Notre Dame Law Review

Volume 92 | Issue 4 Article 7

5-2017

Expired Patents, Trade Secrets, and Stymied Competition

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Patents and trade secrecy have long been considered substitute incentives for innovation. When inventors create a new invention, they traditionally must choose between the two. And if inventors choose to patent their invention, society provides strong legal protection in exchange for disclosure, with the understanding that the protection has a limit: it expires twenty years from the date of filing. At that time, the invention is opened to the public and exposed to competition.

This story is incomplete. Patent disclosure is weak and focuses on one technical piece of an invention—but that piece is often only a part of the market-relevant innovation. Patent-holding innovators use various tactics to distort the patent bargain and prolong effective monopolies beyond the patent's expiration date. These tactics include using patented inventions to generate secret information, relying on the timing difference between patent filing and product marketing to make disclosure nearly irrelevant, and tying secret components to patented frameworks.

While these phenomena have been noted before, this Article joins them together as examples of ways that innovators avoid the competition-promoting function of patent expiration, ultimately limiting the benefit the public receives from patented inventions. It also suggests that the most problematic cases likely involve markets where additional factors, such as regulation or other market irregularities, require that goods be interchangeable. Finally, it proposes the concept of economic enablement: patentees may have a responsibility to enable not just the bare technical invention disclosed in a patent, but rather the minimum information necessary to exploit commercially the patented invention. Against the background of the newly enacted Federal Defend Trade Secrets Act, courts and scholars alike should examine the boundaries between trade secrets and patents to ensure that the overlap does not distort the policy goal of incentivizing and promoting both innovation and competition.

INTRODUCTION

The patent system reflects a bargain between an inventor and society. The inventor invents and discloses the invention, and in return society grants

* Assistant Professor of Law, University of Michigan Law School. For helpful comments, I thank Jonas Anderson, Ana Bracic, Deven Desai, Rebecca Eisenberg, Roger Ford, Mark Lemley, Arti Rai, Rachel Sachs, and Brenda Simon. This work benefited from feedback received at the Junior Intellectual Property Scholars Association's Gnocchi Workshop, the Big Ten Juniors Conference at Indiana University, the Michigan Law School Fawley Workshop, and the *Notre Dame Law Review* Annual Symposium. All errors are my own.

her rights in the invention for a limited period of time.[1] This bargain is carefully crafted; Congress and the courts consistently tinker with the system with the aim of reaching the right balance of incentives and costs. This tinkering also sets the boundaries between the patent system and the incentives provided by the nominally complementary trade secret system.

Underlying these intellectual property mechanisms, and others, is the recognition that the competitive benefits conferred upon inventors are limited, and that when those limits are reached, we expect that broader competition, with its attendant public benefits, becomes possible. Patents expire after twenty years, and trade secrets can be reverse-engineered.[2] These limits function as safety valves to ensure that competition can eventually take place, and doctrines have been created specifically to enable that robust competition once the limits are reached.[3]

But inventors and lawyers are clever. In multiple important types of innovation, firms use the interlocking effects of patents and difficult-to-reverse-engineer trade secrets to maintain monopolies long past patent expiration.[4] These post-expiration monopolies are strongest in markets for interchangeable goods—that is, markets, like those for drugs, weapons, and some medical tests, where competing products must perform the same and be interchangeable.[5] Post-expiration monopolies can be protected in several ways. Information generated about the patented invention itself necessary

1 *See* Shubha Ghosh, *Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor After* Eldred, 19 BERKELEY TECH. L.J. 1315, 1316 (2004) (noting that "[p]atents are commonly understood as a hypothetical contract between the inventor and the government" and later critiquing this conception); *see also* W. Nicholson Price II, *Regulating Secrecy*, 91 WASH. L. REV. 1769, 1775–76 (2016).

2 Regulatory-mediated market exclusivity, a pseudo-IP benefit conferred in some industries, similarly expires. *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 348, 359–64 (2007); Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L.J. 299, 305–09 (2015).

3 *See, e.g.*, 35 U.S.C. § 271(e)(1) (2012) (creating a safe harbor for otherwise infringing conduct taken to prepare a generic drug for regulatory approval to ensure that generic drugs can enter the market promptly upon the expiration of the patent covering the innovator drug).

4 Firms can distort the intended patent bargain in many other ways not discussed in this Article. Among the best recognized is the failure to disclose adequately the features of an innovation at the time of patenting. *See* Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 551 (2009) ("Ineffective disclosure . . . can also prolong the patent right beyond its stated expiration because more of the useful information about an invention remains only in the patentee's hands."); Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123 (2006); Brian J. Love & Christopher B. Seaman, *Best Mode Trade Secrets*, 15 YALE J.L. & TECH. 1 (2012). Various methods of gaming the patent system to maintain patent-protected monopolies through patenting different parts or versions of an innovation are also well described. *See* Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499 (2016); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006).

5 *See, e.g.*, Christianson v. Colt Indus. Operating Corp., 609 F. Supp. 1174, 1176–77 (C.D. Ill. 1985); Feldman & Frondorf, *supra* note 4, at 500.

for economic exploitation but generated after filing may be kept secret, and may thus hinder competition.[6] Relatedly, trade secrecy may be used to protect required economic complements of a patented invention, in a form of innovation bundling, such that neither the invention nor the complements can be reasonably developed without access to the trade secrets.[7] Finally, information generated by the patent-protected technology, and required for market success, may also be kept secret.[8] Through these various mechanisms, patentees can double-dip, obtaining the benefits of the patent system for a limited term but then using trade secrecy to block competition in the patented product after that term expires. This double-dipping is contrary to the goal of the intellectual property system that innovation be driven by *limited* monopolies. The limits on monopolies are important because the public receives benefits from competition in the form of lower prices and increased access.[9]

How might these distortions be undone, and the patent bargain improved, at least in this respect? The enablement doctrine provides a potential blueprint. Under the enablement doctrine, a patentee must provide enough information that an ordinarily skilled artisan can "make and use" the claimed invention.[10] But as described in detail below, mere technical enablement will often fall short of holding up the patentee's end of the patent bargain in terms of social welfare, innovation, and competition.[11] If competitors cannot meaningfully make and use the invention after patent expiration, the patentee hasn't disclosed enough. One could imagine a separate enablement requirement—embedded in patent law or somewhere else—that focuses on economic enablement. Under such a requirement, the patentee would need to provide sufficient information that an ordinarily skilled and similarly equipped market participant would be able to compete reasonably—even if not ultimately successfully—in the market upon expiration of the patent term.

This Article proceeds in four Parts. Part I describes the patent bargain and the relationship between patents and trade secrecy, including the longstanding view that they are substitute inventions and the growing recognition that they may function as complements in some situations. Part II discusses

6 *See infra* Section III.A; *see also* W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023 (2016) (discussing this issue in the context of biologics and biosimilars). An important distinction is between further information created that is necessary for economic exploitation (e.g., non-discoverable product details required for regulatory approval, *see id.*) and information created that merely confers a competitive advantage (e.g., know-how that allows more efficient manufacturing). *See infra* Part IV.

7 *See infra* Section III.B.

8 *See infra* Section III.C; *see also* Dan L. Burk, *Patents as Data Aggregators in Personalized Medicine*, 21 B.U. J. SCI. & TECH. L. 233 (2015); Brenda M. Simon & Ted Sichelman, *Data-Generating Patents*, 111 NW. U. L. REV. (forthcoming 2017).

9 *See* Feldman & Frondorf, *supra* note 4, at 500.

10 35 U.S.C. § 112(a) (2012).

11 *See infra* subsection IV.B.1.

the patent system's express policy of competition after patent expiration. Part III addresses three cases where secrecy is used to distort the bargain contrary to this policy and to limit competition: secret later-generated information about the invention necessary for its economic use, secret economic complements, and secret information generated by patented inventions. Part IV presents a very preliminary framework for limiting these distortions of the patent bargain by creating a requirement parallel to the technical enablement requirement of the patent system: an economic enablement requirement.

I. PATENTS AND TRADE SECRECY

Patents and trade secrets have a complex relationship.[12] Both cover technological or industrial innovation.[13] Both systems have as their goal the development and deployment of such innovation.[14] But they aim to reach these goals through markedly distinct mechanisms.[15] Patents reflect a considered bargain: inventors are rewarded with a limited-term monopoly[16] over the patented invention in exchange for developing and disclosing the invention. An essential part of this bargain is its limit: patents expire, and after patent expiration, the invention is expected to enter free public use.[17] Trade secrets are different; they lack a set expiration date, but have their own limit: competitors can lawfully reverse-engineer or independently invent the trade secret, and protection is then lost.[18] This Part briefly describes the two regimes, and then discusses how the two can interact, whether as substitutes under a traditional view, or as complements.

A. Patents

Patents trade disclosure for a term-limited, legally enforced right to exclude.[19] Under the terms of the patent bargain, an inventor shares the knowledge of her invention with the public through the disclosure of the patent document itself, and receives in exchange (and arguably in exchange for the invention itself) a limited period of time—twenty years from the date of patent filing, with some modifications—during which she may legally pre-

12 *See* Price, *supra* note 1.

13 *See id.* at 1775–76.

14 *See id.* at 1775.

15 *See id.* at 1771–72.

16 I acknowledge that patents often do not in fact result in monopolies. *See* Stephen Yelderman, *Do Patent Challenges Increase Competition?*, 83 U. CHI. L. REV. (forthcoming 2017) (manuscript at 117–54), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2731216. However, the term "monopoly" is useful, if imprecise, shorthand for the competitive advantage conveyed by the right to exclude and reflects the essential nature of the patent bargain. *See id.* at 119 n.62 (noting examples of courts and scholarship taking the monopoly framing as a starting point to evaluate patents' competitive benefits).

17 *See* Price, *supra* note 1, at 1775–76.

18 *See id.* at 1776.

19 *See id.* at 1775–76.

vent others from making, using, selling, or importing the invention.[20] This right of exclusion (theoretically) enables the inventor to capture a greater portion of the social welfare gain from the invention than if other competitors could immediately free-ride on the invention by marketing their own versions of the invention without having had to invest the funds necessary to create it in the first place.[21] At the end of the patent term, the right to exclude terminates, and competitors may practice and sell the previously patented invention, leading to competition and expected price decreases for the public.

B. Trade Secrets

Trade secrecy works differently. Trade secrecy also allows an inventor to appropriate the social welfare gain from his invention through exclusivity, but that exclusivity is primarily based on secrecy; if competitors do not know the necessary information about the innovation, they cannot free-ride.[22] Trade secrecy as a body of law supports the role of actual secrecy, including confidentiality requirements, by providing legal mechanisms to prevent and punish the appropriation of information reasonably kept secret.[23] Trade secrecy was until 2016 a creature largely of state law,[24] but in 2016 Congress passed the Defend Trade Secrets Act, creating a federal civil cause of action for misappropriation of trade secrets.[25] Now state and federal trade secret law exist in parallel. Trade secrets, unlike patents, can persist indefinitely; some last for many decades.[26] They also require no registration or government vetting process, unlike patents.[27] But trade secrets have a strong safety valve that patents lack: independent invention and reverse-engineering are

20 *See* 35 U.S.C. § 154 (2012) (setting the patent term at twenty years); *id.* § 271 (stating what conduct constitutes patent infringement); Universal Oil Prods. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944) (noting that the "quid pro quo [for limited exclusivity] is disclosure of a process or device in sufficient detail").

21 *See* Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129 (2004) (examining the ex ante incentive theory of patents in some depth, and considering ex post justifications as well).

22 *See* Price, *supra* note 1, at 1776. This basic description necessarily omits much. For a view that initial innovators may be helped by sharing information with competitors, see Laura Pedraza-Farina, *Spill Your (Trade) Secrets: Knowledge Networks as Innovation Drivers,* 92 NOTRE DAME L. REV. 1561, 1570–81 (2017).

23 *See* Pedraza-Farina, *supra* note 22, at 1570–81.

24 *See* Christopher B. Seaman, *The Case Against Federalizing Trade Secrecy*, 101 VA. L. REV. 317, 320 (2015).

25 Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, 130 Stat. 376 (to be codified in scattered sections of 18 U.S.C.). In addition, the Economic Espionage Act, enacted in 1996, created criminal penalties for certain invasions of trade secrecy. Pub. L. No. 104-294, 110 Stat. 3488 (codified as amended at 18 U.S.C. §§ 1831–39 (2012)); *see also* 18 U.S.C. § 1831.

26 *See* Price, *supra* note 1, at 1777.

27 *See id.* at 1778.

not forbidden by trade secret law.[28] That is, if an invention is valuable enough, competitors can independently develop or reverse-engineer the information, and then the protection and advantage conferred by trade secrecy is lost.[29] This possibility is not always realizable in practice.[30]

C. Patent-Trade Secret Interactions

As different ways to protect the same sort of innovation, the doctrines of patents and trade secrecy are in substantial dialogue.[31] Traditionally, they have been described as substitutes; that is, inventors pick one or the other, and proceed accordingly.[32] However, there is a growing recognition that they can also be complements; that is, the protections of patents and trade secrecy can be used together to protect an invention or a suite of inventions.[33]

1. Substitutes

The traditional view of patents and trade secrets is that they are substitutes, such that only one may cover any given invention.[34] Inventors must choose one form of protection, depending on which they believe more likely to provide more value, considering the difference in term, expense, enforceability, and other factors.[35] They may not choose both for precisely the same

28 Robert G. Bone, *A New Look at Trade Secret Law: Doctrine in Search of Justification*, 86 CALIF. L. REV. 241, 250–51 (1998).

29 *See id.*

30 As discussed below, reverse-engineering and independent invention are not always realistically possible; this reality can sometimes have quite substantial consequences. *See infra* Section III.A.

31 *See, e.g.*, Price, *supra* note 1; Simon & Sichelman, *supra* note 8.

32 Various sources note the views of patents and trade secrets as substitutes and complements, and will be cited throughout this Section. For an excellent recent summary—to which this Section owes much of its framing—see Simon & Sichelman, *supra* note 8, at 8–15.

33 *See, e.g.*, Karl F. Jorda, *Patent and Trade Secret Complementariness: An Unsuspected Synergy*, 48 WASHBURN L.J. 1 (2008).

34 J. Jonas Anderson, *Secret Inventions*, 26 BERKELEY TECH. L.J. 917, 923–24 (2011); Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, 61 STAN. L. REV. 311, 314 (2008); Gideon Parchomovsky & Peter Siegelman, *Towards an Integrated Theory of Intellectual Property*, 88 VA. L. REV. 1455, 1494 (2002); Simon & Sichelman, *supra* note 8, at 8–12.

35 Various authors have provided guidance on this decision. *See, e.g.*, Andrew Beckerman-Rodau, *The Choice Between Patent Protection and Trade Secret Protection: A Legal and Business Decision*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 371 (2002); Michael R. McGurk & Jia W. Lu, *The Intersection of Patents and Trade Secrets*, 7 HASTINGS SCI. & TECH. L.J. 189, 198–209 (2015) (listing seven factors to consider: patentability, term of protection, enforcement, injunctions, prior user rights, disclosure, and costs); Daniel C. Munson, *The Patent-Trade Secret Decision: An Industrial Perspective,* 78 J. PAT. & TRADEMARK OFF. SOC'Y 689 (1996). In other intellectual property contexts, the presumed-defunct doctrine of "election" was once used to suggest that applicants seeking intellectual-property protection affirmatively had to select one option. *See, e.g.*, Doris E. Long, *First, "Let's Kill All the Intellectual Property Law-*

invention—the traditional account goes—because of the disclosure requirement of the patent system.[36] Under 35 U.S.C. § 112, the inventor must disclose enough information to enable a person having ordinary skill in the art to make and use the invention; the inventor must also provide sufficient information to demonstrate that she "possesses" the information at the time of filing.[37] Once information is disclosed through the patent system, it can no longer be kept secret.

The choice does not always exist for a given invention. The Supreme Court in *Kewanee Oil v. Bicron* described three categories of inventions kept as trade secrets:

> (1) the trade secret believed by its owner to constitute a validly patentable invention; (2) the trade secret known to its owner not to be so patentable; and (3) the trade secret whose valid patentability is considered dubious.[38]

That is to say, while almost all commercially valuable information that can be kept secret can be kept as a trade secret,[39] many inventions are not patentable, whether because they are not absolutely novel, because they may be considered obvious, or because they fail to fall into the categories of statutory patent eligibility.[40] Thus, a particular invention will often not be patentable. In the converse situation, different innovations are patentable but not protectable as trade secrets for the simple reason that they are already public; while an inventor can (in some circumstances) file a patent within a year of publicly disclosing the invention,[41] such disclosure destroys the possibility of using trade secrecy.

In both scholarship and court opinions, the dominant view is that an invention cannot be protected by both a patent and trade secrecy. However, this view relies on the identity of the invention being the same under both regimes. This need not always be the case.

2. Complements

As a number of commentators and practitioners have recognized, patents and trade secrecy can both be used to protect an invention so long as

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yers!": Musings on the Decline and Fall of the Intellectual Property Empire, 34 J. MARSHALL L. REV. 851, 872–90 (2001) (describing the rise, fall, and potential re-rise of the election doctrine).

36 *See* Fromer, *supra* note 4; Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 545 (2012); Note, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007 (2005).

37 35 U.S.C. § 112 (2012); Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (noting that enablement and written description requirements are distinct); *see* J. Jonas Anderson, *Nontechnical Disclosure*, 69 VAND. L. REV. 1573, 1577–80 (2016) (summarizing the requirements of § 112).

38 Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974) (quoting Painton & Co. v. Bourns, Inc., 442 F.2d 216, 224 (2d Cir. 1971)).

39 *See* UNIF. TRADE SECRETS ACT (UNIF. LAW COMM'N 1985).

40 *See* 35 U.S.C. §§ 102, 103, and 101, respectively.

41 *See id.* § 102(b) (creating a statutory grace period).

they do not protect exactly the same thing.[42] This can be accomplished in multiple ways.

Different, linked aspects of an invention may be protected through patents and trade secrets.[43] For instance, a drug may be patented, but the methods of manufacturing that drug may be protected by trade secret.[44] Similarly, details of how to finish, commercialize, manufacture, and market a patented product are typically protectable by trade secret.[45]

A second recognized method of using patents and trade secrets as complements is to disclose the general invention in the patent, but to keep the preferred way to practice that invention as a trade secret. Thus, a patentee can claim a broad group of inventions, but keep secret the precise member of that group she has determined will work best and be most commercially successful.[46] Theoretically, the best mode requirement prevents this practice; under § 112, a patent applicant must disclose what she contemplates as the best way of practicing the invention.[47] But the requirement has many limitations. Best modes discovered after patent filing are not covered; indeed, there is no mechanism by which a patent disclosure can be updated after filing.[48] Best modes developed by a licensee or an assignee need not be disclosed.[49] And after the passage of the America Invents Act (AIA), the best mode requirement is no longer grounds to invalidate a patent, making it a rather toothless requirement enforceable only by a near-psychic patent examiner.[50]

Inventors know about and use this complementarity; law firms encourage it.[51] And much complementarity is entirely reasonable and permitted within the current system. The next Part, however, discusses an aspect of the patent system in tension with at least some complementary uses: the desire for robust competition after the expiration of a patent.

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42 *See, e.g.*, Jorda, *supra* note 33, at 19 ("The goal is to integrate patents and trade secrets for optimal synergistic protection of any innovation."); Love & Seaman, *supra* note 4; McGurk & Lu, *supra* note 35, at 209 ("Patents and trade secrets are not incompatible but complementary."); Simon & Sichelman, *supra* note 8, at 12–15.

43 McGurk & Lu, *supra* note 35, at 211.

44 *See* W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 536–38 (2014) (describing the efficiency gain of a new method of producing veterinary penicillin and the trade secret protection of that new method).

45 *See infra* Part III.

46 *See* Love & Seaman, *supra* note 4; Simon & Sichelman, *supra* note 8.

47 35 U.S.C. § 112(a) (2012) ("The specification . . . shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.").

48 *See* Simon & Sichelman, *supra* note 8, at 14–15.

49 McGurk & Lu, *supra* note 35, at 212.

50 *See* Ryan Vacca, *Patent Reform and Best Mode: A Signal to the Patent Office or a Step Toward Elimination?*, 75 ALB. L. REV. 279, 293–94 (2012).

51 *See* Love & Seaman, *supra* note 4, at 12 & n.58 (quoting AIA updates to clients from Baker Botts and Venable noting that best modes may be kept secret even while patent protection is sought).

II. Competition After Patent Expiration

A key aspect of intellectual property exclusivity is that its protection comes with built-in limits. Most relevant for this context, patents expire after twenty years.[52] This limit reflects an underlying policy: excessive monopolies are disfavored. Monopolies create deadweight loss because a monopolist sets prices at a level higher than those that would maximize aggregate social welfare. The result is that the monopolist is better off—but consumers are worse off, and by a greater amount than the monopolist is better off. The intellectual property system tolerates this as a means to create incentives for innovation—that's the whole point—but longer monopolies than needed to drive innovation are social pain without offsetting gain. Ideally, the monopoly should last just long enough to provide a sufficient ex ante incentive for innovation, and then end in favor of competition and decreased prices.[53] Realistically, trying to tailor monopoly scope like this is very hard and comes with high transaction costs, so the intellectual property system relies instead on uniform terms.[54]

This goal of limited monopolies, followed by competition, appears in numerous doctrines and decisions throughout patent law. Perhaps the most obvious is the best mode requirement. In 2007, the House Judiciary Committee explained the purpose of this requirement: to "reward[ ] inventors for teaching the public how to make and use their inventions in the best, most effective way of which they are aware. *Its inclusion . . . is intended to preclude a patentee from maintaining a competitive advantage after patent expiration.*"[55] That is to say, an inventor should not be able to patent an invention but keep the best way to practice that invention to herself for later competitive benefits; she must share that knowledge with the public, so that competition will be fair after expiration.[56]

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52 *See* 35 U.S.C. § 154(a)(2) (setting patent term). The quasi-patent of agency-enforced regulatory exclusivity lasts a limited time, *see* Eisenberg, *supra* note 2, at 359–60, and trade secrets can be reverse-engineered or independently discovered, respectively, *see* Bone, *supra* note 28, at 257. Copyright, trademark, and rights of publicity have their own limits, but are outside the scope of this Article.

53 *See* Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. Rev. 672, 688–93 (2014).

54 *But see id.* (arguing for a model tailoring patent terms based on time-to-market); *see also* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575 (2003) (arguing that various judicial doctrines already perform some tailoring functions). The quasi-intellectual property regime of regulatory exclusivity offers greater opportunity for tailoring. *See* Heled, *supra* note 2.

55 H.R. Rep. No. 110-314, at 43 (2007) (emphasis added).

56 The best mode requirement lost its teeth with the enactment of the America Invents Act in 2011, which nominally keeps it but precludes its violation as cause for invalidating a patent. 35 U.S.C. § 282(b)(3)(A); *see* Love & Seaman, *supra* note 4 (describing how best modes can—and likely will—now be kept as trade secrets); Vacca, *supra* note 50.

Courts have recognized this rationale in several areas of patent doctrine, including the question of post-expiration royalties in the recent case of *Kimble v. Marvel Entertainment, LLC*.[57] There, the Supreme Court noted,

> Patents endow their holders with certain superpowers, but only for a limited time. In crafting the patent laws, Congress struck a balance between fostering innovation and ensuring public access to discoveries. While a patent lasts, the patentee possesses exclusive rights to the patented article—rights he may sell or license for royalty payments if he so chooses. But a patent typically expires 20 years from the day the application for it was filed. And when the patent expires, the patentee's prerogatives expire too, and the right to make or use the article, free from all restriction, passes to the public.
>
> This Court has carefully guarded that cut-off date . . . : In case after case, the Court has construed those laws to preclude measures that restrict free access to formerly patented, as well as unpatentable, inventions.[58]

The Court went on to describe its own cases limiting state laws that provide protection to formerly patented or unpatentable inventions[59] and holding unenforceable "private contract provisions limiting free use of such inventions."[60] But the Court noted that even though such rules limit private ordering solutions that may be desirable to all parties involved, they conflict with "a broad policy favoring unrestricted use of an invention after its patent's expiration."[61] "Congress . . . made a judgment: that the day after a patent lapses, the formerly protected invention must be available to all for free."[62]

III. Secrecy Barriers to Post-Expiration Competition

Complementary use of patents and trade secrecy is in tension with the goal of open competition outside the bounds of the patent right. Where the protected aspects of the invention are different and separable, this tension may be diffused or justified. But sometimes the protected aspects are inseparable, and any realistic competition in the market requires use of both patented and secret aspects of a single invention. In these cases, trade secrets can effectively completely block competition, even after patent expiration. This, I argue, subverts the bargain central to the patent system, and harms consumers by keeping prices high.

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57 135 S. Ct. 2401 (2015).

58 *Id.* at 2406–07 (internal citations omitted) (citing Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 230 (1964)).

59 *Id.* at 2407 (first citing *Sears, Roebuck & Co.*, 376 U.S. at 230–33; then citing Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 152, 167–68 (1989)).

60 *Id.* (citing Scott Paper Co. v. Marcalus Mfg. Co., 326 U.S. 249 (1945)).

61 *Id.* at 2411. Notably, the Court did not conclude that post-expiration royalties were in fact anticompetitive; it held instead that that logic was not enough to overturn the precedent on which *Kimble* rested, *Brulotte v. Thys Co.*, 379 U.S. 29 (1964). *See Kimble*, 135 S. Ct. at 2411.

62 *Kimble*, 135 S. Ct. at 2413 (citing *Brulotte*, 379 U.S. at 31–32).

The goal of post-expiration competition reflects a considered judgment about the limits of the patent system and how the patent system's levers should be used to drive innovation. As described above, the patent bargain trades disclosure and innovation for a right to exclude—limited in time, and subject to open competition after expiration.[63] The trade secret trade-off is different: no expiration, and potentially lower costs, but a narrower scope and the ability of competitors to invent-around or reverse-engineer. When the two are used to provide complementary protection for the same invention, there is inevitably some tension; any additional protection that trade secrets provide is (of necessity) beyond that contemplated by the patent bargain. But this tension is somewhat diffused, both doctrinally and on a policy level, by the idea that precisely what is being protected is somewhat different—different aspects of the invention, ancillary innovations, or the sort of commercialization data that are recognizably outside the scope of the patent system.

There are, however, situations where both patented and secret aspects of an invention are necessary for any reasonable competition. I look here to the market for interchangeable goods—that is, where "generic" versions of a patented product are meant to be used interchangeably with the patented good as originally marketed. In many instances, important market substitutes are not generic versions meant to be interchanged seamlessly. For instance, consumers buying handheld shavers recognize that different models will perform differently, and different manufacturers can compete along those axes of difference. But competition for other goods really does require relatively seamless interchangeability. Consumers switching from a brand-name drug to a generic version expect them to behave identically. Doctors ordering a diagnostic test for their patients expect to get the same results from different vendors, as long as the ordered test is the same. And when the military purchases firearms from different manufacturers or sub-manufacturers, it expects that the firearms will behave identically. Other examples of interchangeability exist in many contexts.[64] I look here to situations where interchangeability—and the associated static nature of the products—are relatively uncontroversial.[65]

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63 *See supra* Part II.

64 For instance, in any situation where substantial costs have been sunk into a technology that interacts with a specific good, future versions of that good may need to be identical. Printer cartridges, pre-measured coffee pods, and CPU interfaces are all potential examples of varying complexity, and varying levels of sunk costs.

65 A separate question, and one I have considered in other contexts, involves the problems that arise from problematic requirements that products or processes remain static and therefore stifle innovation. *See* Price, *supra* note 44, at 519–22 (describing how regulatory lock-in reduces innovation in drug manufacturing processes). Where interchangeability is required, products don't change. In many contexts, this lack of product innovation is problematic. I focus here on situations where we may be less concerned with static products, such as drugs involved in ongoing medical processes or rifles with large existing stocks in use.

The best examples of this phenomenon—competition among interchangeable versions of a marketed product—occur in the area of drugs. Doctors and patients expect that different versions of a drug produced by different manufacturers—brand-name or generic—will perform identically. Once the patent on atorvastatin expired on November 30, 2011, generic companies gained the ability to make generic versions of the statin Lipitor, at the time the world's best-selling drug.[66] Six months later, the price dropped from approximately $165 to around $15 for a month's supply as several companies entered the market with generic versions that were expected to perform exactly the same.[67]

This dynamic of robust competition by interchangeable generics immediately following patent expiration was the explicit goal of the Hatch-Waxman Act.[68] The Act enabled FDA to approve generic versions of an approved drug so long as they were demonstrated to be equivalent to the reference product, without the requirement of costly (and potentially ethically dubious) duplicative clinical trials of the generic drug.[69] It also included a mechanism designed precisely to enable competition as soon as the patents expired: the safe harbor of 35 U.S.C. § 271(e)(1).[70] This provision allows generic competitors to make and test generic versions of the drug before the patents on the drug expire, which would otherwise violate those patents.[71] The safe harbor is designed to eliminate any potential lag where generic companies would need to wait until the patents expire before developing their own versions, conducting equivalence testing, and arranging manufacturing capability. The Act also includes incentives to hasten generic entry by encouraging challenges to invalid patents that cover a drug.[72] It reflects most clearly a social judgment that the patent bargain on drugs—often considered the industry for which patents are most important and most dominant—includes a clear expiration date and the goal of immediate, interchangeable competition.

66 *See* Cristina Luiggi, *Lipitor Patent Expires*, SCIENTIST (Nov. 30, 2011), http://www.the-scientist.com/?articles.view/articleNo/31457/title/Lipitor-Patent-Expires/.

67 *See* Scott Hensley, *How Cheap Can Lipitor Get? Try Free*, NPR (Sept. 12, 2012), http://www.npr.org/sections/health-shots/2012/09/12/160997059/how-cheap-can-lipitor-get-try-free/ (noting the generic costs of $0.50/pill and that some retailers were giving Lipitor to customers for free in 2012); Todd Hixon, *The High Stakes Games Around Generic Lipitor*, FORBES (Dec. 7, 2011), http://www.forbes.com/sites/toddhixon/2011/12/07/the-high-stakes-games-around-generic-lipitor/#c27561176a35 (noting the $165 price for a monthly prescription in 2011). This equivalence appears not only in doctor and patient expectations, and in the judgment of FDA, but also in state law. State pharmacy laws on generic substitution typically recognize FDA-approved equivalence by creating requirements that pharmacies fill prescriptions for atorvastatin with cheaper generic versions unless the prescribing doctor specifically noted otherwise. *See* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 175–76 (2016).

68 *See* Carrier & Shadowen, *supra* note 67, at 173.

69 *See id.* at 174.

70 *See* 35 U.S.C. § 271(e)(1) (2012).

71 *See id.*

72 *See* Carrier & Shadowen, *supra* note 67, at 173.

This Part describes three different ways that innovators can keep secret information inextricably linked to a product, and can thereby effectively block any real competition in the relevant market. First, innovators can keep secret later-developed information about the product itself necessary to compete in the market. I refer here not just to best modes that might confer a competitive advantage, but rather to information effectively necessary to compete *at all* in the market for the interchangeable invention. Second, innovators can keep secret the details necessary to produce required and bundled economic complements to the invention, such that the interchangeable invention itself cannot be meaningfully made or marketed without those secret complements. Third and finally, innovators can keep secret later-developed information not about the invention itself, but necessary to use it in the way that interchangeability-demanding consumers require.

A. Later-Developed Information About the Product Itself

The first way firms may continue a patent-protected monopoly past the expiration of the patent term occurs when firms keep secret information they develop about patented products after patenting that is necessary to make an interchangeable version of the product itself. If the market then requires that products be interchangeable with the initial product for fair competition, keeping that information as a trade secret can prevent later competition for the product after patent expiration.

Here, too, the best example of this phenomenon occurs in the area of drugs—but here, instead of small-molecule drugs, the story focuses on biologics, which are large-molecule drugs (typically proteins) produced by living organisms.[73] Biologics include many of the top-selling drugs available today, including Avastin, Humira, Enbrel, and others with sales in the billions of dollars annually. Biologics make up a growing fraction of the drug-development pipeline, and are responsible for a similarly growing fraction of drug expenditures.[74]

Unsurprisingly, biologics, like small-molecule drugs, are the subject of an explicit policy judgment promoting interchangeable competition upon patent expiration. This policy is embodied in the Biologics Price Competition and Innovation Act (BPCIA), which mimics the Hatch-Waxman Act in large part.[75] Under the BPCIA, follow-on firms can rely on the safety and

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73 *See generally* Price & Rai, *supra* note 6. A "biological product" is defined as:

> [A] virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

42 U.S.C. § 262(i)(1) (2012).

74 *See* Price & Rai, *supra* note 6, at 1026.

75 *See* Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111–148, §§ 7001–03, 124 Stat. 119, 804–21 (2010) (codified as amended at 42 U.S.C. § 262). The BPCIA was passed as Title VII.A of the Patent Protection and Affordable Care Act. *Id.*

efficacy data of the first biologic sponsor, freeing them from the need to undergo their own full FDA approval process. To do so, they must demonstrate that their product is "highly similar" to the reference product, defined as having "no clinically meaningful differences . . . in terms of the safety, purity, and potency."[76] Such a follow-on biologic may also go a step further and be determined fully "interchangeable" with its reference product, the original biologic, if the follow-on sponsor can show that the biosimilar will have the same clinical effect as the reference biologic for every individual patient; and that for biologics administered multiple times, switching between the reference and the follow-on poses no additional safety or efficacy risk compared to using just the reference product.[77] As under the Hatch-Waxman Act, the BPCIA creates incentives for follow-on firms to challenge the patents covering biologics in the first place and contemplates a robust and competitive market for interchangeable (or almost-interchangeable)[78] products once the patent has expired.[79] Follow-on firms are similarly shielded from patent infringement liability while they prepare for market entry following patent expiration.[80]

But this competition has been slow to materialize, although the BPCIA has been law for half a decade.[81] As Arti Rai and I have argued, this lack of competition is largely due to the trade secrecy surrounding the way biologics are manufactured, which protects innovator firms' monopolies even after their patents on the biologics have expired.[82] Biologics are much more complicated than small-molecule drugs, and many details of their composition are the result of a complex and idiosyncratic manufacturing process. Generally, we lack the scientific tools to characterize biologics adequately just by examining the final product.[83] Nonetheless, FDA, understandably cautious about much larger and more complex drugs, requires substantial evidence of similarity, including characteristics of unknown or benign significance. And because our understanding of biologics and their manufacture is so rudimentary, such requirements effectively mean that would-be biosimilar competitors must attempt the Herculean feat of reverse-engineering a complex and

76 42 U.S.C. § 262(i)(2)(A), (B).

77 *Id.* § 262(i)(3), (k)(4).

78 The BPCIA creates two classes of biosimilars. The easier classification is to show that a product is "biosimilar," meaning that it is "highly similar" to the reference product, without "clinically meaningful differences . . . in terms of the safety, purity, and potency of the product." *Id.* § 262(i)(2)(B). A biosimilar may be "interchangeable"—as that term is defined under the BPCIA—if it will have the same effect for every patient and if switching back and forth between the biosimilar and the reference product poses no additional safety or efficacy risk to using just the reference product. *Id.* § 262 (i)(2), (k)(4).

79 *Id.* § 262(k)(6).

80 The safe harbor of the Hatch-Waxman Act applies to biologics as well as to small-molecule drugs. 35 U.S.C. § 271(e)(1) (2012).

81 *See* Heled, *supra* note 2.

82 *See* Price & Rai, *supra* note 6, at 1046–48.

83 *See id.*

idiosyncratic manufacturing process whose contours cannot be discerned from the final product.[84]

This dynamic is illustrated most clearly by a closely related story about an old blockbuster biologic, Premarin.[85] Premarin is a mixture of conjugated estrogens distilled from the urine of pregnant mares and used to treat symptoms associated with menopause.[86] Wyeth (since acquired by Pfizer) patented the estrogen mixtures and methods of purifying them in the 1940s and 1950s.[87] However, long after these patents expired, Premarin still lacks an interchangeable generic competitor.[88] Why? FDA has stated that because exactly how Premarin works and exactly what it looks like are unknown (as is the case with many biologics), a generic version must be made in the same way.[89] And no one can figure out how to make Premarin that is the same as that made by Wyeth/Pfizer.[90] It is manufactured in secret in a single location in Canada by a process that competitors have been unable to reverse-engineer, more than seventy years after the drug was first marketed.[91] Indeed, the one competitor who claimed to have reverse-engineered the process was found to have actually misappropriated Wyeth's trade secrets by hir-

84 *See id.* at 1048–49.

85 For a more detailed description of Premarin, see Wyeth v. Nat. Biologics, Inc., Civ. No. 98-2469, 2003 WL 22282371 (D. Minn. Oct. 2, 2003), *aff'd*, 395 F.3d 897 (8th Cir. 2005); Price, *supra* note 44, at 534–36. The actual legal regime around Premarin is somewhat different because it is an old product. Premarin was originally approved under the Food, Drug, & Cosmetics Act (FDCA) in 1942, *Wyeth*, 2003 WL 22282371, at *1, before the 1944 enactment of the Public Health Services Act (PHSA), which created a regulatory scheme for biologics. Public Health Services Act, Pub. L. No. 78-410, 58 Stat. 682 (1944). *See* Price, *supra* note 44, at 534 n.294. Under the BPCIA, all biologics are now regulated under the PHSA, so Premarin is now eligible for the biosimilars pathway discussed above. But before the BPCIA, it was approved under the FDCA and therefore subject to the generic drug approval pathway. The essential details of the story remain unchanged.

86 *Wyeth*, 2003 WL 22282371, at *1. Notably, Premarin has become substantially less popular after studies questioned the long-term health benefits—and potentially serious risks—of hormone replacement therapy.

87 Wyeth's estrogen extraction patents included, among others, U.S. Patent No. 2,429,398 (filed May 23, 1944); U.S. Patent No. 2,551,205 (filed Oct. 1, 1947); U.S. Patent No. 2,696,265 (filed Dec. 11, 1948); and U.S. Patent No. 2,834,712 (filed May 27, 1953). *See Wyeth*, 2003 WL 22282371, at *2.

88 One competitor to Premarin, Cenestin, a mixture of synthetic estrogens, has been approved. However, Cenestin is not approved as a generic equivalent of Premarin, and may not be automatically substituted for Premarin by pharmacies. David Goetzl, *Menopause Drug Cenestin Takes on Leader Premarin: Boomers' March Past 50 Attracts Duramed with New Medication*, AdvertisingAge (May 31, 1999), http://adage.com/article/news/menopause-drug-cenestin-takes-leader-premarin-boomers-march-past-50-attracts-duramed-medication/62255/.

89 Press Release, U.S. Dep't of Health & Human Servs., U.S. Food & Drug Admin., FDA Statement on Generic Premarin (May 5, 1997) [https://perma.cc/ZJ7P-STXX].

90 *Wyeth*, 2003 WL 22282371, at *9.

91 *Id.* at *2–5.

ing a research chemist who had consulted for Wyeth, and enjoined from further work on the drug.[92]

The story of Premarin illustrates the competitive problem when information about a patented product, necessary for interchangeable competition, is developed after the patent is filed.[93] Premarin is protected from competition because of secret information about how to manufacture the precise mixture of estrogens later approved by FDA. The patents may well enable a skilled artisan to manufacture *some* mixture of estrogens—but not the mixture approved by FDA. Similarly, patents on other biologics may enable competitors to manufacture *some* version of the patented biologic—some form of erythropoietin, some monoclonal antibody, or some other therapeutic protein—but not the version approved by FDA.[94] And thus competition in those interchangeable products is sharply limited, if it is not foreclosed entirely.

It is worth pausing to answer one potential response. One might ask: Why should innovators enable their competitors to develop an interchangeable version of the product? Aren't we better off if there exists a variety of different products, some better, and some worse? In many instances, the answer may be, "of course." But in this context of biopharmaceuticals, at least, that policy decision has already been made. The Hatch-Waxman Act and the Biologics Price Competition and Innovation Act both reflect a reasoned policy choice for exactly this type of robust competition in interchangeable products upon expiration of the relevant products (and any periods of regulatory exclusivity).[95] In this area, where policy levers are so carefully set, and the incentive scheme so precisely calibrated, trade secrecy throws a wrench into that system. It allows indefinite monopolies to continue after the explicit, limited policy incentives have ended and frustrates the explicit goal of post-expiration competition.[96]

B. Required Associated Goods

A separate but closely related form of monopoly extension happens when a firm maintains a monopoly on other innovations or components

92 *Id.* at *25.

93 *See* Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 360–61 (2010) (describing the need for innovation to develop a commercial product after initial patenting).

94 *See* Price & Rai, *supra* note 6.

95 *See id.* at 1040.

96 One question that arises is why, if trade secrecy is enough to maintain exclusivity after patent expiration, firms choose to patent their invention at all. There are a few potential answers. First, because the trade secrets described here arise after patent filing, it is possible that firms may not know the potential competitive strength of their trade secrets until after they have filed for patents (for instance, a firm may not know ex ante whether its biologic manufacturing process is likely to be reverse-engineerable). Second, trade secrets inherently provide probabilistic protection that requires that competitors not successfully reverse-engineer or independently invent the secret; patents, on the contrary, are more certain. Third, patent protection is typically broader than trade secrecy. Fourth and finally, patents may provide a better signal to markets or competitors about the innovations the firm has developed.

needed to use the patented invention. This pattern has been noted in instances where further patents are used to protect the initial innovation.[97] Other scholarship has noted instances where inadequate disclosure of information known in initial patenting prevents competitors from practicing the patented invention once the patent expires.[98] This Section focuses instead on the use of trade secrecy to prevent others from making necessary interchangeable components or economic complements to a patented device, even once the patent has expired.

In *Christianson v. Colt*, the Federal and Seventh Circuits addressed this particular interaction of patents and trade secrecy.[99] There, Colt had long been the exclusive provider of M-16 assault rifles to the United States and other militaries. Its patents on the assault rifle, as well as on several improvements to parts of the rifle, had expired. However, it maintained technical specifications and manufacturing tolerances for M-16 components as trade secrets. The United States and other militaries require that all M-16 parts be interchangeable with the equivalent parts on other rifles, whenever and however manufactured.[100] The secret status of Colt's manufacturing tolerances and technical specifications thus kept any other manufacturer, not authorized by Colt, from competing in the market for M-16s or M-16 parts. Colt asserted that the M-16 and its parts could not be reverse-engineered, and its

97 *See, e.g.*, C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327 (2012) (discussing the use of additional patents to protect drugs). Other mechanisms for preserving patent monopolies may combine patents and other forms of exclusivity. For instance, if the patent on a drug has expired, but the drug sponsor holds a method-of-use patent on the only FDA-approved method of using the drug for treatment, FDA will not approve generic versions of the drug because there is no patent-free way they can be used.

98 *See* Fromer, *supra* note 4; Holbrook, *supra* note 4.

99 This case is frequently noted for its "peculiar jurisdictional battle," turning on whether the Federal Circuit or the Seventh Circuit properly had jurisdiction over a case where patent law was determinative to the district court's opinion but appeared first not in the complaint, but in a rebuttal to a defense. *See* Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 803–04 (1988). The case was appealed to the Federal Circuit, which held it lacked jurisdiction and transferred to the Seventh Circuit. *Id.* at 806. The Seventh Circuit held the Federal Circuit "clearly wrong" and *sua sponte* transferred the case back. *Id.* The Federal Circuit disagreed, describing the Seventh Circuit as "clearly wrong," and held it lacked jurisdiction, but to end the game of jurisdictional table tennis decided the case on the merits nonetheless. *Id.* at 807. The Supreme Court granted cert., held that jurisdiction properly lay with the Seventh Circuit, and vacated the Federal Circuit's opinion, *id.* at 819—which the Seventh Circuit proceeded nonetheless to cite as persuasive authority when it finally decided the case. *See* Christianson v. Colt Indus. Operating Corp., 870 F.2d 1292, 1298–1302 (7th Cir. 1989).

100 Christianson v. Colt Indus. Operating Corp., 609 F. Supp. 1174, 1176–77 (C.D. Ill. 1985). The reason for this strict interchangeability requirement is that soldiers must be able to scavenge replacement parts on the battlefield or from other, inoperable rifles. *Id.* at 1177.

expert testified that reverse-engineering a part to guarantee interchangeability would be a "massive" task.[101]

Christianson—who wished to make and sell interchangeable M-16 parts to military buyers—alleged that Colt was maintaining an improper monopoly.[102] Colt's patents, Christianson alleged, were invalid for failure to enable and failure to disclose the best mode of practicing the invention, because they did not allow a competitor (Christianson) to make interchangeable parts for the M-16 rifle.[103] The district court agreed, but the Federal and Seventh Circuits both disagreed, the former holding that:

> Patents are not production documents, and nothing in the patent law requires that a patentee must disclose data on how to mass-produce the invented product, in patents obtained on either individual parts of the product or on the entire product . . . . Thus the law has never required that a patentee who elects to manufacture its claimed invention must disclose in its patent the dimensions, tolerances, drawings, and other parameters of mass production not necessary to enable one skilled in the art to practice (as distinguished from mass-produce) the invention. Nor is it an objective of the patent system to supply, free of charge, production data and production drawings to competing manufacturers.[104]

Thus, the Federal Circuit pointed out, the patent that covered the M-16 rifle did not mention the M-16 rifle specifically; it was a patent on a general rifle, not that rifle in particular. No doctrine of patent law—whether enablement or best mode—required that Colt disclose how precisely to make an M-16 rifle or its parts: "Under the law, the question of whether Christianson is enabled by the patents to engage in mass production of the claimed inventions and to incorporate them in a particular rifle in a manner desired by a particular customer is simply and totally irrelevant."[105]

There is no doubt that the Federal Circuit—and the Seventh Circuit, which agreed with this reasoning—was correct as a matter of pure patent doctrine. Enablement and best mode are defined at the time of patenting, and the patent in this case was for a type of rifle, broadly defined, not for the M-16 later adopted by the U.S. military as its principal combat rifle with attendant steep requirements for parts interchangeability. But the fact that patent doctrine does not forbid this practice does not mean that it is good innovation policy, or that it accurately reflects the goals embodied in the patent system. Indeed, the Seventh Circuit noted, with considerably greater sympathy to Christianson,

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101 *Id.* The court also noted, "Use of reverse engineering is also hindered by provisions in Colt's contracts with the Government, that no scrap parts be sold to unauthorized persons unless such parts are damaged and unrepairable." *Id.* at 1182.

102 *Id.* at 1175.

103 *Id.* at 1176.

104 Christianson v. Colt Indus. Operating Corp., 822 F.2d 1544, 1562 (Fed. Cir. 1987) (internal citations omitted).

105 *Id.* at 1563.

> [I]f Colt can validly claim trade secret protection, it will be able to protect its commercial products from competition even after the expiration of its patents. Christianson points out, and we agree, that the best mode requirement is intended to allow the public to compete fairly with the patentee following the expiration of the patents.[106]

The patent bargain—and patent doctrine—is designed to allow fair competition after patent expiration. Mechanisms that block competitors from producing interchangeable and required economic complements frustrate that design.

Notably, the mechanism used by Colt to protect its monopoly involves both the protection of interchangeable parts and the secrecy of later-developed manufacturing information, as described in the previous Section. Much like biologics require detailed manufacturing information to be interchangeable, Colt's M-16 rifle parts required knowledge of strict manufacturing tolerance information—developed after the relevant patent applications—to be interchangeable. However, these two strategies need not always be paired. For instance, a firm could patent a diagnostic test that, in its FDA-approved (or CMS-reimbursable) form, uses proprietary reagents. Once the patent on the test expires, the requirement for proprietary reagents may continue to block competition.

C. Later-Generated Non-Product Information

A third and distinct form of post-expiration limits to competition comes when an innovator uses the patented invention to generate information closely linked to the patented invention, but not about the invention itself. By linked information, I do not mean business-related information, such as customer lists, marketing data, or the like. Instead, I refer to information that enables the effective functioning of the underlying invention for consumers, such as the data necessary to interpret a diagnostic test.[107] Without that information, follow-on innovators cannot meaningfully compete with the original innovator, because their products are not actually interchangeable to consumers.

Brenda Simon and Ted Sichelman have described this class of information-generating innovations.[108] They describe several classes of such innovations, and note the advantage that patents create in collecting later-

106 Christianson v. Colt Indus. Operating Corp., 870 F.2d 1292, 1302 n.8 (7th Cir. 1989) (citing Phillips Petroleum Co. v. Sid Richardson Carbon & Gasoline Co., 293 F. Supp. 555, 555 n.2 (N.D. Tex. 1968)).

107 These innovations may be thought of as a specialized case of research tools, though the research conducted is information closely linked to the tool itself. For examinations of the potentially problematic downstream impacts of research tool patents, see, e.g., Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813 (2001); Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999).

108 *See generally* Simon & Sichelman, *supra* note 8.

generated information.[109] They also lay out an ex post analysis for when such data-generating patents are likely to be socially problematic from an innovation standpoint, focusing on the likelihood that the data generated will preempt competition.[110]

The clearest example of this type of competition limit is the extensively studied case of Myriad Genetics. Myriad Genetics held patents on two genes, BRCA1 and BRCA2, that are related to a predisposition to develop breast or ovarian cancer. Myriad also held patents on diagnostic methods using genetic analysis of those genes to identify a predisposition for such cancer. Accordingly, Myriad had an approximate monopoly on such genetic testing for many years. Myriad's monopoly did not end when the patents expired, but when they were held invalid as claiming unpatentable subject matter.[111] Although competitors promptly rushed to offer BRCA1/2 genetic tests, and although the testing process was readily duplicable, Myriad maintained—and still maintains—the lion's share of the genetic testing market.[112] Competition is limited because, although the underlying technology can be copied, Myriad's after-generated information is secret and proprietary. Over the years of Myriad's monopoly, it collected genetic information on well over a million women, including family histories of cancer incidence.[113] Myriad accordingly has a substantial edge in interpreting the results of a genetic test.[114] While many European genetic testers (who generally were not subject to Myriad's robust patent enforcement) have an approximately twenty-percent rate of returning uninterpretable "variants of unknown significance," Myriad's rate is closer to three percent.[115] From the doctor's point of view, or the patient's, the tests are not interchangeable; one is substantially better than the other.[116]

One response might be that this is exactly the sort of baked-in lead time that we should expect when a patent lets one firm have the market to itself

109 *See id.*

110 *See id.* at 47–52.

111 *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119 (2013) (holding isolated DNA sequences unpatentable and invalidating Myriad's patents on isolated BRCA1 and BRCA2 sequences); Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1333–37 (Fed. Cir. 2012) (holding Myriad's diagnostic methods patents invalid as claiming unpatentable subject matter).

112 *See* Joseph Walker, *Myriad Genetics Fights Off Threats from Rivals*, WALL ST. J. (May 3, 2015), https://www.wsj.com/articles/myriad-genetics-fights-off-threats-from-rivals-1430645582 (noting that two years after the Supreme Court's decision striking down Myriad's patents, BRCA screening continued to account for eighty percent of Myriad's sales, and noting that in addition to other factors, "[d]octors who have stayed loyal say one of Myriad's biggest advantages is its private database of test results from the 1.5 million people it has screened for BRCA mutations, which they say helps Myriad return more accurate results").

113 *See History*, MYRIAD, https://www.myriad.com/about-myriad/inside-myriad/history/ (last visited Mar. 7, 2017).

114 *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).

115 Simon & Sichelman, *supra* note 8, at 19.

116 *See* Walker, *supra* note 112.

for a protected time.[117] But typically we expect other firms to be able to catch up. When doctors and patients don't view competitors' products as interchangeable, it's hard for that to happen. It's also especially hard to duplicate the information involved here; now that patients and doctors have access to a test with low rates of uninterpretability, they should be expected to choose that test (and do) over less informative tests, which may propagate Myriad's data advantage.[118] And as long as it can keep that data as a proprietary trade secret,[119] we should expect that competition in the area will be sharply limited, even though Myriad's patents no longer protect its business.

This case is admittedly muddier than the preceding two. It is hard, ex ante, to draw lines between information that is essential to the functioning of the invention from the point of view of purchasers versus information that is just useful for marketing and other commercial endeavors, or classical "know-how" about how to make, use, or deploy an invention.[120] Nevertheless, it at least demonstrates the possibility that after-arising technical information about a patented product can effectively block competition for that product.

One response to these three stories is an intellectual shrug. Companies are using different intellectual property tools to protect their innovations from competition—what is surprising about that? Even the use of trade secrets alongside patents—long considered mutually exclusive choices—has become more expected. But these stories are about something more than just deriving a competitive advantage. They highlight ways that firms entirely

117 Dan Burk argues this is a feature, not a bug: patents enable one player to aggregate information about many different genetic variants that might otherwise remain dispersed. *See generally* Burk, *supra* note 8.

118 We might expect pricing to play a role, where less informative tests by newer market entrants are priced at a discount. But as has been extensively described elsewhere, the health system does a poor job translating price incentives to consumer behavior, because the roles of choice, use, and payment are separated between doctors, patients, and insurers, respectively.

119 Challenges to this secrecy are arising from an unexpected direction: patients themselves. In 2016, four patients who had undergone Myriad's testing filed requests under HIPAA for their full results, including all information about the underlying sequence variants. *See* Jennifer Couzin-Frankel, *After a Prominent Gene-Testing Firm Declined to Give Patients Their Complete Data, ACLU Filed a Legal Complaint*, SCIENCE (May 19, 2016), http://www.sciencemag.org/news/2016/05/after-prominent-gene-testing-firm-declined-give-patients-their-complete-data-aclu-filed. The Department of Health and Human Services issued a new regulation in January 2016 that required such disclosure under HIPAA when requested. *See Individuals' Right Under HIPAA to Access Their Health Information*, HHS.GOV, https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html (last visited Mar. 7, 2017). Myriad initially provided just their previously-provided test results, then provided the full results in February. The patients nonetheless filed a complaint with HHS in May 2016. At least one has expressed an intention to share the genetic information she receives with publicly available databases. If this phenomenon becomes more widespread, patient access through HIPAA could become a backdoor way to divulge Myriad's proprietary information about BRCA1/2.

120 *See* Simon & Sichelman, *supra* note 8, at 6 ("Identifying problematic patents accurately ex ante will likely be difficult, so we tend to prefer ex post solutions as a general matter.").

subvert the patent bargain, gaining the advantage of legally protected exclusivity for the patent term, but then using trade secrecy to block all or almost all competition in the patented product after that term expires. The public pays the price for the patent, but then gets only a fraction of the bargained-for benefit. To the extent that such a consumer harm is significant, ways to reduce it are worth considering.

IV. Economic Enablement for Interchangeable Goods

How might we improve the competitive landscape for interchangeable goods after patent expiration?[121] The central question is what the patentee actually enables. Under current law, the patentee must enable the technical invention covered by the patent. As described above, however, there are multiple ways to enable a technical invention while continuing to prevent any realistic competition for the marketed good itself after the patent has expired. The answer, then, may require the patentee to enable more than just the bare technical invention, but instead to provide sufficient information to allow at least some competition in the patented good. One might think of this as the idea of "economic enablement," in a parallel to the current doctrine that requires technical enablement.[122] Figuring out how to create an economic enablement requirement presents a complex challenge, and this Article will not attempt to resolve it.[123] Instead, the next Part will briefly canvas some general issues and then consider where the requirement might reside: patent law, trade secret law, or somewhere else.

A. General Considerations

In any policy solution focused on economic enablement, several issues are likely to arise. First, a policy solution must define what information is required to economically enable a product. Second, disclosure requirements may reduce ex ante innovation incentives. Third, requirements could create perverse incentives to avoid the patent system. Fourth, political economy challenges complicate the enactment of new disclosure requirements. Fifth, disclosure regimes must address potential Takings Clause concerns.

The first question concerns what information is necessary to economically enable a product (setting aside the complex question of how to define that product itself).[124] Surely not all secrets must be disclosed; there seems

121 If you're unconvinced that there's a problem, of course, you can probably skip this Part.

122 *See* 35 U.S.C. § 112 (2012).

123 For some thoughts on a parallel issue, see Sichelman, *supra* note 93, at 401–02 (describing the use of the doctrine of equivalents to determine what patents would be covered by a "commercialization patent" that covers only a marketed product and its equivalents—ideally economic equivalents but likely more practical as technological equivalents).

124 The question of defining the product itself is conceptually and practically complicated. What product must would-be competitors be enabled to produce? A whole rifle, or just some of its parts? In some contexts—especially drugs, where the one-product, one-

to be no intuitive case for disclosing customer lists or marketing strategies. On the other end, manufacturing techniques necessary to meet the requirements of interchangeability should be enabled—that is, after all, the point of the exercise. In the middle are manufacturing methods that increase efficiency but are not strictly necessary to produce the interchangeable good. Disclosure of such information could facilitate competition, but could also limit ex ante incentives for innovation. This question also complicates the inevitable task of monitoring and ensuring compliance with any disclosure requirement.[125]

Second, the possibility of a disclosure regime could negatively impact incentives for innovation. The argument for intellectual property incentives is that they create rewards for innovation and therefore drive innovation in the first place. Higher rewards presumably drive more innovation—at least, ex ante. One answer to this concern is that the incentives for innovation are already set explicitly in this area by the rules of the patent system, which presumes competitive entry at the end of the patent term. Extensions and rewards beyond that time are presumably beyond the scope of that bargain.[126] Perhaps more important are the impacts on later innovation. Maintaining trade secrets tied to interchangeability requirements could lead to stasis rather than innovation.[127] Effects on the later innovative behavior of potential competitors are unclear.[128] Overall effects on innovation incentives present an essentially empirical question beyond the scope of this work.

Third, and related, if patent protection becomes particularly unattractive because it creates additional disclosure requirements, firms may choose to forgo patents entirely and rely instead on trade secrecy, potentially supplemented with regulatory exclusivity if available.[129] Increasing trade secrecy would seem a perverse effect of a disclosure regime, but could result to the

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patent syllogism, flawed though it may be, finds support in the FDA definition of products—this question may be easy. In others, such as multicomponent products, it is substantially more complex.

125 *See, e.g.*, Jeanne C. Fromer, *Dynamic Patent Disclosure*, 69 VAND. L. REV. 1715, 1722 (2016) (noting the costs of policing an ongoing disclosure regime).

126 This does not, of course, end the issue of policy calibration. The patent system may just be setting the incentive wrong. However, it seems that if the incentive is set wrong, that concern is best addressed by explicitly addressing that mismatch, rather than by the informal, ad hoc, and largely unrecognized sort of interaction described here.

127 *See supra* Section III.A (noting the lack of manufacturing changes for Premarin for several decades); *see also* Price, *supra* note 44, at 519–22 (describing the idea of regulatory lock-in of manufacturing methods for small-drug).

128 On the one hand, competitors could potentially engage in cumulative innovation if able to enter the market and access the information kept secret by the incumbent firm. On the other hand, competitors might innovate more when required to invent around the incumbent technology.

129 *See* Yaniv Heled, *Patents v. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419 (2012) (describing the interplay between exclusivity and patent life for biologics); Price & Rai, *supra* note 6 (describing the possibility that biologics manufacturers might choose to forgo patent protection in a mandatory disclosure regime).

extent that disclosure requirements are onerous enough to drive firms to choose secrecy instead.[130] This choice by a firm would not result in any change from the status quo in the competitive market for the product itself, because that product would have been protected by secrecy nonetheless. However, society and competitors would lose out on whatever information would otherwise have been disclosed in the patent application.[131] This presumes that firms are able to predict at the time of patent application that trade secrecy will be able to protect the product for longer than the patent term, and that narrower trade secret protection will sufficiently deter competition (e.g., by the market being for an interchangeable good).

Fourth, creation of a disclosure regime involves political economy challenges. Inasmuch as the current situation enables incumbent firms to sharply limit additional competition, we should expect them to react negatively to any attempt to alter the status quo to increase competition. This is a feature, not a bug. In some circumstances, as I have argued previously, disclosure of secret competition-limiting information about manufacturing could lead to broader increases in innovation about manufacturing processes, a rising tide that could theoretically lift all firms' boats.[132] But benefits inuring to incumbent firms are not prerequisite for this type of policy intervention to have a net social benefit. Nevertheless, the current policy environment does not appear to favor disclosure. Congress in 2016 enacted the Defend Trade Secrets Act, creating additional federal protection for trade secrets.[133] Similarly, in the America Invents Act of 2011,[134] Congress arguably made trade secrecy more attractive by limiting its negative impact on patentability.[135]

Fifth and finally, a mandatory disclosure regime would need to address potential Fifth Amendment Takings Clause issues. Unanticipated, ex post, mandatory disclosure of trade secrets could potentially be a taking requiring

130 *See* Anderson, *supra* note 34, at 926; Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 419 (2010) (noting that disclosure doctrines may encourage firms not to patent).

131 *See* Fromer, *supra* note 4, at 548–49; Ouellette, *supra* note 36; Jason Rantanen, *Peripheral Disclosure*, 74 U. PITT. L. REV. 1 (2012).

132 *See* Price, *supra* note 1, at 1801.

133 Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, 130 Stat. 376 (to be codified at 18 U.S.C. §§ 1331–39).

134 Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified at 35 U.S.C. § 1 (2012)).

135 *See* Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 53–57 (2012) (arguing that the AIA does not allow secret prior uses to impact patentability). *But see* Mark A. Lemley, *Does "Public Use" Mean the Same Thing It Did Last Year?*, 93 TEX. L. REV. 1119 (2015) (arguing that the AIA does not change existing law on the issue).

compensation.[136] Addressing this complex issue fully is outside the scope of this Article.[137]

B. Doctrinal Context

In the background of all the concerns raised above is a central question: Where in the law would an economic enablement requirement be located?

1. Patent Law

Patent law provides one obvious candidate for a solution: 35 U.S.C. § 112, which imposes disclosure requirements on a patent applicant.[138] This disclosure requirement could be expanded to include not merely technical disclosure, but economic enablement.

Unfortunately, timing issues create substantial challenges for using patent law to enforce economic enablement. Section 112 creates requirements for patentability, and its requirements must be met at the time of the patent application.[139] But the issues described above arise not at the time of patenting, but years later, when particular manufacturing procedures are adopted, data are collected, or specifications are imposed. Evidence of competitive problems is likely to arise even later, once the patent has expired and competition does not actually materialize despite the presence of would-be competitors. It is difficult to imagine that a patent examiner, at the time of application, could foresee what disclosure is necessary to enable a future would-be competitor to compete upon patent expiration. More importantly, the information often simply will not exist at the time of application.[140] Patents are often acquired early in the development of a new product, before manufacturing methods or specifications are developed, and before ancillary data are collected.[141] Firms cannot disclose information they do not possess, and under current law there are no provisions for patentees to update patent applications after the patent issues.[142] This issue could potentially be

136 *See* Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984). The Court notes the possibility of a taking, but also notes that

> as long as [a firm] is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking.

Id. at 1007.

137 For further discussion, see Price, *supra* note 1, at 1808; Price & Rai, *supra* note 6, at 1054–55.

138 35 U.S.C. § 112 ("The specification shall . . . enable any person skilled in the art to which [the invention] pertains . . . to make and use the same.").

139 *Id.*

140 *See* Love & Seaman, *supra* note 4, at 9.

141 *See* Price & Rai, *supra* note 6, at 1050–52.

142 *See id.* (discussing the timing problems of patent disclosure to enable the production of biosimilars and suggesting the requirement of patent updates upon regulatory approval).

resolved by requiring updated disclosure later in the life of the patent, though such a proposal has its own complexity.[143]

Patent law standing alone also provides relatively little help in defining the product to be enabled, since multiple patents may cover the same marketed product (and typically do), and multiple marketed products may be based on the invention disclosed in single patent (and frequently are).[144]

Finally, it is difficult to know what the appropriate remedy would be for a solution grounded entirely within patent law. In many instances, the problem of limited competition becomes apparent only once the relevant patent (or patents) has expired; invalidating the patent would have no effect.[145]

These concerns suggest that although economic enablement seems like a patent law issue, and although the problem seems rooted in the patent bargain, the solution may best be found outside patent law.

2. Trade Secret Law

If patent law provides unsatisfying opportunities for solving this problem, trade secret law might function better. One potential solution would limit the applicability of trade secret law in the situations described above, where its ongoing use prevents interchangeable competition for a previously-patented good. Economic enablement might be conceived as an affirmative defense to a trade secret misappropriation claim, making remedies unavailable.

The problem with this approach is that trade secrecy merely places legal protections on top of actual efforts to keep information secret.[146] But if firms can continue to keep the information actually secret—as, for instance, Wyeth could long do in the case of Premarin[147]—the unavailability of trade secret protection may make little difference. Competitors will still be unable to compete in the marketplace for the interchangeable good. Nevertheless, eliminating trade secret protection has potentially useful interactions with other approaches, discussed below.

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143 *See id.* at 1051–52; *see also* Fromer, *supra* note 125, at 1722–31 (proposing that patentees be required to disclose whenever they or their licensees commercialize products using technology covered by the patent).

144 *See* Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1548 (Fed. Cir. 1995) (discussing the disconnect between a patent and a marketed product in the context of determining for which products lost-profits damages are available).

145 One possibility might be to look to false marking requirements, which create (small) government-imposed remedies when firms falsely mark their products with nonexistent or inapplicable patents, and also provide a private right of action; a similar provision could allow competitors to sue for inadequate economic enablement. *See* 35 U.S.C. § 292(a)–(b) (2012); Fromer, *supra* note 125, at 1733–34.

146 *See* Price, *supra* note 1, at 1776.

147 *See supra* notes 82–93 and accompanying text.

3. Unfair Competition and Antitrust Law

A third possibility is to step outside intellectual property altogether and turn to unfair competition and antitrust law. Preventing competition can ordinarily run afoul of the Lanham Act or state unfair competition law.[148] Those laws do little now because intellectual property often provides a doctrinal "out" from anticompetitive behavior—intellectual property law, after all, deliberately allows firms to restrict competition to provide incentives for innovation.[149] Thus, a firm's use of trade secrecy to maintain a substantial competitive advantage does not create an antitrust violation, nor does the firm's using patents to keep competitors from the field.

Removing trade secret protection from information that prevents competition in interchangeable once-patented goods could thus enable unfair competition and antitrust actions. If firms' competition-limiting behavior were no longer shielded by trade secret doctrine, competitors or government entities could bring suit.[150] Such an action would be unusual, since unfair competition law typically does not contemplate liability for a firm's failure to actively *help* competitors; the closest parallel is likely the contested and limited essential facilities doctrine.[151] This approach might thus set problematic precedents for other areas of unfair competition law or might otherwise be especially challenging to implement.

4. Interchangeability Requirements

A last possibility relies on more complex interactions with other market factors. This analysis has focused on areas where the particular good is interchangeable because of market requirements. Those requirements can be grounded in the rules of a regulator, the needs of consumers, or the power of some other actor. An economic enablement requirement could be enforced not broadly, but in specific instances by the power of the other actor.

Such an external solution is easiest to imagine when interchangeability requirements come from a regulator. In the case of FDA, the regulator controls access to the market. At least theoretically, market access could be conditioned on the disclosure of information required for economic enablement—either contemporaneous with market access or at some later time. To be more specific, FDA could require that manufacturers seeking

148 *See* Seaman, *supra* note 24, at 383–84.

149 *See* FTC v. Actavis, 570 U.S. 756 (2013) (describing the interaction of intellectual property and antitrust and noting that antitrust principles still apply).

150 Christianson made this argument in his suit against Colt, and the Seventh Circuit held that patent law provided him with no remedy. *See supra* Section III.B. But that does not mean that such an approach is impossible—merely that it does not exist under current law.

151 *See* City of Anaheim v. S. Cal. Edison Co., 955 F.2d 1373, 1380 (9th Cir. 1992) (describing the doctrine's requirements). *But see* Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004) (noting that the Supreme Court "ha[s] never recognized such a doctrine").

approval to sell a biologic deposit with FDA all relevant manufacturing information required to make an interchangeable product,[152] with that information to be made available to competitors once the patents covering the product expire.[153] Arti Rai and I have suggested such an approach in the biologics and biosimilars context.[154]

Another regulator-centric approach might rely not on affirmative agency disclosure, but on loosening the strictures on what information the agency can disclose when asked. Current law creates a substantial hurdle to agency disclosure of secret information. For instance, 21 U.S.C. § 331(j) prohibits FDA from disclosing "any method or process which as a trade secret is entitled to protection" to anyone outside the agency.[155] This prevents competitors from just asking FDA for their competitors' secret manufacturing or other data via the Freedom of Information Act,[156] for instance, or FDA disclosing this information *sua sponte*. But these disclosure limits are tethered to the information's status as a trade secret. Changing trade secret law would remove restrictions on agency speech, and could open avenues to disclosing economically enabling information.[157] This approach is not without complications, including the incentive effects mentioned above, but could be worth exploring.[158]

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152 In large part, this information is already deposited with FDA as the Chemistry and Manufacturing Controls section of a Biologics License Application. This conveniently limits the costs potentially incurred in making tacit knowledge explicit. *See* Price & Rai, *supra* note 6, at 1053.

153 FDA could potentially also mediate some new requirement of updated patent disclosure, perhaps set at the time of FDA approval. *See id.* at 1051–52 (proposing such a scheme).

154 *See id.* at 1053–55.

155 21 U.S.C. § 331(j) (2012).

156 Confidential business information is exempt from disclosure requests under exemption 4 of the Freedom of Information Act, which covers "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4) (2012).

157 One approach could be as follows. A would-be competitor (for instance, a firm wishing to develop a biosimilar) could file a declaratory judgment action seeking to declare that the secret preventing competition prevented economic enablement, and that it should therefore no longer be protected by trade secret law. After obtaining such a declaratory judgment, the plaintiff could then seek the information from a regulator holding the information, via a FOIA request or some other mechanism. Without the limitations of trade secrecy protection, the agency would be free (and indeed, obligated) to disclose the relevant information to the would-be competitor.

158 This process does raise a potential free-riding concern, that other competitors could free-ride off the efforts of the first-mover firm in filing the suit. This dynamic exists in the context of generic drugmakers challenging patents under the Hatch-Waxman Act; to combat the problem, first-movers are given 180 days of regulatory exclusivity. One could imagine a tailored regime under which information is disclosed under a timed release, so that the first entity to file a declaratory judgment action seeking to invalidate trade secret protection would be entitled to a limited period when only it could see the secret information. Such an approach would be outside the existing framework of FOIA disclosures, and its contours are outside the scope of this Article.

Genetic tests present an interesting middle case. On the one hand, genetic tests require regulatory approval—FDA approves genetic tests as in vitro diagnostic devices.[159] FDA could potentially demand disclosure as a condition of approval, just as it could for drugs or biologics. However, FDA does not actually administer an interchangeability regime for diagnostic tests—there are no "generic" versions of a diagnostic test. Instead, such a requirement, to the extent it formally exists, resides with the providers of medical care—hospitals and insurers. Potentially, hospital systems or insurers could demand as a condition of use or reimbursement that original developers—Myriad, for instance—share data as a condition of use. But the mechanisms for such a process would be complex and challenging.[160]

Finally, in situations where the external requirement is contractual—that is, the buyers require that products meet certain specifications, as is the case with the U.S. military and the M-16 rifle[161]—one could imagine a contractual solution. That is, if the military wants robust competition to drive down the price of interchangeable M-16 rifles, could it not require by contract that Colt agree to share technical specifications with competitors? It is unclear why this does not already occur. Perhaps the military, and other potential interchangeable-goods purchasers, might be more concerned with reliability and interchangeability than with competition and lower prices. Timing may also play a role; if contracts are negotiated early in the patent term, the possibility of long-term, secrecy-enforced limits on competition may not yet be apparent. Once those limits actually manifest, sunk costs may limit the possibility of renegotiating those aspects of the contract.

All of this adds up to a rather unsatisfying mélange. Grounding economic enablement in the context of market limitations on interchangeability

159 Notably, genetic tests conducted by a centralized laboratory were long largely immunized from oversight under FDA's decision to exercise enforcement discretion for laboratory-developed tests. FDA announced in 2014 that it intended to apply its standard risk-based regulatory framework to laboratory-developed tests. *See* Letter from Sally Howard, Deputy Comm'r, U.S. Food & Drug Admin., to Tom Harkin, Chairman of the Comm. on Health, Educ., Labor and Pensions, U.S. Senate (July 31, 2014), http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/UCM407409.pdf. However, FDA has since announced that it will delay this plan. *See* Sheila Kaplan, *FDA Puts off Closing Lab-Test "Loophole," Leaving Decision to Congress and Trump*, STAT (Nov. 18, 2016), https://www.statnews.com/2016/11/18/fda-lab-test-loophole/.

160 In the medical context, interestingly enough, another mechanism potentially already exists. Those truly demanding interchangeability are neither doctors nor insurers, but instead the patients—who arguably have a right to their own information under HIPAA. And, in fact, the HHS OIG has recently held that patients have the right to the full details of their genetic data when they undergo genetic testing, including the details of non-cancerous variants. There is a movement developing among patients to request and disclose this information, eliminating the ability of firms like Myriad to keep those data secret. Couzin-Frankel, *supra* note 119; *cf.* Barbara Evans, *Big Data and the Meaning of Autonomy in a Crowd*, *in* BIG DATA, HEALTH LAW, AND BIOETHICS (I. Glenn Cohen et al. eds., forthcoming) (on file with author) (describing the possibility of patient groups contributing to medical dataset on a community level).

161 *See supra* notes 99–101 and accompanying text.

means that different situations will require different interventions. There are benefits, too—in particular, whatever external actor setting interchangeability requirements is presumably in a good place to define what exactly the relevant product is and what sort of information is likely necessary for a competitor to satisfy that requirement.

Overall, economic enablement would be a messy requirement to implement. Assuming it is a worthwhile requirement—a rather substantial assumption, and one about which I remain uncertain—patent law provides little opportunity to impose an economic enablement requirement. Trade secrecy is a somewhat more attractive possibility, but it still needs some mechanism of actual disclosure, rather than just refusing to punish misappropriation. In situations where regulators closely monitor market access and exercise substantial power, the regulator may be able to enforce an economic enablement requirement. But this doesn't cover all situations, though many of the most important may well be in the biopharmaceutical realm and thus amenable to this intervention. Other situations may be even more ad hoc.

Conclusion

The patent system reflects a bargain between inventors and society. Society's carrot for innovation is a limited period of exclusivity protected by a patent—with an emphasis on *limited*. The courts and Congress have both made decisions reflecting a policy that patent terms are designed to end. Several doctrines support the idea that after the patent term's expiration, the expectation is that competition becomes at least possible—and, ideally, prompt and robust. But in markets where the specific contours of a product must be closely duplicated, and are hard to reverse-engineer or independently develop, firms can use trade secrecy to protect innovative information necessary for that matching. In essence, firms can prevent a market for interchangeable goods from getting off the ground. This block on competition harms consumers and subverts the patent bargain, and while there may be no need for opprobrium, there is cause to consider policy moves that could increase the possibility of meaningful competition after the expiration of patent exclusivity.