation between a smaller research-focused biotech company and the larger pharmaceutical company. Burstein, *supra* note 1, at 232–33.

[69] *See*, *e.g.*, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 72–73 (2012) (excluding inventions from patent eligibility unless they are sufficiently applied); Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256, 256 (2015) (concluding that the "most important advances" in diagnostic testing inventions "lie outside the boundaries of patent-eligible subject matter"); Rachel E. Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. DAVIS L. REV. 1881, 1906 (2016) ("[S]imultaneous developments in both patent law and healthcare regulation have threatened the ability of diagnostic method innovators to both obtain and enforce patents on those methods.").

[70] Pisano, *supra* note 18, at 122.

[71] *Id.*

reputational or industry norms during later transactions,[72] the abbreviated timeline for obtaining a return on investment may undercut the usefulness of these mechanisms, as "the biotech industry is not organized to learn from experience over time."[73] For example, one study found that the average length of a research collaboration agreement is four years, which is much less than the time necessary for drug development.[74] In an attempt to address these issues, startups and pharmaceutical firms may prefer to enter into longer alliances, or acquire (or as Peter Lee recently described, semi-integrate) a startup, to allow the larger companies to integrate the know-how of their partners.[75]

A close examination of financing partnerships among firms in the biotechnology and medical technology industries suggests that alternative mechanisms to patent protection in these areas may be facilitating information exchange.[76] For example, although a robust patent regime may not affect the willingness of emerging companies to enter into corporate investment relationships despite expropriation risks, companies were more likely to enter into such relationships where trade secrecy and timing their relationships to coincide with later funding rounds could protect against expropriation.[77] Delaying collaboration—such as where a more developed technology can be embodied within a product—makes it more difficult for a partner to expropriate the technology at issue.[78]

Perhaps part of the decision to rely on trade secrecy for some inventions stems from the difficulty of exchanging information about an invention. For example, biotechnology inventions often "cannot be fully described in writing, because the cause-and-effect principles behind the techniques or know-

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[72] *See* Luis Diestre & Nandini Rajagopalan, *Are All "Sharks" Dangerous? New Biotechnology Ventures and Partner Selection in R&D Alliances*, 33 STRATEGIC MGMT. J. 1115, 1132 (2012) (finding that biotechnology startups are more likely to ally with pharmaceutical firms that have the ability to create value, provided the pharmaceutical firms are incentivized to create, as opposed to appropriate, value).

[73] Pisano, *supra* note 18, at 122; *see also* Josh Lerner & Ulrike Malmendier, *Contractibility and the Design of Research Agreements*, 100 AM. ECON. REV. 214, 214–16 (2010) (describing the design of biotechnology research agreements).

[74] Lerner & Malmendier, *supra* note 73, at 226 (noting that "research collaborations range widely in length, averaging about four years").

[75] Peter Lee, *Innovation and the Firm: A New Synthesis*, 70 STAN. L. REV. 1431, 1488–89 (2018) ("Due to the natural excludability of patent-related tacit knowledge, patents and licenses are inadequate for transferring technologies, thus motivating vertical integration.").

[76] *See* Riitta Katila et al., *Swimming with Sharks: Technology Ventures, Defense Mechanisms and Corporate Relationships*, 53 ADMIN. SCI. Q. 295, 316, 323 (2008).

[77] *Id.*

[78] *Id.* at 304–05. (explaining that "biotech entrepreneurs use this reasoning when they delay R&D collaborations with unfamiliar partners").

how have not been completely identified."[79] Tacit knowledge often plays a key role, as value may be found not in a "specific molecule but data, understanding, and insights relating to how that molecule behaves, what it can do, what its potential problems are, and how it might be developed."[80] Furthermore, much of this type of information may not be patentable under current law, as it may not be deemed sufficiently applied.[81]

The role of patents in exchanging information in the biotechnology industry provides a useful template for considering how patents encourage information exchange in the innovative process more broadly. Issues related to financing, the nature of the technology, and the feasibility of alternative mechanisms to patents, such as trade secrecy, will be explored in greater detail in Part III as they pertain to the medical device industry.

C. Promoting Information Exchange Distinct from the Invention

In addition to encouraging information exchange about inventions during the preliminary stages of seeking investment, patents can promote the exchange of information distinct from the invention itself. Clarissa Long has described signaling theory, which sets forth how patents may function as signals to investors, providing credible information at low cost about the firm that holds the patents, such as its research and development skills, executive team, experience, or resource allocation.[82] Additionally, a firm's patents "can convey information about the lines of research a firm is conducting and how quickly the research is proceeding."[83] This additional information may ultimately prove more valuable to investors than information about the underlying technology itself.[84]

Patents may also communicate to potential investors whether an invention is likely to be viable. The term "viability"

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[79] Pisano, *supra* note 18, at 122.

[80] *Id.* at 122.

[81] *See, e.g.*, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 72–73 (2012) (excluding inventions from eligibility unless they are sufficiently applied).

[82] *See* Long, *supra* note 10; *see also* Clark D. Asay, *The Informational Value of Patents*, 31 BERKELEY TECH. L.J. 259, 267 (2016) (describing patent holders' use of patent pledges "to credibly and efficiently signal information to product, labor, and capital markets about their research and development activities and preferences").

[83] *See* Long, *supra* note 10, at 646.

[84] Investors' Panel, *How to Raise the Funds You Seek for Your Medical Device Company*, 10x MED. DEVICE CONF., at 39:10–39:18 (2017), https://www.medicaldevicesgroup.net/medical-devices/how-to-raise-the-funds-you-seek-for-your-medical-device-company/ [https://perma.cc/4QB9-B9PE]; *see* Interview with Scientist V (Dec. 2017, June 2018) (in-person and telephonic).

as used in this article means providing an objective indication that the idea is likely to have value. An issued patent provides an independent metric that the USPTO found the invention worthy of a patent.[85] It also indicates that investors have a better chance of obtaining a return on their investment, such as by increasing the likelihood that the invention will have at least some enhanced period of exclusivity and extension of first-mover advantage.[86] Investors view robust patent protection "as validating a technology and demonstrating its commercial potential."[87] Of course, this assumes that the patent portfolio tracks the development of the product and can adequately anticipate later product development.[88] Even where patent protection is not a guarantee of a full term of exclusivity,[89] obtaining a large portfolio of patents "in and of itself often scares away would-be competitors simply because of the expense of figuring out how to get around the volume of protection."[90] Additionally, patents are intangible assets that can be licensed or sold if the company faces financial difficulties—providing an independent source of value.[91]

In the 2008 Berkeley Patent Survey, both biotechnology and medical device startups reported that patent protection was important for obtaining investment.[92] From the investors' perspective, the survey found patents are important in the decision about whether to invest in both biotechnology and

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[85] Perhaps this reliance is misplaced, however, given the limited time patent examiners spend in assessing whether a patent should be granted. *See* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1502 (2001) (discussing how an examiner will spend approximately eighteen hours examining a patent application "from start to finish"); *see also* Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 53 (2007) (noting that examiners spend approximately seventeen hours over several years searching for, assessing, and applying the prior art in assessing a given patent application).

[86] *See* Brougher et al., *supra* note 2, at 12 ("Intellectual property, and patents in particular, is crucial to the growth of a life sciences company since it enhances and secures a company's revenue and marketing value.").

[87] *Id.*

[88] *See id.* at 3.

[89] The patent may not provide a full period of exclusivity for several reasons—for example, the patent may be held invalid at some point, or it may differ in scope from the product that actually succeeds in the marketplace.

[90] Jarom Kesler et al., *What Medical Device Companies Need to Know About Intellectual Property*, MED. ELECTRONIC DEVICE SOLUTIONS (MEDS), Aug. 2012, at 33.

[91] *See* Brougher et al., *supra* note 2, at 12 ("In such cases involving distressed companies, intellectual property assets are often a primary source of value."); Joel Rosenblatt, *Theranos Investors May Vie with SEC to Scavenge Unicorn's Remains*, BLOOMBERG (Mar. 28, 2018), https://bloomberg.com/news/articles/2018-03-28/theranos-investors-may-vie-with-sec-to-scavenge-unicorn-remains [https://perma.cc/DS55-YQ43].

[92] Ted Sichelman & Stuart J.H. Graham, *Patenting by Entrepreneurs: An Empirical Study*, 17 MICH. TELECOMM. & TECH. L. REV. 111, 158 (2010).

medical device startups.[93] Venture capitalists typically expect an emerging company to have filed for patent protection prior to providing investment funds.[94] Consistent with the earlier work of Clarissa Long on patent signaling,[95] the survey confirmed that patents often provide a fairly inexpensive way of credibly conveying information about the firm that holds them that is otherwise difficult to obtain, reducing information asymmetries between patent holders and investors.[96]

II. THE INFORMATION-FACILITATING ROLE OF PATENTS DURING COMMERCIALIZATION

To commercialize an invention, an inventor needs to ensure a multitude of actions are completed, such as creating a working model, experimenting with and optimizing the product, manufacturing, complying with any pertinent regulatory requirements, distributing, and marketing—many of these actions depend on the exchange of information between unrelated entities. Two classic organizational models for bringing an invention to market include entering into alliances with separate entities or relying on vertical integration.[97] For the latter model, a company could choose to vertically integrate by engaging in discovery and commercializing new inventions entirely in-house. Commercialization by an integrated (and typically larger) firm would therefore include not only innovation, but also manufacturing, distribution, marketing, and other acts to bring an invention from concept to the market.[98] Some examples of successful vertical integration in the biotechnology industry include Amgen and Genentech.[99] For the former organizational model that involves entering into alliances, firms that are not integrated (generally smaller companies) could separately conduct research and discovery and coordinate with other companies that focus on bringing inventions to market.[100] Typically, companies in the biotechnology space engage in

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[93] *Id.*

[94] *See* Graham et al., *supra* note 14, at 1277–78 (finding that 82 percent of venture-backed firms surveyed have applied for, or received, at least one U.S. patent; they have, on average, almost nineteen U.S. patents and/or patent applications).

[95] *See* Long, *supra* note 10.

[96] *See* Graham et al., *supra* note 14, at 1277–78.

[97] *See* R.H. Coase, *The Nature of the Firm*, 4 ECONOMICA 386, 397 (1937); Barnett, *supra* note 17, at 8.

[98] Barnett, *supra* note 17, at 8.

[99] Amgen, Genentech, and a few other biotech companies "vertically integrated by investing heavily in manufacturing and marketing even as [they] continued to build internal scientific capabilities." Pisano, *supra* note 18, at 118.

[100] Barnett, *supra* note 17, at 8.

research and then enter into agreements with pharmaceutical firms to manufacture and market the drugs as well as carry out costly clinical trials.[101] Of course, firms could be partially integrated as well, executing some commercialization tasks in-house while entering into alliances to have the remainder of the acts executed by larger entities. Or, firms could be semi-integrated, which means they are acquired by a larger firm, but efforts are made to allow them to retain their distinct identities.[102]

Patents can enable efficient allocation of resources, providing a mechanism for firms that are not integrated to specialize in research and discovery, while allowing integrated companies to bear the other costs of commercializing new inventions.[103] As described in more detail below, they can encourage disclosure by reducing the risks of expropriation by the negotiating partner and by providing reassurance for both companies against expropriation by unrelated third parties. They can also promote efficiencies by encouraging coordination and the synergistic exchange of information. Assuming that intellectual property rights are available and enforceable, they can increase the number of potential negotiating partners willing to undertake the expense and risks associated with commercializing invention while concomitantly increasing the flow of information.[104]

A. Mitigating the Risks of Expropriation

Intellectual property rights can encourage the disclosure of information to unrelated parties by providing a way for inventors to structure relationships during commercialization that mitigates the risks of expropriation. Stable patent rights can allow for efficient allocation of the work necessary to translate an idea into a product.[105] Without adequate intellectual property protection, companies may be limited in their decisions about which organizational structure to adopt. They may decide to rely on vertical integration to mitigate expropriation risks, reducing

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[101] *See* Lee, *supra* note 7, at 1511; Josh Lerner & Robert P. Merges, *The Control of Technology Alliances: An Empirical Analysis of the Biotechnology Industry*, 46 J. INDUS. ECON. 125, 126 (1998) (explaining how alliances in the biotechnology industry typically involve "small research-intensive firms" and large pharmaceutical corporations).

[102] *See* Lee, *supra* note 75, at 1488–89.

[103] *See* ARORA ET AL., *supra* note 52, at 278 ("A well-developed and globalized market for technology will enable [specialized technology suppliers] . . . to derive more value from their investments . . . by supplying technology to those able to develop and commercialize it more effectively."); Barnett, *supra* note 17, at 8.

[104] *See* Barnett, *supra* note 17, at 12.

[105] *See, e.g.*, Kieff, *supra* note 35, at 703.

information exchange with unrelated parties and potentially efficiency during commercialization.[106] Such inefficiencies in commercialization may be borne by users in the form of limited availability, higher prices, and reduced innovation.[107]

As in the funding process, alternative mechanisms to intellectual property rights, such as retaining tacit knowledge or engaging in staged disclosure, may be helpful in reducing the risks of expropriation during commercialization, but they are not a guarantee against it.[108] Reputational incentives may mitigate expropriation risks in repeated dealings with established investors during commercialization, but they have less force for new entrants.[109] And even repeat players may decide to deviate from anti-expropriation norms if the anticipated return from engaging in expropriation is sufficiently large.[110] Thus, although startups could use alternative mechanisms to patents at times to protect against the threat of expropriation, patent protection may be more efficient in mitigating the risks.[111]

B. Allowing Greater Flexibility in Organizational Structuring

Research has shown that robust patent protection can encourage information exchange between unrelated entities during commercialization, while weaker protection may inhibit transactions.[112] When intellectual property rights are robust, markets can allow for a more efficient distribution of labor between specialized firms engaging in research and development and their

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[106] *See* Barnett, *supra* note 17, at 19; Jonathan M. Barnett & Ted Sichelman, *Revisiting Labor Mobility in Innovation Markets* (Univ. S. Cal. Legal Studies Working Paper, 2016), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2758854 [https://perma.cc/PZ2G-P9EZ] (noting that expropriation can still occur even in vertically integrated organizations, such as by former employees); Dan L. Burk & Brett H. McDonnell, *The Goldilocks Hypothesis: Balancing Intellectual Property Rights at the Boundary of the Firm*, 2007 U. ILL. L. REV. 575, 617 ("Thus, with overly weak protection of rights, more transactions will be done within firms than is the case at the optimal level of protection for interfirm transactions.").

[107] *See* Barnett, *supra* note 17, at 19–20.

[108] *See supra* notes 45–55 and accompanying text.

[109] *See* Barnett, *supra* note 7, at 133.

[110] *See id.*

[111] *See* ARORA ET AL., *supra* note 52, at 131; Barnett, *supra* note 17, at 18.

[112] *See* Ashish Arora & Marco Ceccagnoli, *Patent Protection, Complementary Assets, and Firms' Incentives for Technology Licensing*, 52 MGMT. SCI. 293, 296, 298 (2006); Ashish Arora & Robert P. Merges, *Specialized Supply Firms, Property Rights and Firm Boundaries*, 13 INDUS. & CORP. CHANGE 451 (2004); Clark D. Asay, *Artificial Stupidity*, 61 WM. & MARY L. REV. (forthcoming 2020), https://ssrn.com/abstract=3399170 [https://perma.cc/27VD-23SW]; Lee G. Branstetter et al., *Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence from U.S. Firm-Level Panel Data*, 121 Q.J. ECON. 321, 347 (2006); Joanne E. Oxley, *Institutional Environment and the Mechanisms of Governance: The Impact of Intellectual Property Protection on the Structure of Inter-Firm Alliances*, 38 J. ECON. BEHAV. & ORG. 283, 288 (1999).

commercialization partners.[113] For example, strengthening patent protection has been shown to increase the propensity of firms to license, at least where they lack the "specialized complementary assets" necessary for commercialization.[114]

Other studies suggest that the availability of patent protection is also an important consideration in the structuring of international alliances, encouraging the flow of information between unrelated parties. Where patent protection is weak in a given country, companies may adopt more hierarchical governance models in an attempt to reduce the risks of expropriation through careful structuring of alliances, such as joint ventures that result in the sharing of equity.[115] In jurisdictions with strong patent protection, however, firms often choose to enter into contractual partnerships directly with local parties.[116] Similarly, intellectual property rights reform has been shown to result in increased "technology transfer among U.S. multinationals."[117] For example, after reforms were adopted, affiliates increased spending on research and development and patenting by nonresidents increased as well.[118] These studies indicate that intellectual property rights can allow for greater flexibility in structuring alliances that facilitate disclosure.

Intellectual property rights can encourage small and large companies in the biotech industry to enter into partnerships, facilitating the exchange of information.[119] Smaller research startups typically lack the resources to meet the regulatory requirements associated with bringing a product to market, let alone to cover the often extensive costs of manufacturing, marketing, and distributing a new product.[120] Without intellectual property protection, other restrictions, or alternative mechanisms to reduce the risks of expropriation, many of these products would be less likely to make it to market.[121] Even when

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[113] *See* Arora & Merges, *supra* note 112; Jonathan M. Barnett, *Intellectual Property as a Law of Organization*, 84 S. CAL. L. REV. 785, 791 (2011) ("Patents mitigate expropriation risk and therefore enable innovators to select freely among organizational forms in order to capture specialization gains through relationships with lower-cost suppliers.").

[114] Arora & Ceccagnoli, *supra* note 112, at 302.

[115] *See* Oxley, *supra* note 112, at 288.

[116] *Id.*

[117] Branstetter et al., *supra* note 112, at 322.

[118] *Id.*

[119] *See* PISANO, SCIENCE BUSINESS, *supra* note 17.

[120] *See* Lerner & Merges, *supra* note 101, at 126; Gary P. Pisano, *The Governance of Innovation: Vertical Integration and Collaborative Arrangements in the Biotechnology Industry*, 20 RES. POL'Y 237, 245 (1991).

[121] *See* Sichelman, *supra* note 18, at 43–44; *see also* Ronald J. Gilson et al., *Contracting for Innovation: Vertical Disintegration and Interfirm Collaboration*, 109 COLUM. L. REV. 431, 435, 473 (2009) (describing "contracting for innovation" as a way to encourage "iterative collaborative innovation" and deter opportunism by increasing switching costs).

alternative mechanisms or restrictions can function to mitigate expropriation risks at certain stages of the transaction, awareness of intellectual property rights may act as a further deterrence to would-be expropriators.[122]

Additionally, commercialization partners that work with smaller R&D companies depend on patent protection to prevent expropriation by third parties.[123] Partners would be reluctant to enter into an alliance without some reassurance that their investments in commercialization will not be rendered worthless.[124] For example, manufacturers would be hesitant to invest in new equipment and processes to manufacture a new product without reassurance that the product would not be copied by a third party or run the risk of infringing another party's patent.[125] Intellectual property rights at the foundation of a commercialization alliance can provide protection both for the company that holds the intellectual property and its commercialization partner.[126] Thus, patents can allow for greater flexibility in structuring alliances that facilitates the sharing of information.

C. Promoting Synergies Through Reciprocal Exchanges of Information

Intellectual property rights can encourage companies to enter into synergistic partnerships that facilitate reciprocal exchanges of information. Patents enable the disclosure of information to unrelated parties, not only in the patent itself, but also in varied, and perhaps more useful, forums.[127] When intellectual property rights are strong, smaller companies that specialize in research and development may have the option to enter into agreements with larger firms that can bear the costs and risks of production, increasing efficiencies and promoting synergistic communication.[128]

The mere existence of a patent increases the likelihood that potential partners will become aware of one another. Research suggests that patents provide a way to communicate to prospective partners and may reduce the time necessary to

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[122] *See* Kesler et al., *supra* note 90, at 32, 34.

[123] *See* PISANO, SCIENCE BUSINESS, *supra* note 17.

[124] *Id.*

[125] *See infra* notes 207–209 and accompanying text.

[126] *See infra* notes 207–209 and accompanying text.

[127] *See* Lemley, *supra* note 5, at 745–46; Merges, *supra* note 22, at 808 n.9; Ouellette, *supra* note 22, at 571 (finding that some researchers do not read patents because they are "duplicative of journal publications").

[128] *See* Arora & Merges, *supra* note 112; Barnett, *supra* note 113, at 791.

commercialize an invention, facilitating the creation of a "market for ideas."[129] Strong intellectual property rights may increase the likelihood that small firms that lack the "specialized complementary assets" necessary for commercialization will enter into an alliance, facilitating disclosure.[130] The availability of patent protection has also been shown to encourage R&D firms to enter into relationships with independent suppliers that may result in the production of new information, in contrast to the more limited flow of information that may ordinarily accompany vertical integration.[131] Thus, intellectual property can provide a mechanism for transferring information, as it provides a means to address the difficulty of negotiating over intangible information goods.[132]

As an example, one study examined the allocation of control rights in alliances between biotechnology startups and pharmaceutical firms; examples of control rights include development, manufacturing, and resultant intellectual property rights.[133] The study indicated that 72 percent of the agreements allowed the pharmaceutical firm to retain at least partial ownership of patents that were the product of the biotechnology startup's research, suggesting that the alliances encouraged the development of inventions as well as the flow of information between the partners.[134] In examining the number of patents that emerging companies had obtained at the time they partnered with larger pharmaceutical companies, the study concluded that "R&D firms with fewer patents give up more control rights."[135] Thus, patent rights may provide some leverage for smaller companies in structuring commercialization alliances and encourage cooperative development.[136]

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[129] Thomas Hellman, *The Role of Patents for Bridging the Science to Market Gap*, 63 J. ECON. BEHAV. & ORG. 624, 624–46 (2007); *see also* Deepak Hegde & Hong Luo, *Patent Publication and the Market for Ideas*, 64 MGMT. SCI 652 (2017) (finding that inventions published eighteen months after patent application filing were licensed on average ten months earlier than those that were not published until patent issuance); *cf.* Gaétan de Rassenfosse et al., *Why Do Patents Facilitate Trade in Technology? Testing the Disclosure and Appropriation Effects*, 45 RES. POL'Y 1326 (2016) (finding that once the parties have met, "disclosure through the patent document does not increase the chance of success during negotiation").

[130] Arora & Ceccagnoli, *supra* note 112, at 293.

[131] *See* Arora & Merges, *supra* note 112; PISANO, SCIENCE BUSINESS, *supra* note 17, at 163–65 (describing vertical integration, organizational boundaries, and information asymmetry).

[132] *See* Arora & Ceccagnoli, *supra* note 112; Arora & Merges, *supra* note 112; Branstetter et al., *supra* note 112; Oxley, *supra* note 112, at 288; Pisano, *supra* note 120.

[133] Lerner & Merges, *supra* note 101.

[134] *See id.* at 143, Table V.

[135] *Id.* at 147.

[136] *See id.*

III. CONTEXTUALIZATION: EXAMPLES FROM THE MEDICAL DEVICE INDUSTRY

The role of patents in facilitating the exchange of information is highly contextual. To provide a richer description of the role of patents throughout the innovative process, this Part examines the important, yet largely-overlooked medical device industry. Information about medical device startups is typically not publicly available. The examples described in this Part, drawn from a series of interviews with medical device professionals from small and medium-sized firms, begin to fill that void. The narrative set forth by the interviews provides a more complete account of the manner in which patents may encourage information exchange during the innovative process.

This Part begins with an overview of the medical device industry and the process of classifying medical devices to ground the discussion. Next, details related to interview methodology are summarized. Drawing upon the interviews with medical device professionals, I then describe the role of patents in information exchange during the early stages of investment seeking, followed by their information-facilitating functions during the later stages of commercialization for medical device startups.

A. The Medical Device Industry Landscape

Characterizing the medical device industry is complex, as it encompasses many industries that supply hundreds of thousands of products.[137] The Federal Food, Drug, and Cosmetic Act (FDCA) defines a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."[138]

Recent data from the USPTO suggests that patents have become increasingly important in the medical device industry. For example, in 2015, the USPTO awarded 17,596 medical device patents.[139] One decade earlier, in 2005, the USPTO granted only 37.5 percent of that number—6,603 medical device patents.[140]

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[137] *See* LOO, *supra* note 23, at 19–20.

[138] Federal Food, Drug, and Cosmetic Act § 201(h)(2), 21 U.S.C. § 321(h)(2).

[139] *Medical Devices: All Classified Utility Patents (OR/XR)*, U.S. PAT. & TRADEMARK OFF, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/meddev.htm#PartA1_1 [https://perma.cc/74YW-GYKV].

[140] *Id.*

Medical devices generally include products of two types: conventional products as well as high-technology products.[141] Conventional products, such as standard wound dressings, gloves, and syringes, are relatively easy to manufacture and price-sensitive.[142] Typically, new entrants to the market for these types of devices will face significant competition and low profit margins.[143] High-technology products, such as implantable orthopedic or cardiovascular devices, generally require costly research and development as well as regulatory review, which are significant barriers to entry for new market participants.[144] A company with a product in this second category that can show clinical utility and limited competition can "command premium pricing."[145] Most of the discussion in this article will focus on innovation resulting in high-technology devices.

The medical device industry is comprised of a comparatively small number of large corporations, such as Johnson & Johnson and Medtronic, and a large number of small to mid-sized companies that seek to develop new technologies in highly-specialized areas.[146] Both types of companies make important contributions in bringing new medical devices to market. Large corporations command the lion's share of revenue in the medical industry.[147] They tend to be diversified, producing both conventional and high-technology products.[148] Through their sales of conventional products, large companies can help provide the necessary resources for R&D and commercialization of high-technology products.[149] Large companies engaging in R&D often focus on making incremental improvements to devices already in existence, as opposed to discovering and developing new

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141 MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 208.

142 LOO, *supra* note 23, at 20.

143 *Id.*

144 *Id.*

145 *Id.*

146 *See id.* at 19–20; *see also* MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 209 (stating that "73% of medical device firms had fewer than 20 employees and 88% had fewer than 100 employees").

147 *See* LOO, *supra* note 23, at 19 ("Large corporations with global scale . . . dominate these fields . . . ."); JANE G. GRAVELLE & SEAN LOWRY, CONG. RESEARCH SERV., R43342, THE MEDICAL DEVICE EXCISE TAX: ECONOMIC ANALYSIS 10 (2015) ("The top 1% of firms (by asset size) accounted for approximately 78.5% of receipts in the industry in 2012.").

148 *See* MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 208; LOO, *supra* note 23, at 19.

149 *See* LOO, *supra* note 23, at 20–21, 28 (noting that although the amount of R&D spending varies greatly among large medical device companies, "the medical technology equipment group plows an average 9% to 11% of annual revenues back into R&D, versus 3% to 4% for all US manufacturers").

technologies.[150] Truly novel products in the medical device industry often originate with small and mid-sized companies.[151] Venture capital firms typically provide funding to these smaller companies, hoping to obtain an attractive return on investment for a promising device.[152] Large companies may also acquire or invest in emerging companies as a way to innovate.

Investment is very important to the development of most new medical devices, given the long time frame involved. Bringing a new medical device to market takes on average from three to seven years.[153] A new medical device is often created as a result of physicians trying to solve a problem they have encountered.[154] Once a prototype is built, or sometimes before, the process of applying for patent protection begins.[155] The process of initial testing, animal testing, and iterative changes in design as a result of additional testing often lasts for two to three years, costing approximately $10 million to $20 million.[156] Consequently, most new medical devices arise out of startups backed by venture capital financing.[157] Additionally, many small companies are initially supported by investment funding because they typically have limited resources and minimal or no revenue prior to receiving regulatory approval and eligibility for insurance

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[150] *See id.* at 21 (explaining that life cycles for medical devices are often shorter than products in the pharmaceutical area because of the incremental improvements made to devices).

[151] *Id.* at 19–20.

[152] *See* MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 210.

[153] Gail A. 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) (stating, in comparison, new drug approval may take an average of twelve years).

[154] *See* MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 211 ("Device makers often seek the input of physicians about the design and potential uses for new products and solicit feedback from physicians who use their products."); Van Norman, *supra* note 153, at 278. Perhaps for this reason, as well as regulatory hurdles, non-practicing entities (NPEs) do not appear to pose as large of a threat in the medical device industry when compared with technology industries more generally. *See* Colleen V. Chien, *Patent Assertion and Startup Innovation*, NEW AM. FOUND. OPEN TECH. INST. 1, 11 (2013), https://ssrn.com/abstract=2321340 [https://perma.cc/F5KV-4DHC] (finding that although 90 percent of technology venture capitalists surveyed reported having invested in a company with a portfolio affected by NPEs, only 13 percent of bio/pharma or medical device venture capitalists had received a demand from a NPE); LANDAN ANSELL ET AL., 2018 PATENT LITIGATION STUDY, PRICEWATERHOUSECOOPERS 11 (2018), https://www.pwc.com/us/en/forensic-services/publications/assets/2018-pwc-patent-litigation-study.pdf [https://perma.cc/PH32-9PSR].

[155] *See* Aaron V. Kaplan et al., *Medical Device Development: From Prototype to Regulatory Approval*, 109 CIRCULATION 3068, 3068–72 (2004); Van Norman, *supra* note 153, at 278.

[156] *See* Kaplan et al., *supra* note 155, at 3069; Van Norman, *supra* note 153, at 278.

[157] *See* MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 210–11; Kaplan et al., *supra* note 155, at 3068; Van Norman, *supra* note 153, at 278.

coverage, payment, and reimbursement.[158] As described above in relation to the biotechnology industry, the expense and long time frame involved in bringing inventions to market in the medical device industry highlights the importance of patents in facilitating investment.[159]

Obtaining venture capital funding has become more difficult for medical device companies in recent years. From 2007 to 2015, the share of total venture capital funding for medical device companies has fallen from 7.9 percent to 6.1 percent.[160] And since 2007, annual venture capital funding for medical device companies declined from approximately $3.7 billion to a range of approximately $2.2 billion to $2.9 billion.[161] Large medical device corporations have filled some of the funding gap by investing in and acquiring smaller medical device companies,[162] but some commentators have expressed concern about whether these declining trends in funding will affect innovation in the medical device industry.[163]

Both large medical device corporations and startups benefit from alliances and acquisitions. As in the biotechnology industry, large corporations benefit by avoiding some of the risks and the long timeframe associated with developing new high-technology devices, and they gain expertise in a particular area as well as the experience of the startup's team.[164] Acquisitions can also enhance large companies' R&D efforts, allowing them to expand into new technological areas.[165] Startups receive an influx of resources, and they benefit from the large companies'

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158 INST. OF MED., *supra* note 25, at 170 ("In general, for nearly all device-based therapies and many diagnostic tests, a device must be cleared or approved and have valid current procedural terminology codes for a medical service before an insurer or payer will consider covering the service."); MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 210 ("These companies typically spend a large share of their revenues on research and development and may be unprofitable for years before developing a viable product or going out of business.").

159 *See supra* Section I.B.

160 MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 210–11.

161 *Id.*

162 *See* Ackerly et al., *supra* note 23, at w68 ("After a product reaches a certain stage of development, these small companies are frequently acquired by larger companies to complete the development, production, and marketing of products.").

163 MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 211.

164 *See* LOO, *supra* note 23, at 19–20; MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 211; *supra* Section I.B.

165 *See* Brougher et al., *supra* note 2, at 12 ("[P]artnerships are especially important as companies are increasingly exploring mergers and acquisitions as a way to leverage existing intellectual property assets and generate new sources of capital and revenue."); MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 211. Biotechnology companies often acquire startups to bolster their R&D as well. *See supra* Section I.B.

established relationships with physicians, hospitals, and their marketing and distribution connections.[166]

B. The Classification of Medical Devices

The importance of obtaining investment depends in part on the costs associated with regulatory review. Before they can be marketed, medical devices undergo regulatory review by the FDA, which classifies medical devices according to risk.[167]

Medical devices are sorted into three classes, with regulatory control increasing from Class I to Class III to assure safety and effectiveness.[168] Class I devices are considered low- to moderate-risk, such as a manually-operated toothbrush or bandages.[169] They need to meet the General Controls provisions, which for example protect against adulteration and misbranding.[170] Class I devices should also ensure Good Manufacturing Practices have been followed, but otherwise tend to be exempt from the regulatory process.[171] Therefore, going through the regulatory process will not comprise the bulk of the costs of commercializing Class I devices, and obtaining early-stage investment funding may be less critical for these types of inventions.

Class II devices are considered moderate- to high-risk; examples include electric wheel-chairs and pregnancy tests.[172] Devices in Class II typically need to comply with both the General Controls as well as Special Controls, which are regulatory requirements to provide "reasonable assurance of the safety and effectiveness of the device."[173] Class II devices generally are subject to a premarket notification process known as 510(k), which requires the applicant to demonstrate that the

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[166] MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 211.

[167] Federal Food, Drug, and Cosmetic Act § 360c, 21 U.S.C. § 360c (classifications).

[168] *Id.*

[169] *See id.* § 360c(a)(1)(A); *see also General Controls for Medical Devices*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm#application_of_provisions [https://perma.cc/JJY4-N4TU] ("Class I devices are not intended for use in supporting or sustaining life or to be of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable risk of illness or injury."); *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm [https://perma.cc/H2XS-VNVE] (approximately 47 percent of medical devices fall within Class I).

[170] 21 U.S.C. § 360c.

[171] *Id.*

[172] *See id.*; *General Controls for Medical Devices*, *supra* note 169; *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, *supra* note 169 (about 43 percent of medical devices are in Class II).

[173] 21 U.S.C. § 360c; *see also General Controls for Medical Devices*, *supra* note 169 (noting Special Controls are typically specific to the device, such as requiring post-market surveillance, patient registries, and special labeling requirements).

new device is "substantially equivalent" in safety and effectiveness to a legal medical device that is already in existence (a "predicate").[174]

Class III devices are viewed as high-risk, or they have not been found substantially equivalent to existing medical devices through the 510(k) process.[175] Examples include breast implants and implantable pacemakers.[176] Prior to marketing, Class III devices that are not eligible for the 510(k) process—as well as truly new devices, even if they are not high-risk—need to go through the expensive and comprehensive premarket approval (PMA) process.[177] The PMA process requires that the applicant submit extensive clinical data "provid[ing] reasonable assurance of [the] safety and effectiveness" of the device.[178]

C. Methodology

Over the course of a year, I conducted interviews with fourteen professionals in the medical device industry, primarily from startup companies.[179] Interviewees were selected based

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[174] Content and Format of a 510(k) Summary, 21 C.F.R. § 807.92. The FDA has exempted some Class II devices from premarket notification required by § 510(k). *See, e.g.*, Medical Devices; Exemptions from Premarket Notification: Class II Devices, 82 Fed. Reg. 31,976, 31,976–32,001 (July 11, 2017); Van Norman, *supra* note 153, at 278 ("Around three-fourths of Class I devices, and a small percentage of [C]lass II devices qualify for 'exempt' status, meaning there is no need for proof of safety or efficacy, nor for clinical trials . . . . [and] the standard pre-market notification (PMN) process." (internal citation omitted)).

[175] *See* 21 U.S.C. § 360c; Content and Format of a 510(k) Summary, 21 C.F.R. § 807.92; *Overview of Device Regulation*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm [https://perma.cc/G6HU-WV55]. New devices are typically grouped under Class III and typically need to go through the PMA process described below. Van Norman, *supra* note 153, at 278. Applicants can request reclassification if the new device is not high-risk as a "de novo" device, which enables it to go through the 510(k) process instead of the PMA process. *Id.*; *see also Evaluation of Automatic Class III Designation (De Novo) Summaries*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm232269.htm[https://perma.cc/5UV6-W3S9].

[176] *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, *supra* note 169 (noting that approximately 10 percent of medical devices are within Class III).

[177] *See* 21 U.S.C. § 360c; Content and Format of a 510(k) Summary, 21 C.F.R. § 807.92; *see also Overview of Device Regulation*, *supra* note 175; H.R. REP. NO. 101-808 (1990), *as reprinted in* 1990 U.S.C.C.A.N. 6305, 6307 (stating that "98 percent of the estimated 5000 devices that enter the market every year do so on the basis of a claim by their manufacturer that they are substantially equivalent to an earlier device . . . . [and] over 80 percent of the devices that are potentially the most dangerous (Class III) enter the market on the basis of a claim by the manufacturer that they are 'substantially equivalent' to a device already on the market"); Michael Drues, *Are You Sure You Know the Best Regulatory Pathway for Your New Medical Device?*, MED DEVICE ONLINE (Mar. 18, 2015), https://www.meddeviceonline.com/doc/are-you-sure-you-know-the-best-regulatory-pathway-for-your-new-medical-device-0001 [https://perma.cc/TG95-ACQ5] (describing additional pathways by which 5 percent of medical devices are "brought to market").

[178] 21 U.S.C. § 360c(a)(C).

[179] Even though the interviews described are not meant to provide quantitative evidence as to the frequency or regularity of occurrences, one question is whether the

upon their experience in the medical device industry and their agreement to be interviewed. The subjects are or were active participants in the medical device industry, either in a legal, business, technical, or mixed capacity. The individuals interviewed were determined in a variety of ways. Many were professionals from companies located throughout the country that I met at a conference. Others were located based on introductions provided by previous interview subjects.

The majority of interviews were conducted in-person, with a few taking place telephonically, as indicated, on the dates stated in Appendix B. Each interview lasted at least thirty minutes, though several lasted over sixty minutes. Each interviewee consented to participate in the research project and was given the opportunity to review a draft of this article prior to publication. The interview subjects were promised anonymity for themselves as well as their companies. As such, I use the term "Executives" to refer to Investors, CEOs, Presidents, Vice Presidents, General Counsels, IP Strategists, and outside counsel of medical device companies. The term "Scientists" includes researchers, scientists, CTOs, and product developers. These terms, set forth in Appendix B, are used to refer to each interview in the body of the article.

The interviews were semi-structured, meaning that the same set of open-ended questions was used for each subject, with some variation depending on relevance to the individual's situation. Detailed follow-up questions were tailored to each interviewee's response. The general questions were directed to the following areas: how important patents were to the subject's business and to obtaining investment, including how patents were used to communicate with prospective investors; to what extent the availability or absence of patent protection for the subject's inventions, as well as those of its competitors, had a bearing on commercialization; and how patents were used in structuring

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number of interviews is sufficient to provide contextualization of the innovative process. Numerous studies have shown that conducting fourteen interviews is typically considered adequate to obtain a decent perspective for this purpose before saturation, where little new information is obtained with each subsequent interview. *See, e.g.*, Ray Galvin, *How Many Interviews Are Enough? Do Qualitative Interviews in Building Energy Consumption Research Produce Reliable Knowledge?*, 1 J. BUILDING ENGINEERING 2, App. B (2015) (demonstrating that fourteen interviews, if randomly drawn, could reliably identify views held by 20% to 100% of a target population); Greg Guest et al., *How Many Interviews Are Enough? An Experiment with Data Saturation and Variability*, 18 FIELD METHODS 59, 79 (2006) (concluding that "[f]or most research enterprises . . . in which the aim is to understand common perceptions and experiences among a group of relatively homogeneous individuals, twelve interviews should suffice"); Ashley K. Hagaman & Amber Wutich, *How Many Interviews Are Enough to Identify Metathemes in Multisited and Cross-Cultural Research? Another Perspective on Guest, Bunce, and Johnson's (2006) Landmark Study*, 29 FIELD METHODS 23, 23 (2016) (stating that "16 or fewer interviews is enough for studies with relatively homogeneous groups").

partnerships with other companies, such as in creating alliances for manufacturing, marketing, and distribution.

The examples set forth in this article are limited to the perceptions of the subjects that agreed to be interviewed. As such, the discussion is necessarily incomplete. Despite these limitations, however, the examples provided are helpful to understanding the role of patents in the innovative process, particularly as it pertains to startups in the medical device industry, given the small size of the vast majority of companies in this industry and that data about them is not typically publicly available.[180]

D. The Innovative Lifecycle

In the beginning of the innovative timeline, there are two prototypical startup models for medical device firms when a device requires FDA review: (1) the "PMA model," for those involving high-risk devices, which typically must go through the premarket approval process before entering the market; and (2) the "510(k) model," for other devices, which are generally subject to the premarket notification process.[181]

Medical device companies generally prefer to engage in the quicker, simpler, and less costly 510(k) process.[182] The PMA process requires the submission of detailed clinical trial data that is expensive and time-consuming to acquire, while the 510(k) process typically only requires applicants to submit information to "provide an understanding of the basis for a determination of substantial equivalence" between the new device and the predicate device.[183] For devices that must go through the PMA process, patent protection is often essential to securing the

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[180] MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 209.

[181] Telephone Interview with Exec. V (July 2017); *see* Content and Format of a 510(k) Summary, 21 C.F.R. § 807.92.

[182] *See* INST. OF MED., *supra* note 25, at 170–71 ("Because the 510(k) pathway is less expensive and less time-consuming than the PMA pathway, medical-device companies view it as a useful mechanism for bringing moderate-risk devices to market."); *see also* Drues, *supra* note 177 ("90 percent of medical devices (by volume) that are brought to market in the U.S. go through the 510(k). . . . Only about 5 percent of devices brought to market are PMAs."); MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 210–11 ("One study found that 67 percent of medical devices that entered the market between 2003 and 2007 were exempt from any FDA review (these are mostly Class I devices that need to be registered only before they can be marketed), 31 percent entered through the 510(k) process, and 1 percent entered through the PMA process.").

[183] Content and Format of a 510(k) Summary, 21 C.F.R. § 807.92(a). Sometimes, devices that undergo the 510(k) process contain some amount of clinical data. *See* Jordan Paradise et al., *Evaluating Oversight of Human Drugs and Medical Devices: A Case Study of the FDA and Implications for Nanobiotechnology*, 37 J.L. MED. & ETHICS 598, 602 (2009) ("The average review time for a 510(k) submission is approximately three months. . . . [A]nd the average review time for a PMA is approximately 8.5 months.").

investment necessary to undertake the costs associated with that process. One survey from 2010 found that the average cost to undergo the PMA process is $94 million.[184] Clinical trials generally take place over a few years, may involve up to one thousand patients, and may require follow-up after treatment.[185]

Even under the less onerous 510(k) model, intellectual property rights provide a way for medical device firms to recoup the costs of research and development. Bringing a product from idea to market using the 510(k) process has been found to cost $31 million on average.[186] Obtaining 510(k) clearance is often viewed as "an event that triggers transactions that result in change in ownership of intellectual property and return of investment to venture capitalists and other investors."[187]

Startups generally make sure that their inventions are protected long before entering the regulatory process because of its high costs and long timeframe.[188] For startups undergoing the PMA process, patents play a pivotal role in facilitating discussions with investors to obtain funding. A medical device startup might be able to negotiate and obtain "friends and family" investment without patents, but typically not "smart money"; intellectual property rights are often critical for each additional round of financing to be successful.[189] In obtaining funding, the strength of the startup's intellectual property position is not only about the number of patents in a given company's portfolio, the breadth and freedom to operate also

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[184] *See* JOSH MAKOWER ET AL., FDA IMPACT ON U.S. MEDICAL TECHNOLOGY INNOVATION 28 (Nov. 2010), http://www.advamed.org/sites/default/files/resource/30_10_11_10_2010_Study_CAgenda_makowerreportfinal.pdf [https://perma.cc/ES4N-K5DC]; Telephone Interview with Exec. V (July 2017); Telephone Interview with Exec. VI (July 2017) (companies "need that [patent] reward at the end because it's very expensive," especially if they have to go through the expensive PMA or de novo processes).

[185] *See* Kyle M. Fargen, *The FDA Approval Process for Medical Devices: An Inherently Flawed System or a Valuable Pathway for Innovation?*, 5 J. NEUROINTERVENTIONAL SURGERY 269, 269–75 (2013); Van Norman, *supra* note 153, at 278.

[186] MAKOWER ET AL., *supra* note 184, at 28; *see also* INST. OF MED., *supra* note 25, at 170.

[187] INST. OF MED., *supra* note 25, at 170.

[188] *See* Brougher et al., *supra* note 2, at 3 ("By protecting its intellectual property, the medical device company can ensure that its technology has the intellectual property market value it needs to attract venture capital . . . ."); Kesler et al., *supra* note 90, at 32–33.

[189] Interview with Scientist II (June 2017); *see* Brougher et al., *supra* note 2, at 12 ("Obtaining venture capital funding often depends on the nature and extent of a company's intellectual property portfolio."); Joan Farre-Mensa et al., *What Is a Patent Worth? Evidence from the U.S. Patent "Lottery"* 27 (USPTO Econ., Working Paper 2015-5, 2019), https://ssrn.com/abstract=2704028 [https://perma.cc/L8PS-QWYJ] (finding startups that obtain a patent are more likely to secure venture capital funding); *see also* Graham et al., *supra* note 14, at 1277–78; Kesler et al., *supra* note 90, at 33 ("Venture funding often hinges on the strength of a start-up's patent portfolio and how effectively that portfolio protects the ideas behind the start-up.").

matters.[190] Freedom to operate means that the company's production of its product or service will not infringe another's patent rights.[191] In recent years, venture firms have been "requiring more information, in more different areas of a business proposal and in much greater depth than ever before."[192] In the early stages when medical device startups are trying to obtain financing, interviewees stated that companies prefer to have at least one issued patent, and many pending applications.[193] In the development stage, obtaining funding is necessary to work on improvements and conduct clinical trials.[194] At this point in the timeline, startups may still rely on the initial patents in negotiating with investors.[195]

Once the FDA approves the device, medical device companies need to obtain funding to cover the costs of setting up a sales force and commercializing, as well as conducting studies to obtain health care reimbursement.[196] Investors take patents very seriously at this point; they view patents as a way to prevent follow-on competition and expropriation by unrelated parties.[197] Consistent with this view, medical device companies will often broaden their portfolio by filing additional applications as often as possible at this point.[198] Interviewees stated that investors expect to see at least two to four patents to ensure a larger competitor does not "bully" the startup out of the market.[199] Without adequate patent protection, a competitor can "lurk" in the background while an inventor's company "leads the struggle to gain FDA approval, and emerge from the pack just

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[190] Interview with Scientist V (Dec. 2017, June 2018) (in-person and telephonic).

[191] Tom Ewing & Robin Feldman, *The Giants Among Us*, 2012 STAN. TECH. L. REV. 1, 30.

[192] Brougher et al., *supra* note 2, at 27.

[193] Telephone Interview with Exec. V (July 2017); Telephone Interview with Exec. VI (July 2017).

[194] Telephone Interview with Exec. V (July 2017).

[195] *Id.* (Investors want to know that the groundwork has been laid, and the investment will "bear fruit." They also expect the company to have a "good handle" on freedom-to-operate, which is assurance that the device will not be infringing another company's patent.)

[196] *Id.*; *see* Brougher et al., *supra* note 2, at 1, 3 ("Medical device products are being reimbursed by government-funded programs, such as the Centers for Medicare & Medicaid Services (CMS), as well as by commercial payers.").

[197] Telephone Interview with Exec. V (July 2017); *see* Kesler et al., *supra* note 90, at 32–33.

[198] Telephone Interview with Exec. VI (July 2017); *see* Kesler et al., *supra* note 90, at 33–34.

[199] Telephone Interview with Exec. V (July 2017); *see* Kesler et al., *supra* note 90, at 32 ("Without patent protection, once the idea is publicized there is no way to stop an often larger, better-funded company from simply taking or copying [the startup's] inventions.").

in time to claim substantial similarity and gain streamlined FDA approval for its competing product."[200]

The last stage in the supply chain is manufacturing. Key components are sometimes made by external component manufacturers who seek the reassurance of patents before entering into agreements.[201] Manufacturers who make investments in specialized equipment and processes to manufacture a new product want to feel secure that the product will not be expropriated or the subject of an infringement suit.[202] When the key components can be combined in-house, however, the need for strong patents is decreased because the risks of expropriation similarly decrease.[203]

For funding the development of devices that are subject to 510(k), as well as for Class I devices not subject to FDA regulation, patents are important at the beginning to facilitate negotiation between startups and investors, similar to their role in the PMA process.[204] Because of the abbreviated timeframe of the 510(k) process, however, interviewees explained that expedited processing at the USPTO is especially important, and startups will generally have many patent applications filed if they have the resources available.[205]

Devices subject to the 510(k) process are often manufactured internationally, especially in Mexico and China.[206] For large contract manufacturers, intellectual property is important. According to one interviewee, factories do not have enough capacity, so they can be selective about the companies they choose to work with.[207] Large manufacturers do not want a startup to be "eclipsed" by a larger company and have to manufacture a new product.[208] So, a startup usually will not be able to enter into an alliance with a top tier manufacturer unless the startup has patent protection.[209] Without patents, startups

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[200] *See* Kesler et al., *supra* note 90, at 32.

[201] Telephone Interview with Exec. V (July 2017).

[202] *See infra* notes 207–209 and accompanying text.

[203] *See infra* note 209 and accompanying text; Barnett & Sichelman, *supra* note 106, at 9 ("[T]he expropriation risk posed by a departing employee would be limited to informational assets that fall outside its patent portfolio.").

[204] Telephone Interview with Exec. V (July 2017); *see* Brougher et al., *supra* note 2, at 3; Farre-Mensa et al., *supra* note 189; Graham et al., *supra* note 14, at 1277–78.

[205] Telephone Interview with Exec. V (July 2017).

[206] *See id.* (explaining that for some countries, having patents anywhere, and in their country in particular, is a "weighing factor" that helps with reimbursement and the regulatory approval process); *see also* LOO, *supra* note 23, at 29 ("Many Western medical products companies are outsourcing manufacturing to countries with low production costs, mostly in Latin America and the Far East.").

[207] Telephone Interview with Exec. V (July 2017).

[208] *Id.*

[209] *Id.* (noting, however, that the manufacturers may not be that thorough with their diligence, so the quality of the patents may not be high).

can usually only enter into partnerships with lower tier manufacturers, where there are often quality issues.[210]

The role of patents in funding discussions with investors can also vary depending on sales of the product. According to one interviewee, when revenue is between $1 million and $5 million each year, medical device companies typically have obtained a patent before they enter into negotiations with potential investors to signal their innovativeness and that the product will be viable in the marketplace.[211] At approximately $10 million to $20 million of revenue per year, companies "become interesting to competitors," and patents are important to deter copying.[212] As revenues approach $20 million, potential acquirers and follow-on investors care about the company's intellectual property position.[213] For companies that go through an initial public offering, the amount and strength of intellectual property and freedom to operate become critical to ward off competition—companies want to have "solid protection" in place to prevent "knock-offs."[214]

At the acquisition stage, patents can help facilitate communication between large companies and potential targets. Large companies often seek to acquire innovative startups in the medical device industry, viewing acquisition as "an important method of sustaining both revenue growth and margin expansion."[215] Potential acquirers have an expectation that the patent will provide some measure of protection against expropriation.[216] Startups typically have "locked down coverage" at this stage, meaning they have received patents that cover the commercial product.[217] Potential acquirers care about the freedom-to-operate position—the startup will be able to use its intellectual property protection to gain market share and create a "new niche or carv[e] into a competitor's space."[218]

To gain a more complete understanding of the role of patents in the acquisition of medical device companies, I

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[210] *Id.*

[211] *Id.* (At that point, investors are most concerned with sales and whether the company can maintain double-digit growth.).

[212] *Id.* (If a company has less than $10 million in revenue each year, competitors believe the company will likely "plateau.").

[213] *Id.*; Telephone Interview with Exec. VI (July 2017) ("There's nothing like a patent claim you can enforce to make your market.").

[214] Telephone Interview with Exec. V (July 2017); *see* Ewing & Feldman, *supra* note 191, at 26–28; Kesler et al., *supra* note 90, at 33.

[215] LOO, *supra* note 23, at 30.

[216] Telephone Interview with Exec. VIII (June 2018); Telephone Interview with Exec. VI (July 2017) (stating the main question is whether the startup can "keep people out of the space"); *see* Kesler et al., *supra* note 90, at 32.

[217] Telephone Interview with Exec. VIII (June 2018); *see* Interview with Exec. IX (June 2018); Kesler et al., *supra* note 90, at 32–33.

[218] Brougher et al., *supra* note 2, at 3; *see* Interview with Exec. IX (June 2018).

examined publicly-available information about acquisitions of medical device companies by the three largest medical device firms, in terms of revenue—Johnson & Johnson, Medtronic, and Philips—analyzing their 10-K annual reports and press releases from approximately the last six years.[219] I evaluated the number of patents that each acquired company had obtained before their respective acquisition dates (through July 13, 2018).[220] The results of the research are set forth in Appendix A. For medical device companies that were acquired between June 2012 and July 2018 by one of the three largest firms in the medical device industry, 87 percent of targets had obtained at least one issued patent prior to the date the companies were acquired.[221] The median number of issued patents held by a target prior to acquisition was five patents. This data indicates that the vast majority of targets hold at least one issued patent prior to acquisition by the three largest medical device firms.

E. Exchanging Information with Investors in the Medical Device Industry

Patents play numerous roles in encouraging the exchange of information during the investment-seeking process in the medical device industry. One role is reducing the likelihood that the medical device will be expropriated. The risks of expropriation at this stage vary depending on the circumstances, which were set forth from a theoretical perspective in Part I and will be contextualized with examples from the medical device industry in this Part. Some of the variables in assessing expropriation risks, and consequently the function of patents in enabling information exchange, include whether the medical device is self-disclosing and easily reverse engineered, the importance of reputational and industry norms, and whether staging disclosure over time is an option.[222] Time and resource constraints may limit the efficacy of some of these alternative mechanisms to patents in mitigating the risks of expropriation.[223]

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[219] *See The Top 50 Medical Device Companies*, HS&M, June-July 2017, at 23–24, http://www.hsandmdigital.com/hsandm/june_july_2017/?pm=2&u1=friend&pg=NaN#pgNaN [https://perma.cc/R3PY-N593]; *Big 100 2016: Medtech's 100 Largest Players*, MED. DESIGN & OUTSOURCING, Sept. 2016, at 12, https://www.medicaldesignandoutsourcing.com/2016-big-100/ [https://perma.cc/YG28-3BXB]. Forms were found using the U.S. Securities and Exchange Commission website. *See Edgar Company Filings*, U.S. SEC. & EXCHANGE COMMISSION, https://www.sec.gov/edgar/searchedgar/companysearch.html [https://perma.cc/55ZW-N54E].

[220] *See* U.S. PAT. & TRADEMARK OFF., www.uspto.gov [https://perma.cc/A2SB-GPNF].

[221] *See infra* App. A.

[222] *See infra* Section III.E.1.

[223] *See infra* Section III.E.1.

Apart from their ability to ensure exclusivity, patents have an independent function of providing a useful signal to investors about information distinct from the medical device invention, such as resource allocation and the experience of the executive team, similar to their role in the biotechnology industry.[224] An issued patent can also provide an indication about the viability of the invention, such as the ability to limit competition, extend the first mover advantage, and provide an independent source of value to the company through licensing or sale.[225]

One survey of twenty venture capital fund managers looked at the importance of intellectual property protection in assessing the risk-return ratio of portfolio companies.[226] For medical device companies, respondents ranked intellectual property protection third, after reimbursement and regulatory concerns at the FDA.[227] The authors of the survey reasoned that intellectual property protection was a concern of venture fund managers, given the high patenting rates among venture-backed companies and that the size of medical device companies necessitated "their reliance on patent protection to maintain barriers to market entry by competitors."[228] Additionally, court decisions that cast doubt on whether patent protection would be available for some medical devices have also raised concerns.[229]

1. The Role of Patents in Facilitating Information Exchange for Self-Revealing Medical Devices

For many medical devices, the "gist" is mechanical—they are self-revealing.[230] These inventions typically require significant investment for commercialization, and they usually can be duplicated comparatively inexpensively once they have been disclosed, absent intellectual property protection or other restrictions.[231] Because this technology is fully disclosed when it is demonstrated to investors, disclosing in stages is not a feasible option. Where the invention is "not Coca Cola—there's no secret sauce," obtaining patent protection is viewed as essential before

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[224] *See supra* Sections I.B, I.C.

[225] *See supra* Section I.C.

[226] *See* Ackerly et al., *supra* note 23, at w71–72.

[227] *Id.*

[228] *Id.*

[229] *Id.* at w72.

[230] Telephone Interview with Exec. V (July 2017); *see* Telephone Interview with Exec. VII (Aug. 2017).

[231] *See* Kesler et al., *supra* note 90, at 32; Adam Lewin, Note, M*edical Device Innovation in America: Tensions Between Food and Drug Law and Patent Law*, 26 HARV. J.L. & TECH. 403, 411–12 (2012).

negotiating with investors to mitigate expropriation risks.[232] Inventors prefer to have a patent application filed before meeting with investors to protect against the investor taking it or creating something very similar through another investment.[233] In early-stage financing negotiations, medical device startups typically will not be able to obtain financing without a patent application on file.[234]

Although company founders initially may be focused on trying to solve a problem rather than securing intellectual property rights, they quickly realize that patents are very important when they reach out to potential investors.[235] In these early stages, where the startup may not have customers or profit, sophisticated investors carefully examine the intellectual property position of the startup and how far along it is in the patent prosecution process.[236] For example, issuance or even a substantial office action[237] holds significant weight, while provisional applications do not, given the often vast difference between the patent application that is initially filed and the claims that ultimately issue.[238]

Investors "fast forward to commercialization" during the early stages of negotiations with startups, recognizing companies that do not have patents at commercialization will be "dead."[239] Investors examine whether, later in the commercialization process, the patent will be broad enough to protect the product but narrow

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[232] Interview with Scientist II (June 2017); *see* Interview with Exec. I (June 2017); Interview with Scientist IV (June 2017); Iliev et al., *supra* note 2, at 66; Kesler et al., *supra* note 90, at 32.

[233] Telephone Interview with Exec. V (July 2017); *see* Iliev et al., *supra* note 2, at 66; Kesler et al., *supra* note 90, at 32.

[234] *See* David S. Levine & Ted Sichelman, *Why Do Startups Use Trade Secret?*, 94 NOTRE DAME L. REV. 751, 796 (2018) (noting that "for medical device companies, secrecy stood just behind first-mover advantage and patents—and greatly exceeded the value of reverse engineering [as an appropriability mechanism]," but recognizing study limitations of a relatively modest sample size and average response rate in some technological areas); Farre-Mensa et al., *supra* note 189, at 4; Iliev et al., *supra* note 2, at 66; Kesler et al., *supra* note 90, at 32; Telephone Interview with Exec. VII (Aug. 2017).

[235] Interview with Exec. IV (June 2017); Interview with Exec. I (June 2017); *see* Iliev et al., *supra* note 2, at 66; Kesler et al., *supra* note 90, at 32.

[236] Interview with Scientist V (Dec. 2017, June 2018) (in-person and telephonic); *see* Interview with Exec. IX (June 2018).

[237] *Office Action Research Dataset for Patents*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/learning-and-resources/electronic-data-products/office-action-research-dataset-patents [https://perma.cc/UJ5Z-YHFQ] (defining an office action as "a written notification to the applicant of the examiner's decision on patentability [that] generally discloses the grounds for a rejection, the claims affected, and the pertinent prior art").

[238] Interview with Exec. IX (June 2018) (reasoning that investors tend to not place much weight on provisional applications because patent scope can change significantly prior to issuance). As described previously, issued patents can also indicate viability. *See supra* Section I.C.

[239] Interview with Exec. IX (June 2018); *see* Brougher et al., *supra* note 2, at 3; Iliev et al., *supra* note 2, at 66; Kesler et al., *supra* note 90, at 32–33.

enough to survive a prior art challenge.[240] Consequently, the prosecution of the patent portfolio has to be aligned with the development of the commercialized product.[241] If the patent portfolio can protect the product as well as competitive alternatives, it can act as an additional barrier to competition, extending the startup's first mover advantage.[242] Even though issued patents by themselves are not a guarantee that a product will have exclusivity, investors still rely on issued patents as increasing the likelihood that the product will have some limited period of exclusivity.[243] Investors are interested in whether similar devices exist in the marketplace, and whether the startup has "patents plus a better product" to have a viable business model.[244]

Timing is important for self-revealing inventions. Intellectual property is essential early in the fundraising process, where it can signal the startup's innovativeness and protect against expropriation.[245] Several interviewees described how startups recognize the importance of obtaining fast track approval to obtain prioritized review of their patent applications from the USPTO prior to meeting with investors.[246] Before entering into investment negotiations for mechanical devices, they try to be aggressive in filing applications on their ideas and competitive approaches.[247] Similarly, attorneys advising startups emphasized the importance of having patents on file for these types of inventions prior to disclosing them to investors.[248] The startup cannot disclose or sell the invention without patents, as it will be exposed to the risks of expropriation for self-disclosing inventions and will likely lose the ability to obtain patent protection later.[249]

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[240] Interview with Exec. IX (June 2018); *see* Kesler et al., *supra* note 90, at 33–34.

[241] Interview with Exec. IX (June 2018); *see* Kesler et al., *supra* note 90, at 34.

[242] Interview with Exec. IX (June 2018); *see* Kesler et al., *supra* note 90, at 33–34.

[243] Interview with Exec. IX (June 2018); *see* Kesler et al., *supra* note 90, at 32–33.

[244] Interview with Exec. IX (June 2018); *see* Iliev et al., *supra* note 2, at 66; Kesler et al., *supra* note 90, at 33–34.

[245] Interview with Scientist V (Dec. 2017, June 2018) (in-person and telephonic); *see* Kesler et al., *supra* note 90, at 32–33.

[246] *See Prioritized Patent Examination Program*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patent/initiatives/usptos-prioritized-patent-examination-program [https://perma.cc/DSG7-GHBT]; Telephone Interview with Exec. V (July 2017); Telephone Interview with Exec. VI (July 2017); Telephone Interview with Exec. VII (Aug. 2017).

[247] Telephone Interview with Exec. VII (Aug. 2017); *see* Kesler et al., *supra* note 90, at 33–34.

[248] Telephone Interview with Exec. VIII (June 2018); *see* Kesler et al., *supra* note 90, at 34.

[249] Interview with Exec. IX (June 2018); *see* 35 U.S.C. § 102; Kesler et al., *supra* note 90, at 32.

2. The Role of Patents in Facilitating Information Exchange for Inventions that are not Entirely Self-Revealing

For some medical devices, not all aspects of the invention will be self-revealing. Some medical devices allow for manufacturing techniques, the generation of user data, software, or other components to remain secret. For example, patents on medical devices that allow for generation of user data may be particularly attractive to investors.[250] A patent on a heart monitor or smart contact lens can allow a patent holder or its partners to collect information about a variety of biometric data about users, such as information about a given patient's blood pressure, drug usage, and stress levels.[251] As Ted Sichelman and I previously described, "data-generating patents" allow patent holders to obtain trade secret protection over user data generated through the usage of a patented device.[252] The collected user data can be analyzed and maintained as a trade secret even after the patent on the device is no longer in effect.[253]

Doctrinal shifts in the last decade have narrowed patent eligible subject matter for inventions related to diagnostic testing, further complicating negotiations related to these types of inventions.[254] In *Mayo v. Prometheus*, the U.S. Supreme Court held that Prometheus' personalized medicine dosing process was not eligible for patent protection.[255] It found that the patent claims covered "the underlying laws of nature themselves" and only "simply describe these natural relations."[256] The Court's decision effectively called into question the future of many diagnostic testing patents, likely changing the nature of negotiations with potential partners in this space.[257] Although inventions related to

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[250] Simon & Sichelman, *supra* note 9, at 393, 402; *see* Interview with Scientist V (Dec. 2017, June 2018) (in-person and telephonic) (describing the value of collecting biometric data generated by a patented medical device).

[251] Ted Sichelman & Brenda M. Simon, *The Pathologies of Data-Generating Patents*, *in* BIG DATA, HEALTH LAW, AND BIOETHICS 324, 324–27 (2018).

[252] Simon & Sichelman, *supra* note 9.

[253] *Id. See generally* Robert Cook-Deegan et al., *The Next Controversy in Genetic Testing: Clinical Data as Trade Secrets?*, 21 EUR. J. HUM. GENETICS 585 (2013) (describing incentives to promote sharing of clinical data); Leslie P. Francis, *Genomic Knowledge Sharing: A Review of the Ethical and Legal Issues*, 3 APPLIED TRANSNAT'L GENOMICS 111 (2014) (describing the "general view" that "patients do not own their information or tissue samples" and an Alaskan statute providing "that DNA samples and the results of DNA tests are the 'exclusive property' of the person analyzed").

[254] *See, e.g.*, Mayo Collaborative Servs. v. Prometheus Labs, Inc., 566 U.S. 66 (2012).

[255] *Id.* at 92.

[256] *Id.* at 77, 92.

[257] *See* Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 J. SCI. & TECH. L. 256, 270–74 (2015); Rachel E. Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. DAVIS L. REV. 1881, 1906 (2016).

diagnostic testing are not self-revealing like traditional mechanical inventions, negotiations with investors may still be challenging without the signaling function of patents and their ability to ensure some amount of exclusivity for the underlying technology. Because laboratory-developed in vitro diagnostic tests are not clearly subject to the same FDA regulatory review process as other medical devices, the ability to obtain patents in this space would be especially useful to extend first mover advantage.[258]

Patents play a different role where the "key" is in the software, as opposed to traditional medical devices.[259] Software can optimize the use of a device, such as a pacemaker, so companies must make a strategic decision about how much information about the software to include in the patent application, as patent protection for software is often unlikely to provide an adequate scope of protection.[260] As such, when software is the "real meat" of the technology, companies may attempt to maintain the technology as a trade secret or obtain copyright protection.[261] If part of the software technology can be easily duplicated, however, there would be little reason not to include it in the application.[262]

Courts have limited patent protection for software-related inventions in recent years, as they have often viewed software as too abstract to be patent eligible. In *Alice v. CLS Bank*, the Supreme Court invalidated Alice's method patent claims, finding that the generic application of a computer to the concept of intermediated settlement was not enough to "transform that abstract idea into a patent-eligible invention."[263] The Court held that something "significantly more" is needed, but it did not

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[258] *See Laboratory Developed Tests*, U.S. FOOD & DRUG ADMIN. (Sept. 27, 2018), https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/laboratorydevelopedtests/default.htm [https://perma.cc/EL66-UN4Q] ("The FDA has generally not enforced premarket review and other applicable FDA requirements because [laboratory developed tests] were relatively simple lab tests and generally available on a limited basis. . . . [O]n January 13, 2017, the FDA issued a discussion paper on [laboratory developed tests]. The synthesis does not represent the formal position of FDA, nor is it enforceable." (internal citation omitted)).

[259] Telephone Interview with Exec. V (July 2017); *see* Simon & Sichelman, *supra* note 9, at 411–12.

[260] Telephone Interview with Exec. V (July 2017); *see also* Telephone Interview with Exec. VII (Aug. 2017) (stating if the code for digital health inventions can be kept private, trade secret would likely be preferable to patent, particularly considering recent limitations on subject matter eligibility for information-intensive inventions).

[261] *Id.* Copyright does not protect the functionality of the software; it protects the expression of ideas, but not the underlying ideas themselves. *See, e.g.*, Harper & Row Publishers, Inc. v. Nation Enters., 471 U.S. 539, 556 (1985).

[262] Telephone Interview with Exec. V (July 2017).

[263] Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 212 (2014).

define what would be sufficient to allow such abstract ideas to be eligible to obtain patent protection.[264]

Ambiguity in the scope of patent protection for software-related medical devices often requires a different approach to negotiating with potential investors. When patent protection in the software space was more definitive, interviewees described how negotiations concerned coverage and validity of the company's patents. At that point, companies could direct investors to "read the words" of the patent—there was something akin to a "deed" to which the parties could refer.[265] In light of recent changes in the availability and scope of patent protection for software-related inventions, emerging companies now may have to describe what they have done to protect their trade secret and whether their technology is reproducible.[266] Negotiations can be challenging because most investors will not sign nondisclosure agreements, yet they want to know about the market and regulatory opportunity.[267] But, if too much information about the technology is provided to potential investors, "the cat's out of the bag."[268] The challenges of obtaining intellectual property protection for software associated with medical devices can also make valuation difficult.[269]

Tacit knowledge and the multifaceted character of information can be used to protect information during the negotiating process for the aspects of devices that are not self-revealing. For example, although a device may be patented, the dataset obtained through it, as well as other knowledge that cannot easily be replicated, may provide the main source of value to the company.[270] An interviewee from one company had invented a superior injection device.[271] The company was required to disclose certain data about its injection device to obtain FDA approval, such as information related to needle depth, so it also decided to include the previously-disclosed information in its patent filings with the USPTO.[272] The company chose to keep information about a later-discovered beneficial aspect of the spring construction used in the device as a trade secret, however,

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[264] *Id.* at 225 (citation omitted).

[265] Telephone Interview with Exec. V (July 2017).

[266] *Id.*; *see* Telephone Interview with Exec. VII (Aug. 2017).

[267] Telephone Interview with Exec. VII (Aug. 2017); *see* Rantanen, *supra* note 39, at 34, 34 n.145 (noting that "a critical third party may refuse to sign an NDA" in situations "when the refusing third party has significant power relative to the inventor").

[268] Telephone Interview with Exec. V (July 2017).

[269] *Id.*

[270] Interview with Exec. I (June 2017); *see* Interview with Scientist II (June 2017); Interview with Scientist IV (June 2017).

[271] Interview with Exec. IX (June 2018).

[272] *Id.*

providing another way to differentiate its product in the marketplace and obtain a competitive advantage.[273]

Similarly, information related to the manufacturing process sometimes can be kept as a trade secret, even when the product is patented. Returning to the example of the pain-free device for measuring biometric data discussed in the Introduction, the startup in that situation maintains a proprietary process for manufacturing its product that it conducts on-site.[274] It keeps key details about the manufacturing process and related know-how as trade secrets.[275]

Communication with investors about the proprietary aspects of the spring construction of the injection device and manufacturing processes of the biometric monitor described above can still occur, but in a high-level way.[276] As one interviewee explained, investors are not "domain experts"—rather, they are most concerned about execution.[277] In the unlikely event that the investor decides to "dig into the weeds," reputational norms among established players in the investment community also limit the risks that investors would disclose such information to the competition.[278] If an investor were to share the information with a competitor, the regulatory hurdles associated with undergoing the PMA or 510(k) process also limit the speed with which disclosed information could afford a competitive advantage.

In the medical device space, investors and companies often operate under time constraints that may make using alternative mechanisms to patents, such as staging disclosure over time, less feasible as a means of protecting against expropriation.[279] Given the costs associated with undergoing the regulatory review process at the FDA, "any delay in the ability to commercialize can have serious consequences, not only to specific devices and device companies but to the entire medical-

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[273] *Id.*; *see* Simon & Sichelman, *supra* note 9, at 389 (describing how "if an inventor files a patent early in the R&D process, the disclosed best mode of making and using the invention may greatly differ from the ultimate commercial embodiment"); *see also* Dennis Crouch, *The Trade Secret Value of Early Patent Filing*, PATENTLY-O (Oct. 23, 2008), http://www.patentlyo.com/patent/2008/10/the-trade-secre.html [https://perma.cc/3JEZ-RPVS] ("[M]any if not most patent applications are filed well before the associated product or method is ready for public consumption – before the inventor knows the best *commercially viable* mode.").

[274] Interview with Scientist V (Dec. 2017, June 2018) (in-person and telephonic).

[275] *Id.*

[276] *Id.*; Interview with Exec. IX (June 2018).

[277] Interview with Scientist V (Dec. 2017, June 2018) (in-person and telephonic).

[278] *See* Interview with Exec. IX (June 2018) (stating that an investor that improperly disclosed would be "shunned"); Interview with Scientist V (Dec. 2017, June 2018) (in-person and telephonic) (A "reputable" investor would be unlikely to disclose such information to the competition—that would be "poor dealing.").

[279] *See supra* notes 153–155.

device ecosystem."[280] Because the timeline for obtaining a return on investment is very limited in the medical device space, delays resulting from decreased availability of patents can hinder information exchange, reducing opportunities to secure financing and ultimately the ability to bring a medical device invention to the market.

When available as a source of intellectual property protection, patents often give emerging medical device companies an edge in communicating with investors.[281] From the perspective of investors, companies need to get into the "freedom to operate realm," and they are rewarded for having strong patents filed and "being able to clear a space" to prevent copying.[282] Potential investors are very interested in whether a company will be able to "block others from carving into this space," as it is "incredibly important to stake out the landscape early on."[283] And even if the startup does not survive, the patent still provides some value to investors.[284]

From the perspective of investors, the decision about whether to invest in a given company is "really around the IP and the potential for the IP," but the composition of the team involved may be as important, if not more so.[285] Investors recognize the importance of the team's prior experience and leadership skills, and understand that the team may have tacit knowledge that the investors value. Indeed, patent signaling theory may explain why some startups continue to apply for patents, despite questions about their validity in certain subject matter areas and the costs of enforcement. For example, consider medical devices subject to 510(k) clearance. Although determining whether a medical device is "substantially equivalent" in safety and effectiveness to a predicate device under 510(k) involves a different analysis than determining whether a patent claim is obvious in light of the prior art, courts may still consider statements made during the 510(k) process

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[280] INST. OF MED., *supra* note 25, at 136.

[281] *See* Interview with Exec. III (June 2017) (describing patents as a "tie breaker" in obtaining funding as a medical device company); Iliev et al., *supra* note 2, at 66; Kesler et al., *supra* note 90, at 32.

[282] Investors' Panel, *supra* note 84, at 39:30–39:38; *see* Ewing & Feldman, *supra* note 191, at 25, 30; Iliev et al., *supra* note 2, at 66; Kesler et al., *supra* note 90, at 32–34.

[283] Telephone Interview with Exec. VI (July 2017); *see* Kesler et al., *supra* note 90, at 32–34.

[284] Interview with Exec. III (June 2017); *see* Kesler et al., *supra* note 90, at 32–33.

[285] Investors' Panel, *supra* note 84, at 39:10–39:18; *see* Interview with Scientist V (Dec. 2017, June 2018) (in-person and telephonic) (stating that, for investors, the most important aspect in funding is the "founding team" as they "execute toward a product" and they "come up with novel ideas" and intellectual property, noting that intellectual property is second to the team).

relevant to these inquiries.[286] Thus, companies that have devices cleared through 510(k) may hold patents that are more likely to be subject to validity challenges.

Further, medical device patents for incremental improvements tend to be narrow, easy to design around, and result in a short product lifecycle.[287] Typically, a new version replaces an existing medical device every eighteen to twenty-four months—resulting in a relatively short lifecycle compared with pharmaceuticals.[288] The high rate with which medical device modification takes place means that a product may become obsolete long before its underlying patent expires.[289] Some interviewees lamented how patents are often difficult and expensive to obtain and enforce for small companies.[290]

Despite these challenges, small medical device companies continue applying for patents,[291] perhaps as a way to signal to investors that they have the technical expertise and resources to deserve investment. Patents can also communicate that the team has the ability to deliver a product and provide the intangible value that investors seek.[292] Investors may view patents as an indication of the "sophistication of the founders," their "aggressive approach," and that they "invested in IP early."[293] Thus, patents provide an additional source of useful information that can be communicated to potential investors and partners at an early stage.

F. Information Flow During Commercialization of Medical Devices

Getting a new medical device into the marketplace is no small feat. Patents become of particular interest to small medical device companies during commercialization, where the need to partner often becomes evident. Most medical device companies

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[286] *See* 35 U.S.C. § 103; 35 U.S.C. § 271; Content and Format of a 510(k) Summary, 21 C.F.R. § 807.92.

[287] *See* LOO, *supra* note 23, at 25; MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 212.

[288] *See* LOO, *supra* note 23, at 25; MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 212.

[289] *See* LOO, *supra* note 23, at 25; MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 212.

[290] Interview with Exec. II (June 2017); *see* Telephone Interview with Exec. V (July 2017); Telephone Interview with Exec. VI (July 2017).

[291] The practice is reminiscent of a scene from the movie *Annie Hall*, where one woman tells another, "The food at this place is really terrible," and the friend responds, "I know, and such . . . small portions." ANNIE HALL (Twentieth Century-Fox Film Corp. 1977).

[292] Interview with Scientist V (Dec. 2017, June 2018) (in-person and telephonic); *see* Telephone Interview with Exec. VII (Aug. 2017) ("If they [the investors] care about patents, we care about patents.").

[293] Telephone Interview with Exec. VII (Aug. 2017).

have fewer than fifty employees; they typically lack the resources to commercialize a given invention in-house, so they seek a partner to do so.[294] Thus, intellectual property rights can provide a means to license out the technology small companies cannot manufacture or distribute themselves.[295] For example, a small medical device startup might have the resources to make a prototype, but not to scale it, so it needs to partner with a larger company to bring the invention to market.[296]

1. Expropriation Risks in Commercialization

During commercialization, interviewees described how negotiating with manufacturing and distribution partners is similar to talking with investors but "more scary" because they can "run off" with the technology.[297] Patents, especially for self-revealing technologies, can be useful to prevent manufacturers from copying the technology that the startup partner has hired them to make.[298] If a startup decides to outsource, its partners "know all the details" so it feels particularly "vulnerable"; the partners will know if there is a "loophole" where they can compete.[299] Consequently, a startup can highlight to prospective partners that the invention is protected by patents, so "going off and doing it themselves is not an option."[300]

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[294] *See* Ackerly et al., *supra* note 23, at w68 ("After a product reaches a certain stage of development, these small companies are frequently acquired by larger companies to complete the development, production, and marketing of products."); INST. OF MED., *supra* note 25, at 170; *see* LOO, *supra* note 23, at 30 ("The smaller firms are typically eager to align themselves with big producers, which can provide them with funds to finance needed clinical trials and eventually to commercialize their products."); ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY 212 (2011).

[295] Interview with Exec. IV (June 2017); *see* Telephone Interview with Exec. VIII (June 2018); MERGES, *supra* note 294, at 212 (noting "IP is more important" to small companies, compared to larger companies, because small companies "must often sell a specialized component to other companies for incorporation into a larger product").

[296] Interview with Scientist IV (June 2017); *see* LOO, *supra* note 23, at 28 ("A manufacturer must invest heavily in R&D, obtain product approval from the US FDA, get clearance for reimbursement by Medicare and private-sector managed care payers, and achieve acceptance of the product in key hospital and physician markets. Leading companies also need global marketing capabilities and must compete effectively with foreign device manufacturers.").

[297] Telephone Interview with Exec. VII (Aug. 2017); *see* MERGES, *supra* note 294, at 212 ("[L]arger trading partners may sometimes copy new technologies . . . .").

[298] *See* Interview with Scientist I (June 2017); Interview with Scientist II (June 2017); MERGES, *supra* note 294, at 212 ("[W]ithout patents the smaller company has little effective recourse."); Telephone Interview with Exec. VII (Aug. 2017) (stating patents are valuable to prevent competitors from "ripping you off"—otherwise, they can "take advantage of the path you've forged"); Iliev et al., *supra* note 2, at 66; Kesler et al., *supra* note 90, at 32.

[299] Telephone Interview with Exec. VII (Aug. 2017).

[300] Telephone Interview with Exec. VII (Aug. 2017); *see* Iliev et al., *supra* note 2, at 66; Kesler et al., *supra* note 90, at 32.

When the invention is not self-revealing, however, the strategy changes. For example, one interviewee described his company's product, a device that monitors balance through sensors placed on a user; the sensors send information to an app.[301] The goal is to reduce the risk of falling.[302] In this situation, the value is in the data gathered and the software. The crux of invention is not easy to reverse-engineer based on the sensors. As such, his company is not concerned about the risks of expropriation by the manufacturers of the sensors. For devices that are self-revealing, however, his company feels more secure with a patent than with "just a technical specification" to prevent the commercialization partner from taking the invention when they scale it.[303]

Intellectual property rights can facilitate the communication necessary to encourage manufacturers and distributors to enter into alliances with medical device startups. Patents protect not only the startup that holds the intellectual property, but also provide "cover" for its partner.[304] Manufacturers and distributors want to know that there will be exclusivity, as they do not want a "commodity pricing situation."[305] Without effective intellectual property protection in place, manufacturers might be hesitant to partner with a startup, as their investments in commercialization might be undermined by the acts of unrelated parties.

2. Organizational Flexibility in Structuring Alliances

In the medical device industry, patent rights can permit greater organizational diversity in structuring alliances.[306] They provide a means for protecting intangible assets against the risk of expropriation that allows for efficiencies in commercialization, enabling the formation of partnerships that encourages disclosure.[307]

A recent study has set forth a framework for assessing commercialization approaches for medical device start-ups and

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[301] Interview with Scientist IV (June 2017).

[302] *Id.*

[303] Interview with Scientist IV (June 2017).

[304] Interview with Exec. IV (June 2017).

[305] Telephone Interview with Exec. VI (July 2017) (knowing "you're not infringing is very important" to manufacturers).

[306] *See* Brougher et al., *supra* note 2, at 12 ("A comprehensive patent portfolio further enhances a company's ability to enter into a variety of ventures including collaborations, partnerships, licensing agreements, joint ventures, mergers or acquisitions.").

[307] *See id.*; Kesler et al., *supra* note 90, at 32, 34.

described case studies applying their framework.[308] It found that the appeal of alliances for startups increases as: (1) the strength of the startup's patent position increases, and (2) the expense of obtaining complementary assets needed to compete in the product market increases.[309] If an invention is protected by stable legal rights, transaction costs in negotiating an alliance and the threat of expropriation are likely to decrease.[310]

Another example of the role of patents in innovation from the medical device industry can be found in a longitudinal study of the development of the cochlear implant.[311] The study describes how 3M's decision to develop the cochlear implant technology, rather than focus on hearing aids, stemmed from the "lack[] of a strong patent position on hearing aids."[312] In evaluating potential partners, 3M considered different companies already attempting to develop implantable medical devices, evaluating the strength of the companies' patent protection.[313] For example, an Australian company's difficulty in demonstrating "a strong patent position" and exclusive rights factored into 3M's decision not to fund R&D expenses for that company.[314]

An area where patents are particularly important in facilitating alliances is in combination products, which are products that contain at least two components. Through the combination of pharmaceuticals, biologics, medical devices, and other areas of technology, these products can be customized to a patient's particular needs.[315] As an example, a bone implant used in treating fractures can be coated with a biologic, enabling delivery to the precise point needed for a specific orthopedic patient.[316] Combination products have the potential to increase the success of a given treatment, allowing targeted treatment with fewer side effects.[317] Partnerships are particularly important in the development of combination products, as a single company typically works on only one part of the product.[318] Returning to the example of the bone implant, one company might develop the

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[308] *See* Briana Sell Stenard et al., *Commercialization Strategies: Cooperation Versus Competition*, *in* 26 TECHNOLOGICAL INNOVATION: GENERATING ECONOMIC RESULTS 289, 289–308 (Marie C. Thursby ed., 2d ed. 2016).

[309] *Id.* at 292–93.

[310] *Id.* at 292.

[311] *See* ANDREW H. VAN DE VEN ET AL., THE INNOVATION JOURNEY 223–90 (2008).

[312] *Id.* at 227.

[313] *Id.* at 227–34.

[314] *Id.* at 228–29.

[315] Brougher et al., *supra* note 2, at 10.

[316] *Id.*

[317] *Id.*

[318] *See id.* at 12 ("Having a strong patent portfolio in place will not only permit that partnership to occur, it will also help that partnership prosper.").

implant, while another develops the biologic coating. By having patents in place to protect their respective contributions, the companies can work together to develop the combination product.

One founder of a medical device company described the role of patents in exchanging information in a relationship his startup had with an "Asian company."[319] The Asian company had a patent on a coating, on which his company secured a license. His company had a patent on the combination device, which was his startup's patented device with the licensed-in coating.[320] The startup was very concerned about sharing any technology that was not essential to the relationship because the Asian company was attempting to make a competitive end product, though the founder viewed his company's product as the "Cadillac" of devices in its class.[321] The interviewee described the relationship as "antagonistic"—it was difficult to get delivery or performance.[322] The startup had to be careful it was not disclosing its "crown jewels" on how to make the device or the best material for adherence.[323] At the same time, his company appreciated that the in-licensed patent on the coating from the Asian company provided some "cover" to the startup for the combination product.[324] The patent also allowed for the exchange of necessary information with the Asian company, but the startup was able to prevent the disclosure of information that could allow the Asian company to build a competing device.[325]

Patents sometimes cover incremental improvements in the medical device space, and they tend to be less specific than they are for pharmaceuticals.[326] These overlapping rights and ambiguity in coverage for some types of medical devices can increase the likelihood of patent infringement litigation throughout the industry.[327] As a result, many medical device companies cross-license each other's patents.[328] The scope of patent licenses in the medical device space can be "deal breakers or deal makers" in terms of obtaining the investment and

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[319] Telephone Interview with Exec. VII (Aug. 2017).

[320] *Id.*

[321] *Id.*

[322] *Id.*

[323] *Id.*

[324] *Id.*

[325] *Id.*

[326] *See* LOO, *supra* note 23, at 25.

[327] *See id.*; ANSELL ET AL., *supra* note 154, at 11–12 (detailing the distribution of patent infringement litigation and the median damages awards from 1998-2017 among the top ten industries). The medical device industry, however, seems to face a lower threat of litigation from non-practicing entities than other industries. *See id.*

[328] *See* LOO, *supra* note 23, at 25.

alliances necessary for commercialization.[329] From the perspective of a company engaged in developing a patent licensed from a university, the breadth and scope of patent licenses are important to make commercializing the technology worthwhile.[330] Companies need to be able to "generate enough new technology" to make a reasonable return on their investment.[331] For example, if a patent license from a university is "broad enough and long enough," investors will appreciate that there is at least some stability and the ability to enforce the patent against third parties.[332]

Licensing-in technology may also offer supplemental protection against competition, as two patent portfolios together can provide the necessary breadth and depth of protection.[333] By licensing-in technology identified during freedom-to-operate searching, a startup can obtain an earlier priority date and direct prosecution of related patents, providing additional protection against competition.[334] Priority is a patent application's effective date, after which prior art can be considered in examining whether an invention is novel and nonobvious.[335] Obtaining an early priority date can provide a competitive advantage in securing patent protection, as less prior art can be considered for patents with an earlier priority date. Conversely, interviewees described that if the licensor "holds back too much" on the rights conveyed, it can be a "death spiral" in terms of obtaining investment because of the lack of exclusivity.[336] For example, if a professor is engaged in ongoing research and the emerging company is doing the same, a company can create its own competitor, which can be a "major deterrent factor" in securing investment to commercialize.[337]

3. Synergistic Exchanges of Information

Patents can encourage alliances that promote the synergistic exchange of information that can benefit both partners

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[329] Telephone Interview with Exec. V (July 2017).

[330] Interview with Scientist III (June 2017).

[331] Telephone Interview with Exec. V (July 2017).

[332] *Id.*

[333] *Id.*; *see* Telephone Interview with Exec. VI (July 2017) (noting in-licensing to prevent patent challenges is important, as they are "financially stressful, expensive, and distracting" to a small company).

[334] *See* Telephone Interview with Exec. VIII (June 2018); Ewing & Feldman, *supra* note 191, at 21.

[335] *See* 35 U.S.C. § 102; 35 U.S.C. § 103.

[336] Telephone Interview with Exec. V (July 2017).

[337] *Id.*; *see* Telephone Interview with Exec. VIII (June 2018) (stating any resulting intellectual property would be owned by the startup "ideally").

to the agreement.[338] Smaller companies can use patents as a "bargaining chip" or as a means to negotiate with larger companies.[339] By licensing-in technology, medical device companies can "join forces" and "provide energy for inventor developments."[340] In-licensing technology often involves not only patents, but also "technology and people."[341] An inventor who is a "subject-matter expert" often has a "wealth of knowledge" that can be "more critical than the actual patent claims."[342] So, companies may seek continued inventor participation in an "advisory role."[343]

For example, a recent case study of a medical device company in the orthopedic area, Medjoint, highlights the importance of inventor-developer partnerships in the innovative process.[344] The Medjoint study detailed how highly specialized emerging companies may be hesitant to seek generalized venture funding, as venture capitalists may not have expertise in the particular medical device area.[345] Instead, startups may choose to rely on friends and experts in certain areas, such as orthopedics in this case study, who can bring their expertise to the development process.[346] Medjoint benefited from its product development partnership by learning about "the processes of product development and manufacturing capabilities."[347] Drawing upon the expertise of the partner in commercialization, Medjoint ultimately hired two employees who had "worked in tandem with the partner."[348]

Licenses can encourage the creation of new technology and efficiencies in scaling and manufacturing medical devices. This Part has set forth how intellectual property rights can allow for greater organizational diversity, flexibility in structuring alliances, and synergistic exchanges of information essential to the innovative process.[349] As one interviewee concluded, patents are "critical in making markets" in the medical device industry.[350]

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[338] *See* Brougher et al., *supra* note 2, at 12 ("A comprehensive patent portfolio further enhances a company's ability to enter a variety of ventures . . . [with other companies].").

[339] Interview with Exec. III (June 2017).

[340] Telephone Interview with Exec. VI (July 2017).

[341] *Id.*; *see* Lee, *supra* note 7, at 1536–37.

[342] Telephone Interview with Exec. VI (July 2017).

[343] *Id.*

[344] Stenard et al., *supra* note 308, at 292.

[345] *Id.* at 302.

[346] *Id.*

[347] *Id.* at 301.

[348] *Id.*

[349] *See* Brougher et al., *supra* note 2, at 12 (concluding that robust patent protection can "maximize opportunities for a variety of partnerships").

[350] Telephone Interview with Exec. VI (July 2017).

IV. IMPLICATIONS FOR PATENT POLICY

Evaluating the effectiveness of patents in the medical device industry provides broader insights into the functioning of the patent system that takes into account its foundational purpose—promoting the progress of science and encouraging the development of new technology.[351] As Professor Rob Merges explains, "small companies [are] a major source of new technologies."[352] Given the small size of most medical device startups and the need for protection against dominant players in the field, patents are often essential for progress in this space—they matter.[353]

Two issues surfaced during the interviews with medical device professionals. First, difficulties in obtaining adequate patent protection may decrease innovation incentives and information flow for some inventions in this area, particularly given the role of patents in obtaining investment and commercialization for some medical devices. Second, limitations on patent enforcement, and in particular, injunctive relief, may restrict the ability to prevent expropriation, potentially hindering the disclosure of and investment in the development of new medical device technologies.

Surprisingly, few respondents described issues with either non-practicing entities or patent thickets. Non-practicing entities, which have also been referred to as "patent assertion entities" or "patent trolls," do not make or sell products that "embody their patented technologies."[354] Patent thickets have been defined as "an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees."[355] Interviewees may not have had experience with these situations, given that most of the companies represented were in the early stages of their development. In addition, although the majority of the professionals interviewed described their

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[351] *See* U.S. CONST., art. I, § 8, cl. 8.

[352] MERGES, *supra* note 294, at 212.

[353] *See id.* (describing how "small, specialized technology companies are especially reliant on IP rights because, compared to larger companies, they have fewer ways to capitalize on research and development investments"); Clark D. Asay, *Patenting Elasticities*, 91 S. CAL. L. REV. 1, 9 (2017) (describing how weakening patents are likely to reduce patenting rates by resource-constrained companies because their demand for patents is more elastic than for other types of companies, and suggesting that such an outcome may harm innovation).

[354] John R. Allison et al., *How Often Do Non-Practicing Entities Win Patent Suits?*, 32 BERKELEY TECH. L.J. 237, 237 (2017).

[355] Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 119 (Adam B. Jaffe et al. eds., 2001).

startups' inventions as groundbreaking, some respondents described products that seemed to incorporate more modest improvements. Patents that cover incremental improvements typically involve narrow claims that are not difficult to design around. Products that differentiate based on incremental improvements also tend to have a relatively short product lifecycle.[356] New versions of medical devices typically supplant existing devices less than every two years.[357] Consequently, a medical device may be superseded even with a substantial term remaining on the patent covering it.[358] Perhaps these considerations are part of the reason that patent thickets sometimes appear to pose less of a problem for certain types of medical devices than for technologies in other fields, such as semiconductors.[359] In the semiconductor industry, the possibility that a manufacturer of a single product could infringe hundreds of patents is "hardly a theoretical curiosity," as "many thousands of patents are issued each year."[360] In the medical device realm, some researchers have speculated that the convergence of technologies associated with medical devices in the area of mobile health may result in the development of patent thickets for those types of products in the near future.[361]

The first area of concern for many interviewees focused on how shifts in patent law have limited the scope of protection for many types of medical devices. Courts have narrowed the scope of patentable subject matter in both the diagnostic testing and software-related fields.[362] Patent applicants also face a heightened requirement to show nonobviousness and greater challenges in

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[356] *See* LOO, *supra* note 23, at 25; MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 212.

[357] *See* LOO, *supra* note 23, at 25; MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 212.

[358] MEDICARE PAYMENT ADVISORY COMM'N, *supra* note 2, at 212.

[359] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698–701 (1998).

[360] Shapiro, *supra* note 355, at 125.

[361] *See* Orion Armon, *Is Mobile Health About to Enter a Patent Thicket*, MOBIHEALTH NEWS (Oct. 23, 2012), https://www.mobihealthnews.com/18771/is-mobile-health-about-to-enter-a-patent-thicket/ [https://perma.cc/8PNW-HYC8] (stating that "[c]ompanies in the medical device, computer, networking, and communications industries are all patenting in the mHealth space, and the likely result will be a thicket of overlapping patents on mHealth products and their components"); Iliev et al., *supra* note 2, at 65–66 (concluding that although there was "broad agreement" among the eight interviewees in the UK-based study that "the medical devices space as a whole is not yet particularly crowded, . . . the rate of patenting [in the Telehealth space] is now increasing, and it is probable that it will become crowded").

[362] *See* Mayo Collaborative Servs. v. Prometheus Labs, Inc., 566 U.S. 66, 92 (2012); Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 221 (2014).

satisfying the written description requirement.[363] As one executive described, patents are "narrow" and "harder to get."[364] Further, the America Invents Act (AIA) has raised obstacles for emerging companies seeking to protect their inventions with patents.[365] The increased emphasis on rapid filing may adversely affect smaller companies, which include the vast majority of medical device companies, as they may lack sufficient resources to devote to patent prosecution early in their development. These challenges in obtaining adequate intellectual property rights to protect medical device inventions may influence disclosure of new technologies and investment.[366]

Even in those situations where medical device companies are able to obtain adequate intellectual property protection, interviewees described how an issued patent no longer provides as much certainty or reassurance to its grantee or assignee, investors, or potential commercialization partners as it used to provide.[367] Post-grant challenges questioning the validity of issued patents have become more commonplace.[368] These additional periods of uncertainty can stall the transfer of technology in an industry that is already plagued with high levels of both technological and demand uncertainty—especially challenging circumstances for emerging companies that have limited resources to weather lengthy delays in commercialization.[369]

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[363] *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007) (holding that if "a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one"); Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) ("[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." (citations omitted)).

[364] Telephone Interview with Exec. VI (July 2017).

[365] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (amending various sections of 35 U.S.C.).

[366] *See* ARORA ET AL., *supra* note 52, at 140 ("[A]n important benefit of broader patents would be to encourage innovation by research intensive firms . . . , which lack the capabilities for commercializing innovations.").

[367] *See supra* notes 260–269 and accompanying text.

[368] *See* Paul R. Gugliuzza, *(In)valid Patents*, 92 NOTRE DAME L. REV. 271, 272 (2016) ("[P]ost-issuance proceedings have become very popular in the past few years, due largely to the America Invents Act . . . .").

[369] *See* Gaétan de Rassenfosse et al., *Do Patents Shield Disclosure or Assure Exclusivity When Transacting Technology?*, (Melbourne Inst. Working Paper No. 05/13, 2013), https://ssrn.com/abstract=2226729 [https://perma.cc/WRP6-G4GW]; Jeff Dyer et al., *The Industries Plagued by the Most Uncertainty*, HARV. BUS. REV. (Sept. 11, 2014), https://hbr.org/2014/09/the-industries-plagued-by-the-most-uncertainty [https://perma.cc/J9MW-H4EV] (ranking medical equipment as the number one industry with the highest levels of uncertainty in demand and technology); Telephone Interview with Exec. VI (July 2017) (noting "exits take longer," if they even happen).

Restrictions on remedies may similarly reduce the attractiveness of relying on patent law to protect inventions.[370] In particular, limitations on obtaining injunctive relief disproportionately affect the medical device industry.[371] In *eBay v. MercExchange*, the Supreme Court unanimously rejected the "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances."[372] Instead, in deciding whether to grant or deny an injunction, courts must apply the traditional four-factor test, requiring a patentee to show (1) irreparable injury; (2) inadequate alternative remedies, such as monetary damages; (3) the balance of hardships favors the plaintiff; and (4) the public interest will not be harmed by granting injunctive relief.[373] In deciding whether to grant injunctive relief, courts often focus on whether the infringer and the patentee are direct competitors.[374]

Medical device firms are a remarkable example of competitors that are denied injunctive relief frequently.[375] A recent study found that almost one-third of medical device companies that sued a competitor did not receive injunctive relief, despite being able to demonstrate irreparable harm.[376] Courts grant injunctions in cases related to medical devices at a much lower rate than in cases related to other types of technology, "even after controlling for the litigants' status as competitors."[377] Substantial challenges in obtaining meaningful injunctive relief in the medical device industry may hinder the ability to prevent expropriation. With weakened enforcement mechanisms, inventors may face difficulties in securing investment and may be less inclined to

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[370] In addition to the limitations on injunctive relief described, the AIA expands the prior use defense to patent infringement for the commercial use of trade secrets in a manufacturing process more than one year prior to the filing of patents filed after September 16, 2011. 35 U.S.C. § 273 (amended to expand the prior use defense). In some circumstances, the expanded prior user defense may affect the decision to pursue patent protection in a crowded field. *Id.*

[371] *See* Christopher B. Seaman, *Permanent Injunctions in Patent Litigation After* eBay*: An Empirical Study*, 101 IOWA L. REV. 1949, 1991 (2016).

[372] eBay, Inc. v. MercExchange, 547 U.S. 388, 391–94 (2006) (citation omitted).

[373] *Id.* at 391.

[374] *See, e.g.*, Andrew Beckerman-Rodau, *The Aftermath of* eBay v. MercExchange*, 126 S. Ct. 1837 (2006): A Review of Subsequent Judicial Decisions*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 631, 654–55 (2007); Edward D. Manzo, *Injunctions in Patent Cases After* eBay, 7 J. MARSHALL REV. INTELL. PROP. L. 44, 53 (2007).

[375] Seaman, *supra* note 371, at 1991.

[376] *Id.* (explaining that "the district court nonetheless denied an injunction because removing the infringing product from the market might adversely affect patients' health and safety").

[377] *Id.* (reasoning that courts likely base the decision to deny injunctive relief on the fourth factor, that limiting access to the infringing devices could harm the public interest).

disclose their inventions to third parties.[378] Greater difficulties in obtaining and enforcing intellectual property rights may further affect investment in the medical device industry, impeding the disclosure and development of new technologies.

CONCLUSION

The extent to which patents are useful in facilitating the exchange of information is highly contextual. They provide insights both about an invention and distinct from it. When an emerging company is in the process of seeking investment funding, patents can help mitigate the risks of expropriation, act as a signaling mechanism to convey valuable information at relatively low cost, and serve as an objective measure of the viability of an invention. During commercialization, patents not only shield small and mid-sized medical device companies from copying by partners and third parties, but also foster alliances and synergies in development.

Examples from the medical device industry help elucidate the role of patents in the innovative process. Although large corporations dominate the medical device landscape, most truly innovative devices originate with small to medium-sized medical device companies. These emerging companies often depend on patent protection as a way to communicate with investors and negotiate the alliances necessary to commercialize their ideas. Consequently, limitations on obtaining and enforcing intellectual property rights are especially problematic. These restrictions may further decrease disclosure and investment incentives in a technological area where they already may be lacking.

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[378] *See* Marco Ceccagnoli & Frank T. Rothaermel, *Appropriability Strategies to Capture Value from Innovation*, *in* TECHNOLOGICAL INNOVATION: GENERATING ECONOMIC RESULTS 2, 27, Table 4 (Gary D. Libecap & Marie C. Thursby eds., 2016) (finding that the majority of "Medical Instruments" firms surveyed rank "Patent Protection" as "First or Second Most Important" in their "Appropriability Strategy").

APPENDIX A

INFORMATION ABOUT ACQUISITIONS BY THE THREE LARGEST MEDICAL DEVICE FIRMS

Acquired Medical Device Company (6/2012-7/2018)	Acquiring Firm (three largest medical device firms in terms of revenue)[379]	Patents Obtained by Acquired Medical Device Co. Before Acquisition[380]
Orthotaxy	J&J	0
Megadyne Medical Products	J&J	57
Abbott Medical Optics	J&J	258
Torax	J&J	0
Neuravi	J&J	8
Tearscience	J&J	50
Neuwave	J&J	5
Flexible Stenting Solutions	J&J	3
Synthes	J&J	441
Calibra	J&J	16
Visionsense	Medtronic	20
Crospon	Medtronic	1
Responsive Orthopedics	Medtronic	0
Heartware	Medtronic	52
BellCo.	Medtronic	7
Aircraft Medical	Medtronic	9
Sophono	Medtronic	2
Covidien	Medtronic	1847

[379] *See supra* notes 219–220 and accompanying text.
[380] *See supra* notes 219–220 and accompanying text.

CardioInsight	Medtronic	4
Aptus Endosystems	Medtronic	21
Medina Medical	Medtronic	2
RF Surgical Systems	Medtronic	12
Twelve, Inc.	Medtronic	4
Lazarus Effect	Medtronic	5
Advanced Uro-Solutions	Medtronic	2
Sapiens Steering Brain Stimulation	Medtronic	6
Visualase	Medtronic	3
TYRX, Inc.	Medtronic	9
Corventis	Medtronic	11
China Kanghui Holdings	Medtronic	0
Remote Diagnostic Technologies	Philips	2
EPD Solutions	Philips	0
Spectraganetic-s Corp.	Philips	90
Nightbalance	Philips	1
Respiratory Tech. (RespirTech)	Philips	3
Electrical Geodesics	Philips	12
Cardioprolific	Philips	1
Volcano Corp.	Philips	99
Unisensor	Philips	2

APPENDIX B[381]

Date(s)	Interviewee	Reference Term	In-Person
Executives			
June 2017	CEO, Angel Investor	Executive I	Yes
June 2017	President	Executive II	Yes
June 2017	CEO	Executive III	Yes
June 2017	Vice-President	Executive IV	Yes
July 2017	General Counsel	Executive V	No
July 2017	CEO, President, General Counsel	Executive VI	No
August 2017	Founder, General Counsel	Executive VII	No
June 2018	Outside Counsel	Executive VIII	No
June 2018	Director of IP	Executive IX	Yes
Scientists			
June 2017	Architect	Scientist I	Yes
June 2017	Director of Product Development	Scientist II	Yes
June 2017	Scientist	Scientist III	Yes
June 2017	Senior Scientist	Scientist IV	Yes
December 2017, June 2018	Founder, CTO	Scientist V	Yes, with follow-up by telephone

[381] Please see *supra* Section III.C for information about methodology.