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## Regulating Secrecy

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## REGULATING SECRECY

W. Nicholson Price II\*

*Abstract:* Inventors face a stark choice between two intellectual property systems of protecting innovative ideas: patents and trade secrecy. But accounts of this choice underexplore the role of the regulators that dominate some areas of innovation. Regulation interacts with intellectual property exclusivity in socially problematic ways by encouraging secrecy at the expense of innovation, efficiency, and competition. This Article theorizes how regulation empowers intellectual property generally, explains why this strengthening is problematic for trade secrecy but not for patents, and offers the solution of regulator-enforced disclosure.

When a regulator defines a product or a process, it becomes much harder to successfully commercialize minor variations on that product or process. Any associated intellectual property exclusivity thus gets much more powerful. When the FDA approves a new drug, patents covering that chemical become much costlier to invent around because similar but non-identical chemicals lack the tremendous benefit of FDA approval. This interaction between patents and regulation interaction, however, can be noted and explicitly addressed by policy. The Hatch-Waxman Act, for example, facilitates generic drug entry once drug patents expire. Regulation strengthens trade secrecy too, but more problematically. Biologics, which comprise the most innovative and expensive drugs today, are the path-dependent result of complex, secret manufacturing processes. Meeting the FDA's definition of a biologic requires reverse-engineering its complex, secret process, making trade secrecy much more valuable, but stifling competition and innovation. In such situations, regulation can push firms to choose secrecy over patents in precisely those socially important industries, like drugs, medical devices, and pesticides, where disclosure is most important.

Where regulation creates problems, however, it also offers the hope of a solution. Regulators are in a strong position to require disclosure directly: regulated firms have strong incentives for candor, regulators have the necessary expertise, and regulatory incentives can offset the costs of disclosure. More effective regulator-mediated disclosure would increase oversight and enable cumulative innovation, while retaining incentives for invention in regulated industries.

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## INTRODUCTION

Five years after Congress enacted a scheme to promote competition for biologic drugs, very few competitors have entered the market.<sup>1</sup> Biologics are wildly expensive and look to stay that way. Why is there so little competition?

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1. In 2010, the Biologics Price Competition and Innovation Act, Pub. L. No. 111-148, Sections 7001-03, 124 Stat. 804, was passed as part of the Patient Protection and Affordable Care Act. The FDA approved only its fourth biosimilar application on September 23, 2016. Ezequiel Minaya, *FDA Approves Amgen's Biosimilar Version of Humira*, WALL ST. J. (Sept. 23, 2016), <http://www.wsj.com/articles/fda-approves-amgens-biosimilar-version-of-humira-1474669560> [https://perma.cc/3F BX-BY9Y].

Traditional intellectual property explanations provide no answers. The patents on the biologics in question are expired or expiring.<sup>2</sup> Trade secrecy is foreclosed (at least theoretically) by the disclosure necessary to obtain those patents in the first place.<sup>3</sup> And under the statutory scheme governing biologics, the pseudo-patent protection of regulatory exclusivity has also expired for these biologics.<sup>4</sup> Instead, the lack of competition reflects a potent interaction between tight regulatory control and intellectual property, one that has gone largely unnoticed in the scholarly discourse on innovation policy. This Article is the first to theorize how regulation empowers intellectual property generally, to explain why this strengthening is problematic for trade secrecy but not for patents, and to offer the solution of regulator-enforced disclosure.

The modern economy thrives on innovation, and the incentives available to help drive that innovation are an accordingly significant focus of academic and policy attention. Scholars debate when patents are most appropriate, the limits of patentability, and how best to set patent parameters to create ideal incentives.<sup>5</sup> Similarly, they discuss whether and when trade secrecy is a fruitful alternative to patents, and the scope and strength of trade secrecy doctrine.<sup>6</sup> These debates about the function of intellectual property and the available incentives can be substantially enriched by considering a key dynamic: the role of regulation.

Trade secrecy and patents interact powerfully with regulatory control. The most important interaction is when a regulator defines a product based on characteristics that are themselves independently protected by intellectual property.<sup>7</sup> Regulatory benefits—approval of a drug,

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2. Bruno Calo-Fernández & Juan Leonardo Martínez-Hurtado, *Biosimilars: Company Strategies to Capture Value from the Biologics Market*, 5 PHARMACEUTICALS 1393, 1394 (2012).

3. See *infra* section I.B.

4. See Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 359–66 (2007) (describing FDA-administered periods of regulatory market or data exclusivity, where competitors are prevented from entering the market or from using the first firm's data, as "pseudo-patents," and characterizing their role in innovation policy).

5. For a sampling of this extensive literature, see, e.g., Mark A. Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315 (2011); John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. 435 (2004); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990); Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503 (2009); Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341 (2010).

6. See, e.g., J. Jonas Anderson, *Secret Inventions*, 26 BERKELEY TECH. L.J. 917 (2011); Richard A. Epstein, *The Constitutional Protection of Trade Secrets and Patents under the Biologics Price Competition and Innovation Act of 2009*, 66 FOOD & DRUG L.J. 285 (2011); Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, 61 STAN. L. REV. 311 (2008); Michael Risch, *Why Do We Have Trade Secrets?*, 11 MARQ. INTELL. PROP. L. REV. 1 (2007).

7. See *infra* section II.A.

acceptability of a pesticide, or even just a slightly faster path through regulatory checks thanks to regulatory familiarity—then strengthen whatever intellectual property protects that product characteristic.<sup>8</sup> Essentially, regulation makes inventing around the intellectual property boundaries much harder—even if the technical task of inventing around is unchanged, the economic benefits of doing so are decreased except for a much narrower subset of that invention. This intellectual property strengthening happens whether the protection is supplied by patents or by trade secrecy.

Regulation can push firms to choose trade secrecy over patents by changing their relative strengths and weaknesses. Trade secrecy has an indefinite duration, but is narrow in scope; if regulators' product definitions make it hard or impossible to invent around that narrowness, the indefinite duration becomes much more attractive.<sup>9</sup> When regulatory hurdles promote static practices, a similar effect applies. Accordingly, highly regulated industries may see problematically high levels of secrecy. As firms disclose less information, cumulative innovation becomes harder.

The importance of these dynamics is magnified by the role of heavily regulated industries. Almost by definition, industries with powerful regulators carry high social welfare costs and benefits.<sup>10</sup> To provide a few key examples, the pharmaceutical and medical device industries are crucial for public health, the nuclear industry matters for both power and national defense, and pesticides have strong environmental and agricultural implications. Accordingly, systemic problems of innovation and competition in these industries may have particularly large social welfare effects.

The innovation problems resulting from regulatory interaction with intellectual-property exclusivity are not merely theoretical; they have major practical consequences in the real world. This Article focuses on two examples in the biopharmaceutical industry—biologics manufacturing and small-molecule drug manufacturing—to demonstrate the depth of potential innovation failures. Biologics face a potent interaction where regulatory product definitions interact with secret but essential manufacturing processes to not only retard innovation in manufacturing itself, but also to prevent competitors from entering the

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8. *See infra* section II.C

9. *See infra* section II.C.2.

10. *See infra* section II.B.

market.<sup>11</sup> Small-molecule drug manufacturing techniques are subject to regulatory hurdles to innovative change, and, at least partially as a consequence, rely on the long-term protection of secrecy.<sup>12</sup> This lack of change has tremendous efficiency costs as well as the human costs of drug shortages and contamination events.<sup>13</sup>

Regulatory oversight, however, creates both problems and the possibility of a novel solution. Regulators in heavily regulated industries are uniquely suited to enforcing a disclosure obligation to counteract regulatory incentives toward secrecy. Because firms seeking regulatory approval are trying primarily to convince the regulator of the quality of their process or product, they have incentives to disclose more candidly and fully than in other situations, such as when seeking a patent.<sup>14</sup> Regulatory disclosure could thus avoid many of the problems that plague the patent system's disclosure function.<sup>15</sup> To remove the decreased incentives arising from reducing trade secrecy, disclosure could be coupled with regulatory exclusivity.<sup>16</sup>

Broad disclosure requirements would have significant implications, most of them positive. Cumulative innovation would become significantly easier, and innovations requiring network effects or widespread licensing—both difficult in a secrecy regime— would become more attractive.<sup>17</sup> Employee mobility could be enhanced to the extent that trade secrecy demands non-compete agreements.<sup>18</sup> Disclosure would enable the possibility of informed citizen oversight, a task currently left largely to overburdened regulators.<sup>19</sup> Finally, and more neutrally, a strong disclosure regime may have both positive and negative effects on the strength of intellectual property protection for

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11. W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1044 (2016).

12. W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 510–22, 532–38 (2014).

13. *Id.*

14. *See infra* section IV.A.

15. *See infra* section I.D.2.

16. *See infra* section IV.C. This coupling would in some instances provide an additional incentive, but in others would remove the possibility for triple-dipping engaged in by some companies that rely on regulatory exclusivity, patents, and trade secrecy to protect the same patent. *See infra* section III.B. For a proposal to limit problematic double-dipping by firms seeking both patent protection and regulatory exclusivity for biologics, see Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 464–70 (2012).

17. *See infra* section IV.B.1.

18. *See infra* section IV.B.2.

19. *See infra* section IV.B.3.

innovation; while trade secrecy becomes unavailable, patents become easier to enforce because information about infringement is more transparent.<sup>20</sup> Thus, the overall amount of intellectual property protection may not actually change much, as firms may pursue previously unenforceable patents.

This Article proceeds in four Parts. Part I outlines the basic doctrines of patents and trade secrecy and discusses the scholarly debate about the appropriate balance between the two in different innovation situations. Part II describes the theoretical interactions of patents and trade secrecy with regulation in the context of heavily regulated industries, and in particular the problematic effects of trade secrecy in such industries. Part III further details the problematic on-the-ground effects of manufacturing secrecy in the heavily regulated industries of small-drug and biologics. Part IV suggests regulator-mediated disclosure as a policy solution. A few brief thoughts conclude.

## I. PATENTS AND TRADE SECRECY

Inventors face a stark choice between two intellectual property systems of protecting innovative ideas: patents and trade secrecy.<sup>21</sup> Under the first, inventors receive defined protection of broad scope and limited duration, but must disclose their inventions to the public. Under the second, inventors receive protection that is narrow in scope, but which can last as long as the secret is kept and which of necessity eschews disclosure. This Part describes the doctrinal basics of patents and trade secrecy, notes key differences in legal structures and in implementation costs, and concludes by briefly summarizing the scholarly debate on the appropriate balance between the two systems.

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20. See *infra* section IV.B.4.

21. This framing is typical, though an increasing literature recognizes that sometimes inventors can avail themselves of both patents and trade secrecy for different parts of an invention. See, e.g., Brian J. Love & Christopher B. Seaman, *Best Mode Trade Secrets*, 15 YALE J.L. & TECH. 1 (2012); Ted Sichelman & Brenda Simon, *Data-Generating Patents*, 111 N.W.U. L. REV. (forthcoming 2017), [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2753547](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2753547) [https://perma.cc/QPA6-ZLQP]. Intellectual property is not the only way of creating incentives for innovation; a significant literature focuses on alternative mechanisms. See, e.g., Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115 (2003); Heled, *supra* note 16; Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303 (2013); Maxwell R. Morgan, *Regulation of Innovation Under Follow-On Biologics Legislation: FDA Exclusivity as an Efficient Incentive Mechanism*, 11 COLUM. SCI. & TECH. L. REV. 93 (2010); Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999 (2014). This Article focuses on the still-dominant mechanisms of intellectual property: patents and trade secrecy.

### A. *Doctrinal Basics*

The need for intellectual-property protection arises because innovation is typically a public good. Innovative information is usually both non-excludable—that is, it is difficult to prevent others from using it once known<sup>22</sup>—and non-rival, meaning that the use of the information by some does not make the information unavailable for use by others.<sup>23</sup> This makes it hard for innovators to internalize the full social value of their innovation.<sup>24</sup> Consequently, from a social welfare standpoint, innovators will tend to underinvest in innovation.<sup>25</sup> Society would prefer high investment in innovation; excludability mechanisms that let inventors capture more of the value of their innovations help increase that level of invention.

For technological inventions, the two principal mechanisms for exclusion are patents and trade secrets.<sup>26</sup> Under patent law, inventors may file for a patent on an invention that is new, useful, and nonobvious, so long as that invention comprises a patentable subject matter.<sup>27</sup> The inventor must disclose the subject matter of the patent, including a sufficient written description to demonstrate that she possesses the invention, as well as to enable a person having ordinary skill in the art to practice the invention.<sup>28</sup> If the inventor fulfills these statutory criteria, a patent will issue. The patent gives the inventor the right to exclude

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22. There is some debate over whether the availability of secrecy means that information that can be kept secret is not actually a public good. Mark Lemley argues that the information retains its public-good nature. Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1052 n.87 (2005). Jonas Anderson argues that the availability of secrecy removes the free-riding aspect of information public goods by allowing excludability, so that whether the goods are technically still public is irrelevant. See Anderson, *supra* note 6. For the purposes of this Article, the distinction is without much difference; trade secrecy functions as an alternative to patent law to allow excludability of information, and whether the underlying goods remain public does not change that calculus.

23. Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 129 (2004).

24. *Id.*

25. *Id.* at 129–30, 130 n.2 (noting limits to such ex ante incentive justifications).

26. In the pharmaceutical industry, trademarks also play a substantial role, including interactions with regulatory regimes. Drug packaging, coloration, and shape can all influence consumer behavior, and may be regulated as well. Drug names also play a major role, including in prescribing behavior by physicians. See, e.g., Ed Silverman, *Biosimilars: What's in a Name?*, 348 BMJ 272 (2014) (describing the naming of follow-on biologics). These issues are outside the scope of this Article.

27. 35 U.S.C. §§ 101–03, 112 (2012).

28. *Id.* § 112.

others from making, using, selling, or otherwise practicing the invention for a period of twenty years from the patent application date.<sup>29</sup>

Trade secret law provides the principal alternative to patent law.<sup>30</sup> Under the doctrine of trade secrecy, an inventor may elect to keep her invention secret. Trade secret law protects secret information that is subject to reasonable efforts to maintain secrecy and derives independent economic value from its secrecy.<sup>31</sup> Those who misappropriate that information are liable for that misappropriation.<sup>32</sup> Trade secrecy, notably, does not protect against reverse engineering or independent invention.<sup>33</sup>

### B. *Legal Differences*

An extensive scholarly literature addresses the differences between patents and trade secrecy from the point of view of an inventor seeking to maximize the return on her invention. Drawing with very broad strokes, there are three key differences between the two schemes: the requirement of disclosure, the scope of protection, and the duration of protection.

The first central distinction—indeed, a defining distinction—between patents and trade secrecy is that obtaining a patent requires disclosing the subject matter of the invention, while trade secrecy requires the opposite; the invention must be kept secret to be the subject of trade secrecy protection.<sup>34</sup> The extent to which these actually differ in practice is a matter of some debate; Mark Lemley argues that trade secrecy law actually increases the disclosure of secret inventions,<sup>35</sup> and many argue that the disclosure role of the patent system functions poorly.<sup>36</sup> However, the difference in disclosure remains significant both formally and in the courts, even if its practical significance is disputed.

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29. *Id.* §§ 154, 271.

30. Robert G. Bone, *A New Look at Trade Secret Law: Doctrine in Search of Justification*, 86 CALIF. L. REV. 241, 248–49 (1998). Variations in the interpretation of trade secret law by different states are outside the scope of this Article, but the basic contours of the doctrine are relatively constant. A subset of trade secrecy misappropriation is covered by the Economic Espionage Act, 18 U.S.C. § 1831 (2012). Congress has also recently enacted the Defend Trade Secrets Act to create a federal trade secrecy private right of action. Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, (May 11, 2016).

31. Bone, *supra* note 30.

32. *Id.* at 250–51.

33. *Id.*

34. Anderson, *supra* note 6, at 925.

35. Lemley, *supra* note 6, at 333–37.

36. *See infra* section I.D.2.

A second key distinction between trade secrecy and patents is the scope of the protection available, both what information is protected and from whom that information is protected.<sup>37</sup> Patents provide the patentee with the right to exclude all others from making, using, or offering to sell the invention within the United States;<sup>38</sup> this protection applies regardless of whether the other party independently invented the patented subject matter, stole it, reverse-engineered it, or acquired it in any other way. Trade secrecy, on the other hand, provides only a right against misappropriation of the information kept secret. If others reverse-engineer the innovation or invent it independently, trade secret law gives no rights against those others to the original inventor.<sup>39</sup>

Finally, trade secrecy and patents differ substantially in the duration of protection provided. Patents have a clearly defined term of twenty years from the date of the application.<sup>40</sup> Although this term can be lengthened—most notably for administrative delays on the part of the patent office<sup>41</sup> or, in the case of a drug, by the Food and Drug Administration (“FDA”)<sup>42</sup>—it nonetheless has a distinct end.<sup>43</sup> Trade secrecy, on the other hand, lasts as long as the information is kept secret.<sup>44</sup> Once the information is disclosed, trade secret protection ceases; until that point, it can last indefinitely.

### C. *Practical Differences*

In addition to the legal differences between the two regimes, both innovators and policymakers face practical differences in

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37. Anderson, *supra* note 6, at 924–25.

38. 35 U.S.C. § 271 (2012). Selling the invention or importing it into the United States also constitutes patent infringement, as do various other, more specific, actions. *See* Anderson, *supra* note 6, at 924–25.

39. UNIF. TRADE SECRETS ACT § 1 cmts. 1–2 (amended 1985).

40. 35 U.S.C. § 154(a)(2) (2012).

41. *Id.* § 154(b).

42. *Id.* § 156.

43. Firms frequently try to extend the effective patent protection on a product by acquiring ancillary patents that cover the commercial product, methods of use, or other aspects other than the product itself; this process, known as “evergreening,” is especially prevalent in the pharmaceutical industry. *See* C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327 (2012). However, evergreening can only do so much, and each individual patent remains a right with a defined duration. *Id.*

44. Anderson, *supra* note 6, at 924; *see also* Price, *supra* note 12, at 534–36 (describing a trade-secret protected monopoly on the drug Premarin that has existed since 1942).

implementation.<sup>45</sup> The patent system is substantially more expensive for the government and innovators, both in terms of its administration—that is, obtaining patents—and the enforcement of patents once granted.

With respect to administration, the patent system generates significant costs for both firms and the government.<sup>46</sup> Patent applications are formal legal documents that are costly to draft, partly because they must meet the stringent statutory requirements of the Patent Act.<sup>47</sup> Once drafted, patent applications are filed and, after an often lengthy back-and-forth with examiners at the United States Patent and Trademark Office (“PTO”), patents may be granted. The PTO employs approximately 8,300 patent examiners, charged with evaluating the more than 500,000 patent applications filed each year.<sup>48</sup> Patent applications cost an average of \$10,000 to \$30,000 to file, and thousands more to maintain once granted.<sup>49</sup> Trade secrecy, by contrast, requires no legal formalities to obtain; the information must simply be kept secret.<sup>50</sup>

Firm-level enforcement costs are also substantially higher for patent law than for trade secrecy. Significant passive enforcement of patents occurs; firms may avoid practicing an invention in the shadow of patent litigation, especially since knowledge of a patent increases the likelihood of treble damages for infringement.<sup>51</sup> In those instances where active enforcement is needed, however, patentees must identify infringement—

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45. Both regimes also come with systemic costs in the form of deadweight loss to consumers resulting from supracompetitive pricing. This deadweight loss is offset by the social value of the innovation incentivized. Anderson and Strandburg have noted that the deadweight loss created by patent monopolies is unnecessary if trade secrecy is available, Anderson, *supra* note 6, at 939–40 (citing Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 111 (2004)), but to the extent that trade secrecy allows supracompetitive pricing—that is, to the extent that it creates *ex ante* incentives for innovation—that pricing should be expected to create the same deadweight as if the monopoly were patent-protected. Cf. Oren Bracha & Talha Syed, *Beyond the Incentive-Access Paradigm? Product Differentiation & Copyright Revisited*, 92 TEX. L. REV. 1841, 1861–63 (2014) (discussing similar deadweight loss in the copyright space).

46. Anderson, *supra* note 6, at 925.

47. *Id.*; 35 U.S.C. §§ 101–03, 112 (2012).

48. See U.S. PATENT & TRADEMARK OFFICE, U.S. PATENT STATISTICS CHART CALENDAR YEARS 1963–2015 (2016), [http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us\\_stat.htm](http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm) [https://perma.cc/MMK9-F5CR] (noting 571,612 utility patents filed in 2013).

49. Anderson, *supra* note 6, at 925 (citing Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1498–99 (2000)).

50. UNIF. TRADE SECRETS ACT § 1 (amended 1985). Jonas Anderson has argued that trade secret law would be better served by a registry of trade secrets, which would impose some small administrative costs; however, no such registry currently exists. Anderson, *supra* note 6, at 975–77.

51. See Jon E. Wright, Note, *Willful Patent Infringement and Enhanced Damages—Evolution and Analysis*, 10 GEO. MASON L. REV. 97, 107 (2001).

a substantial challenge for methods patents, which are often difficult to observe<sup>52</sup>—and then bring a costly infringement suit.

Trade secrecy is typically cheaper to enforce for two reasons. First, although successful secrecy carries implementation costs,<sup>53</sup> it is self-enforcing: competitors cannot capitalize on information denied to them by secrecy.<sup>54</sup> Second, where misappropriation does occur, trade secret litigation is often substantially less expensive than patent litigation.<sup>55</sup> On the other hand, detecting misappropriation under a trade secrecy regime can also be quite difficult, given the defenses of independent invention and reverse engineering.<sup>56</sup>

#### D. Tradeoffs

The tradeoff between trade secrecy and patent law is the subject of intense debate. On the question of whether patents or trade secrecy better provides *ex ante* incentives for innovation, scholars differ, though the courts have broadly taken the view that patents are preferable. This section briefly outlines this debate.

##### 1. General Considerations

Court rulings in intellectual property cases generally suggest an underlying policy preference for patent law and its accompanying disclosure over trade secrecy in cases where both are available. The Supreme Court has described disclosure as the “quid pro quo” for patent protection;<sup>57</sup> it has also noted that federal patent law does not currently preempt state trade secrecy law, but could do so if state law were found to interfere with the policy of patent law.<sup>58</sup> Patent law doctrines evince

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52. Jeffrey I. D. Lewis & Art C. Cody, *Unscrambling the Egg: Pre-Suit Infringement Investigations of Process and Method Patents*, 84 J. PAT. TRADEMARK OFF. SOC'Y 5, 7–9 (2002).

53. See Lemley, *supra* note 6, at 355 (discussing practical costs of keeping secrets).

54. Competitors can reverse-engineer or independently discover some secrets, but that process requires investment and is not always successful. See, e.g., Price, *supra* note 12, at 534–38 (describing failed attempts to independently invent or reverse-engineer drug manufacturing processes).

55. Anderson, *supra* note 6, at 953 n.197 (comparing costs of trade secret and patent litigation).

56. Price, *supra* note 12, at 536–38 (noting the difficulty of detecting misappropriation of secret biologic manufacturing methods).

57. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974).

58. *Id.* at 489–90 (“If a State, through a system of protection, were to cause a substantial risk that holders of patentable inventions would not seek patents, but rather would rely on the state protection, we would be compelled to hold that such a system could not constitutionally continue to exist.”).

this policy preference for patents over trade secrets. Inventors must patent an invention within a year of putting it “in public use [or] on sale.”<sup>59</sup> In addition, the lack of broad prior user rights means that a first inventor who practices a patent as a trade secret may be enjoined from practicing her invention by a second inventor who patents that invention.<sup>60</sup> The preference for patents over secrecy has been slightly diminished by 2011’s America Invents Act, but doctrines still push firms toward patents.<sup>61</sup>

Scholars debate whether this preference for patents is good or bad, generally framing the question as the desirability of trade secrets against the well-understood backdrop of patent-law incentives.<sup>62</sup> In a pair of prominent articles, Robert Bone has argued that trade secrecy is a doctrine without justification and that its purposes are better served by

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59. 35 U.S.C. §§ 102(a)–(b) (2012). Under § 102(a), an invention is unpatentable if in public use or on sale prior to the filing date of the patent; however, § 102(b) creates an exception for disclosures by the inventor within the year prior to filing. Before 2011’s enactment of the America Invents Act, a preference for patenting was also demonstrated in the context of interference proceedings to determine patent priority among contemporaneous patent applications, where an inventor who had “abandoned, suppressed, or concealed” his invention lost priority to one who had not. Anderson, *supra* note 6, at 933–34. The America Invents Act arguably changed whether an inventor’s own secret prior use will prevent patentability under § 102, though this issue has yet to be definitively resolved. *See, e.g.*, Examination Guidelines for Implementing the First Inventor To File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,084 (Feb. 14, 2013) (“102(a) was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art. That will no longer be the case.”) (*quoting* 157 CONG. REC. S1496 (2011)). *But see* Mark A. Lemley, *Does “Public Use” Mean the Same Thing It Did Last Year?*, 93 TEX. L. REV. 1119 (2015) (arguing the definition of “public use” is and should be unchanged); Dmitry Karshedt, *The Riddle of Secret Public Use: A Response to Professor Lemley*, 93 TEX. L. REV. 159 (2015) (agreeing with Lemley on statutory grounds but rejecting secret prior use based on precedent and policy); Edward D. Manzo, *The Impact of the America Invents Act on Trade Secrets*, 13 JOHN MARSHALL REV. INTELL. PROP. L. 497, 502–17 (2014) (describing the debate and concluding no change to prior law).

60. Anderson, *supra* note 6, at 934–35. A limited prior user defense was created by the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011), § 5. *See* Manzo *supra* note 59, at 518–22.

61. Section 5 of the AIA creates a limited prior use defense. 125 Stat. at 297–99, *amending* 35 U.S.C. § 273 (2012). Section 15 of the AIA makes essentially unenforceable the requirement to disclose an invention’s best mode, leading to the possibility of patenting while keeping the best mode as a trade secret. 125 Stat. at 328, *amending* 35 U.S.C. § 282; *see* Love & Seaman, *supra* note 21, at 8. Finally, the Act arguably changed the definition of “public use,” *see supra* note 59.

62. The incentives and structures of the patent law system have been explored in depth by many scholars; that literature need not be recapped here. For a few examples, *see, e.g.*, Burk & Lemley, *supra* note 5 (describing industry-specific shaping of patent law); John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439 (2004) (arguing that patent races are beneficial by promoting early expiration of patent rights); Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J. L. & ECON. 265 (1977) (describing the prospect theory of patents); Lemley, *supra* note 23; Merges & Nelson, *supra* note 5.

common law doctrines focused on misappropriation or contract.<sup>63</sup> Mark Lemley has argued to the contrary that trade secrecy has significant benefits when considered as a form of intellectual property. He argues that trade secret law actually promotes disclosure because it lets inventors invest less in physical barriers to disclosure by relying instead on legal protections; trade secret law can allow trade-secret holders to share information within the bounds of a confidential relationship.<sup>64</sup> More recently, Jonas Anderson has argued affirmatively that secrecy should be favored in some circumstances, because it is cheaper to administer and may provide greater *ex ante* incentives for innovation of some types.<sup>65</sup> The background policy, however, tilts toward disclosure, as evidenced in part by the very structure of the patent system.

## 2. *The Role of Disclosure*

An important thread in this debate challenges the effectiveness of disclosure in the patent system as the alternative to trade secrecy, although the centrality of disclosure as a justification for the patent system is itself debated.<sup>66</sup> Katherine Strandburg has argued that disclosure that speeds follow-on innovation is the principal benefit of

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63. Bone, *supra* note 30; Robert G. Bone, *The (Still) Shaky Foundations of Trade Secret Law*, 92 TEX. L. REV. 1803 (2014).

64. Lemley, *supra* note 6; *see also* Anderson, *supra* note 6, at 945–46; Sharon K. Sandeen, *Keweenaw Revisited: Returning to First Principles of Intellectual Property Law to Determine the Issue of Federal Preemption*, 12 MARQ. INTELL. PROP. L. REV. 299, 344 (2008). For other justifications of trade secrecy, see Risch, *supra* note 6. For a collection of recent scholarship on trade secrecy, *see* THE LAW AND THEORY OF TRADE SECRECY: A HANDBOOK OF CONTEMPORARY RESEARCH (Rochelle C. Dreyfuss & Katherine J. Strandburg eds., 2011).

65. Anderson, *supra* note 6.

66. For arguments for disclosure's centrality, see, e.g., Dan L. Burk, *The Role of Patent Law in Knowledge Codification*, 23 BERKELEY TECH. L.J. 1009, 1012 (2008) (“[M]any familiar provisions of the patent statute may be viewed as incentives for codification of otherwise tacit knowledge . . . .”); Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 542 (2009) (arguing for disclosure's “centrality in the patent system”); Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 627 (2010) (arguing that “[i]t is now time to transform the patent into a readable teaching document.”). For arguments against the role of disclosure as a patent system justification, *see, e.g.*, Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 403 (2010) (“[D]isclosure is both ineffective and potentially poisonous to larger social goals.”); Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 146 (2006) (finding “disclosure obligations inconsistent with the theoretical justifications of patent law . . . .”); Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709, 745 (2012) (“Disclosure theory cannot . . . support the modern patent system.”). Ouellette, after a useful summary of this literature, suggests that argument about rationales is to some extent beside the point; we should take the existence of the patent system as a revealed preference for disclosure, and ask how well patents incentivize disclosure. Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 545, 546–47 (2012).

patent disclosure,<sup>67</sup> though this is not its only benefit.<sup>68</sup> If patents do not, in fact, promote effective disclosure of information, then a key reason to prefer patents to trade secrecy drops away. Patents may inadequately drive disclosure for several reasons, related both to the transmission of information by the patentee and the receipt by other potential innovators.

On the transmission side, the disclosure requirements of patent law are not particularly effective. A patent must contain a written description sufficient to enable a person having ordinary skill in the art to practice the invention.<sup>69</sup> In reality, however, “most scientists and engineers find patents to be repetitive and often incomprehensible.”<sup>70</sup> It is not particularly challenging to draft a patent application that provides enough information to obtain a patent but does not reveal how to practice the invention commercially.<sup>71</sup> In addition, patent applications are not published for eighteen months after filing (and sometimes not even then), slowing the transfer of timely information to other innovators.<sup>72</sup> And although the protection afforded by a patent can potentially enable the sharing of information through other, more effective means of disclosure, such as scientific publications, firms wishing to keep their innovation secret will not engage in this optional extra sharing.<sup>73</sup>

The disclosure function of patents is also lessened by doctrinal considerations that decrease the likelihood of receipt; that is, other potential innovators finding, understanding, and using the information

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67. Strandburg, *supra* note 45, at 111–13.

68. Edmund Kitch argued that patents serve a key notice function, informing the public that a claim has been staked to a piece of intellectual property. Kitch, *supra* note 62, at 273–74. Notice does not require that others be able to use the innovative information, just that they know what is off limits.

69. 35 U.S.C. § 112(a) (2012) (“The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . .”).

70. Anderson, *supra* note 6, at 943–44 (citing Fromer, *supra* note 66, at 560–62; Benjamin N. Roin, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. J.L. & TECH. 2007, 2025 (2005)).

71. *Id.* See *Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 1562 (Fed. Cir. 1987), *vacated on jurisdictional grounds*, 486 U.S. 800 (holding that the firm could keep its secret process for mass-producing rifles and making interchangeable parts as required by the government contract, despite acquiring patents related to nine separate parts of the rifles. The Federal Circuit held that “[p]atents 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.”).

72. 35 U.S.C. § 122(b) (2012); Holbrook, *supra* note 66, at 133–34.

73. Anderson, *supra* note 6, at 944.

contained with the patent document. Timothy Holbrook has noted that receipt and use of information is undermined in at least three ways.<sup>74</sup> First, the limited experimental use exception to patent infringement means that competitors cannot easily experiment with and improve upon a patented innovation without infringing the patent.<sup>75</sup> Second, the “moribund” reverse doctrine of equivalents fails to shield those who use patent disclosures to develop conceptually new innovations that still infringe the literal scope of patent claims.<sup>76</sup> Finally, those who do examine prior patents for information and are later found to infringe run the risk of being found to have infringed willfully, with possible treble damages.<sup>77</sup> Other scholars have generally agreed that the disclosure function of patents performs relatively poorly.<sup>78</sup>

This debate about innovation incentives, while still ongoing, has tended to focus on the bilateral choice between trade secrets and patent law, and has, as a consequence, neglected the impact of another significant area of law: regulation. The next Part addresses the interaction of regulatory oversight, principally premarket entry requirements, with the protection afforded by patent law and trade secrecy.

## II. THE IMPACT OF REGULATION

The dynamics of innovation and social welfare change in significant ways in the context of heavily regulated industries, especially where a premarket approval regime exists.<sup>79</sup> Two aspects of regulated industries

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74. Holbrook, *supra* note 66, at 133–34.

75. *Id.*

76. *Id.*

77. *Id.*

78. See, e.g., Anderson, *supra* note 6, at 940–46; Roin, *supra* note 70; Strandburg, *supra* note 45, at 111–18. But see Ouellette, *supra* note 66 (finding that engineers in the field of nanotechnology glean useful information from patent disclosures).

79. Although the world of heavily regulated industries is a varied one, this paper, especially the next section, focuses on regulation in the context of the biopharmaceutical industry, specifically the production of drugs and biologics. These industries are large, important, and paradigmatic examples of active innovation policy. An extensive literature focuses on innovation in drugs and biologics. For a brief sample, see, e.g., Ron A. Bouchard, et al., *The Pas de Deux of Pharmaceutical Regulation and Innovation: Who's Leading Whom?*, 24 BERKELEY TECH. L.J. 1461 (2009); Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717 (2005); Eisenberg, *supra* note 4; Hemphill & Sampat, *supra* note 43; Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813 (2001); Roin, *supra* note 5. Detailed application to other regulated industries, including aerospace, pesticides, medical devices, military equipment contracting, and

change the way patents and trade secrecy operate. First, regulated industries typically feature large public benefits—that is, the technologies involved are almost by definition important to public welfare or health; otherwise the industry would not be regulated. Thus, disclosure potentially has more significant public benefits. Second, regulatory limits on technology, especially in premarket approval contexts, may strengthen the exclusive effects of patents and trade secrecy by requiring through regulation that the protected product be closely matched, a matching made difficult or impossible by secrecy or patent protection. This Part first briefly describes some forms of regulatory control, then discusses these two innovation features of heavily regulated industries.

### A. *Regulatory Control*

Regulators can exercise varying degrees of control over their regulated industries, including access to the market, the imposition of civil or criminal penalties, and informal control such as faster or slower passage through regulatory processes. Each type of control can be viewed as a regulator-imposed cost (exclusion from markets, penalties, slow processing) for noncompliance, or, simply from a different baseline, a benefit associated with compliance (access to markets, freedom from penalties, quick processing).

In a premarket approval regime—such as exists for drugs and biologics (collectively, “biopharmaceuticals”) or medical devices, regulated by the FDA, or pesticides, regulated by the Environmental Protection Agency (EPA)—the ability to sell a product is conditioned on meeting the regulator’s requirements, whether set by statute,<sup>80</sup> regulation,<sup>81</sup> or less formal means.<sup>82</sup> Since market access is totally controlled by the agency, it can exert predictably tight control over aspects of the industry leading up to market entry.<sup>83</sup> Agencies can also

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nuclear power may yield further insight—for the latter two, including the implications of more direct government control and involvement—but are beyond the scope of this Article.

80. See Federal Food, Drug, and Cosmetics Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 901) (regulating drugs); Public Health Service Act, Pub. L. No. 73-410, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. § 601) (regulating biologics).

81. See 21 C.F.R. § 314 (2014) (Application for FDA Approval to Market a New Drug); 21 C.F.R. §§ 600–80 (regulating Biologics License Applications).

82. See, e.g., U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY ON BIOSIMILARS: Q & AS REGARDING IMPLEMENTATION OF THE BPCI ACT OF 2009: QUESTIONS AND ANSWERS (2012).

83. For an introduction to the many ways the FDA regulates the drug industry both formally and informally, see DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND

exercise control through the ability to remove noncompliant products from the market.<sup>84</sup> I describe this control as the power of “regulatory definitions,” since regulators can define—whether formally or informally—the contours a product must have to achieve regulatory approval. In this setting, regulatory approval creates the benefit of market access.

Market-access types of control are particularly powerful since costs of regulatory noncompliance cannot be offset by increased profits or market share of the nonsalable regulated product. Such control, of course, does depend on the ability of the regulator to observe the regulated behavior. However, regulatory noncompliance is easier to observe in the case of premarket approval where voluminous submissions are required to receive that approval in the first place.<sup>85</sup>

Lighter control may also be exercised by regulators without keeping products out of the market. For instance, a regulator may have the ability to impose civil monetary penalties or criminal penalties for regulatory noncompliance.<sup>86</sup> These penalties can increase the cost for noncompliant products, but—at least theoretically—can be offset by the benefits of noncompliant sales. This is particularly true in instances where the likelihood of enforcement is low, for instance in the enforcement of manufacturing standards by an agency with a limited inspection workforce<sup>87</sup> or ambiguous statutory authority.<sup>88</sup> This type of control can be exercised over the characteristics of products, the methods used to

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PHARMACEUTICAL REGULATION AT THE FDA (2010); W. Nicholson Price II & I. Glenn Cohen, *Nudging the FDA*, 10 AM. INT. 35 (2014).

84. *See, e.g.*, 7 U.S.C. § 136k (2012) (permitting the EPA to stop the sales of, seize, and destroy noncompliant pesticides or pest-control devices); 42 U.S.C. § 262(d) (2012) (authorizing FDA recall of biologics). Notwithstanding statutory authority, most recalls are voluntary, though they occur under the powerful—if sometimes implicit—threat of potential agency action. *See* Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873 (1997); Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901 (2008).

85. *See, e.g.*, 21 C.F.R. Part 314 (2014) (enumerating requirements for a New Drug Application).

86. *See, e.g.*, 7 U.S.C. § 136l (2012) (establishing the Environmental Protection Agency’s authority to pursue civil and criminal penalties for violations of pesticide regulations).

87. The FDA, for example, inspected 19% of domestic drug or device manufacturing facilities in FY 2014, and only 10% of foreign facilities. U.S. FDA, 2015 ANNUAL REPORT ON INSPECTIONS OF FACILITIES IN FY 2014, 3, 7 (2015), <http://www.fda.gov/downloads/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/UCM432287.pdf> [<https://perma.cc/4V MN-6YSZ>].

88. *See, e.g.*, Michael Snow, Note, *Seeing Through the Murky Vial: Does the FDA Have the Authority to Stop Compounding Pharmacies from Pirate Manufacturing?*, 66 VAND. L. REV. 1609 (2013) (describing the ambiguity in the FDA’s authority to oversee compounding pharmacies and the resulting quality gaps).

produce those products, or other aspects such as the way products are marketed and sold.<sup>89</sup>

Finally, regulators can informally exercise control and confer benefits by modulating the speed at which regulatory processes occur. Bureaucratic “red tape” can be expensive to firms, and conversely, quick approval process can be highly valuable.<sup>90</sup> Familiarity with a process can lead to quicker agency action, which in turn may be consequential to firms adopting that process. This informal control, while difficult to observe, can significantly impact firm choices.<sup>91</sup>

### B. *Social Costs and Benefits*

Another important characteristic of regulated industries is something of a truism: they are regulated for a reason. Regulated industries have significant social costs and benefits, which provide the rationale for their regulation above the free-market baseline. The social welfare implications can come in a variety of different forms. For instance, the FCC regulates products that emit wireless radiation to ensure that they minimize interference; every wireless product must certify FCC compliance.<sup>92</sup> Interference from noncompliant devices creates significant costs for others using the spectrum.<sup>93</sup>

Similarly, the biomedical industries, including biopharmaceuticals, have major social cost implications. Most obviously, the state has a strong interest in ensuring that drugs are safe and effective, especially considering the difficulty in acquiring high-quality information on that safety and effectiveness.<sup>94</sup> Health care costs make up 17.5% of the

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89. See, e.g., Christopher Robertson, *When Truth Cannot Be Presumed: The Regulation of Drug Promotion Under an Expanding First Amendment*, 94 B.U. L. REV. 545 (2014) (discussing FDA regulation of pharmaceutical promotion).

90. See, e.g., Aaron S. Kesselheim, Lara R. Maggs, & Ameet Sarpatwari, *Experience With the Priority Review Voucher Program for Drug Development*, 314 J. AM. MED. ASS'N. 1687–88 (2015) (finding that priority review vouchers that speed FDA approval have sold for tens to hundreds of millions of dollars); Price, *supra* note 12, at 512–14 (discussing the consequences of regulatory delays in approving manufacturing techniques).

91. Price, *supra* note 12, at 512–14.

92. 47 C.F.R. § 15 (2014) (setting requirements for radio frequency devices).

93. See Kevin Werbach, *Supercommons: Toward a Unified Theory of Wireless Communication*, 82 TEX. L. REV. 863, 941–42 (2004).

94. Eisenberg, *supra* note 4; see Daniel Carpenter, *Confidence Games: How Does Regulation Constitute Markets?*, in GOVERNMENT AND MARKETS: TOWARD A NEW THEORY OF REGULATION, 164, 175–81 (Edward J. Balleisen & David A. Moss eds., 2010) (discussing health care products as credence goods); cf. Abigail Alliance For Better Access v. Von Eschenbach, 495 F.3d 695, 713 (D.C. Cir. 2007) (describing FDA justification for requiring completion of clinical trials before allowing access to experimental drugs).

national economy, and 45% of those costs are borne by federal, state, and local governments.<sup>95</sup> Accordingly, the cost of products and the existence of competition matter in the scheme of regulation; this importance is exemplified by the creation of the statutory managed-competition schemes for small-molecule drugs and biologics.<sup>96</sup> Similar national health implications arise from the resiliency of the drug supply chain,<sup>97</sup> the quality of manufactured drugs,<sup>98</sup> and the ability (or lack thereof) of firms to quickly manufacture new drugs, such as the recent push to ramp up production of treatments for Ebola.<sup>99</sup>

The social costs and benefits in regulated industries function not so much to change the way that innovation incentives function as to magnify their effects and to place other values in the balance. For instance, in debates about the appropriate role of patents for pharmaceuticals, their role in creating incentives for innovation is frequently juxtaposed against questions of access both domestically and internationally.<sup>100</sup> Were there not tremendous social implications of health and access to lifesaving medication, the juxtaposition would lose force. In other contexts, we *expect* that incentives to invent will result in higher prices, lower access, and deadweight loss, but those changes are all part of the patent bargain: trading exclusivity for innovation and disclosure.

The regulated nature of an industry serves therefore to flag that other important social values, such as public health, transparency, and equity, may need to be placed on the scale in determining the appropriate level

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95. CENTERS FOR MEDICARE AND MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURES 2014 HIGHLIGHTS 1–2, [www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf](http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf) [https://perma.cc/PW73-R24L].

96. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (creating a generic system for small-molecule drugs); Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 804 (codified at 42 U.S.C. § 262) (creating a biosimilar competition system for biologics).

97. *See, e.g.*, Mandy L. Gatesman & Thomas J. Smith, *The Shortage of Essential Chemotherapy Drugs in the United States*, 365 NEW ENG. J. MED. 1653 (2011); S. L. Kweder & S. Dill, *Drug Shortages: The Cycle of Quantity and Quality*, 93 CLINICAL PHARMACOLOGY THERAPEUTICS 245 (2013); J. Woodcock & M. Wosinska, *Economic and Technological Drivers of Generic Sterile Injectable Drug Shortages*, 93 CLINICAL PHARMACOLOGY THERAPEUTICS 170 (2013).

98. Price, *supra* note 12, at 506–08.

99. Andrew Pollack, *Fast Track on Drug for Ebola Has Faltered*, N.Y. TIMES (Jan. 22, 2015), <http://www.nytimes.com/2015/01/23/business/fast-track-on-drug-for-ebola-has-faltered.html> [https://perma.cc/L2G3-5VC3].

100. *See, e.g.*, Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L LAW 27, 27 (2002); Bryan C. Mercurio, *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211, 217 (2004).

of innovation incentive and in tailoring that incentive regime. This tailoring includes not only access and price, but also the disclosure of information. Data resulting from clinical trials of drugs and devices, for instance, is considered to have significant value for follow-on innovation leading to socially valuable health goals.<sup>101</sup> Accordingly, a movement to encourage or require the disclosure of clinical trial data is gaining steam, despite the arguably negative effects of that disclosure on *ex ante* innovation incentives and the ability of companies to commercialize their research expenditures fully.<sup>102</sup>

In heavily regulated industries, we should expect that disclosure and access will frequently be especially important; therefore, the cost of exclusivity, especially when obtained through trade secrecy, will typically be high.

### C. *Regulatory Definitions and IP*

Regulation does not only change the stakes; it also substantively strengthens intellectual property protection. As described above, regulators can and do condition benefits on matching regulatory definitions—whether formal or informal—of a product.<sup>103</sup> Those benefits can include access to the market<sup>104</sup> or exemption from strenuous requirements,<sup>105</sup> at one extreme, to a practically easier approval pathway

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101. See, e.g., Richard Lehman & Elizabeth Loder, *Missing Clinical Trial Data*, 344 *BMJ* 8158, 8158 (2012); Michelle M. Mello, et al., *Preparing for Responsible Sharing of Clinical Trial Data*, 369 *NEW ENG. J. MED.* 1651, 1651 (2013).

102. *Id.*

103. See *supra* section II.A.

104. See, e.g., 21 C.F.R. § 314.108(b) (2014) (stating that no Abbreviated New Drug Application may be filed for a drug involving a previously new active ingredient (a “New Chemical Entity”) within five years of the first drug’s approval, or four years if the patent on the new drug is challenged).

105. Sarah Sorscher, Note, *A Longer Monopoly for Biologics?: Considering the Implications of Data Exclusivity as a Tool for Innovation Policy*, 23 *HARV. J.L. & TECH.* 285 (2009) (describing data exclusivity for biologics; under a data exclusivity regime, competitors are not barred from market participation, but must undertake their own expensive clinical trials). It is debatable whether exemption from strenuous regulatory requirements (for instance, undertaking costly clinical trials) is actually a benefit or merely an absence of a cost. Generic firms do not, after all, have a right to bypass the clinical trial/NDA process; the ANDA pathway gives them that possibility, but is the inaccessibility of that pathway really a regulatory benefit to the originator firm, or just the status quo before the ANDA pathway existed? This concern comes into play when asking, among other things, whether regulatory data exclusivity should be considered a form of intellectual property. See, e.g., Eisenberg, *supra* note 4, at 359–66 (describing regulatory exclusivity as a “pseudo-patent”). The question is essentially a baseline problem, though one with potential theoretical implications. This Article focuses on implications for incentives and takes no position on the baseline question.

at the other.<sup>106</sup> When achieving that regulatory benefit requires matching a product or process protected by an excludability mechanism, whether patent- or trade-secret-based, the regulator increases the power of that mechanism.

### 1. *Patents*

Patents are especially strong when bolstered by regulatory requirements. This effect helps explain the strength of patents in the pharmaceutical industry, an industry where patents are especially important for excluding competition.<sup>107</sup> The FDA defines a drug as a particular dose of active pharmaceutical ingredients administered in a particular way.<sup>108</sup> A firm wishing to receive approval to market that drug must demonstrate to the FDA—through nonclinical investigations and a set of expensive clinical trials—that the drug is safe and effective for the intended use. The total process typically costs firms several hundred million dollars at least.<sup>109</sup> But this second requirement runs squarely into patent protection on the original drug.<sup>110</sup> Normally, competitors can try to invent around patents to develop a competitive product, but the FDA approval regime, and the mechanics of generic competitor approval, makes inventing-around much less profitable; as a result, patents are incredibly strong on pharmaceuticals.<sup>111</sup> Competitors seeking to invent around a drug patent by making a slightly different drug must undertake the very high costs of independent clinical trials and approval. More broadly, regulation limits inventing-around when market entry is

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106. Price, *supra* note 12, at 519–22 (describing increased ease of regulatory oversight when drug characteristics match the already-approved processes, rather than requiring justification of new processes).

107. Roin, *supra* note 5, at 511–13.

108. More precisely, the FDA defines “pharmaceutical equivalents” as drugs that “contain the same active ingredient(s), are of the same dosage form, route of administration and are identical in strength or concentration.” U.S. FOOD & DRUG AGENCY, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2016), <http://www.fda.gov/Drugs/Development/ApprovalProcess/ucm079068.htm> [<https://perma.cc/URK8-JBKW>].

109. Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 *MANAGERIAL DECISION ECON.* 469, 475 (2007).

110. This intersection is explicit in the statute; under 35 U.S.C. § 271(e)(2) (2012); submitting an Abbreviated New Drug Application to piggyback on the approved New Drug Application of an innovator is an act of infringement of patents claiming that drug. The same logic applies for biosimilar applications. *Id.*

111. Janet Freilich, *The Paradox of Legal Equivalents and Scientific Equivalence: Reconciling Patent Law’s Doctrine of Equivalents with the FDA’s Bioequivalence Requirement*, 66 *SMU L. REV.* 59, 107 (2013) (noting how FDA bioequivalence requirements restrict the ways generic drug-makers can alter innovator drugs).

conditioned on product characteristics that can be protected by a patent, even if that patent protection might otherwise be very weak.<sup>112</sup>

In the context of patents, a built-in safety valve exists for regulation-strengthened exclusivity: patents have defined scopes and expire after twenty years.<sup>113</sup> Practically speaking, given the delay in regulatory implementation, this period of exclusivity will often be significantly less. The average nominal period of patent protection for an approved drug is only sixteen years rather than twenty, because the FDA approval process takes years and drugs are typically patented early in the development process.<sup>114</sup>

In a somewhat parallel context, this effect anchors the policy landscape of standard-essential patents. Such patents cover aspects of a technology required to comply with an industry standard, such as the Institute of Electrical and Electronics Engineers' (IEEE) standards for ethernet and wi-fi.<sup>115</sup> While standards facilitate technical interoperability and promote cumulative innovation, patents that cover technology needed to meet a standard become potent weapons for hold-up.<sup>116</sup> Essentially, the standard-setting organization functions as a private regulator, defining the contours of a market-acceptable product. Inventing around the patent would violate the standard; noncompliance penalties—that is, losing the market benefits of standardization—therefore strengthen patents covering necessary technology.

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112. *Id.* at 61–62 (discussing the narrow space between FDA-mandated bioequivalence and patent-required differences). The dynamics of FDA approval give substantial power even to very weak patents. Under the Hatch-Waxman Act, any patent covering a drug may be listed by the drug's sponsor in the Orange Book. Rebecca S. Eisenberg & Daniel A. Crane, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TELECOMM. & TECH. L. REV. 197, 207–11 (2015). Companies seeking FDA market approval for a generic version must typically participate in patent litigation on all patents listed in the Orange Book before the generic can be approved, and Hatch-Waxman imposes an automatic 30-month stay on that litigation—delaying generic approval for 30 months. *Id.* at 208. This applies even to weak patents listed in the Orange Book, and the FDA explicitly does not police Orange Book patents for quality or even relevance. *Id.* at 211–28.

113. 35 U.S.C. § 154(a)(2) (2012).

114. Hemphill & Sampat, *supra* note 43, at 330 (noting that drugs in their dataset were covered by a mean of 2.7 patents with a mean nominal patent term of 15.9 years.); *see also* 35 U.S.C. § 156 (2012) (setting patent term extensions based on regulatory review time). This feature of reduced nominal life has been noted as a positive benefit of patent races. *See* John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 444 (2004).

115. Mark A. Lemley & Carl Shapiro, *A Simple Approach to Setting Reasonable Royalties for Standard-Essential Patents*, 28 BERKELEY TECH. L.J. 1135, 1136 (2013).

116. *See generally* Joseph Farrell, et al., *Standard Setting, Patents, and Hold-Up*, 74 ANTITRUST L.J. 603 (2007); Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 CAL. L. REV. 1889, 1893 (2002).

Regulatory interactions with patents are powerful enough, and clear enough, that deliberate policy choices can be and often are made to address them. Accordingly, most standard-setting organizations require that standard-essential patents be licensed on fair, reasonable, and non-discriminatory terms to blunt the power of potential patent hold-up.<sup>117</sup>

In the drug context, Congress made deliberate choices to counteract regulatory strengthening of patents within the Hatch-Waxman Act.<sup>118</sup> Generic drug manufacturers have been given an incentive to challenge weak drug patents; their challenges in response reduce the period of patent protection from a nominal sixteen years to an effective eleven to thirteen years.<sup>119</sup> Generics are also statutorily shielded from infringement liability for work they do to prepare FDA regulatory submissions while the patent on the lead drug is still in force.<sup>120</sup> This lets generic companies prepare for regulatory submissions before patent expiration so that they can enter the market as soon as possible. They can also obtain invalidity and infringement decisions before entering the market, obviating the need to launch products at risk and lowering the risk of compensatory damages. Congress essentially recognized that patent protection is incredibly strong when bolstered by the FDA's approval requirements. Accordingly, the Act makes countervailing policy choices to increase competition by shortening the effective life of drug patents and hastening competition once those patents do expire.

## 2. *Trade Secrecy*

The interaction between regulatory definitions and trade secrecy is parallel but more severe and problematic. The role of regulatory definitions strengthens trade secrecy just as it does for patents, if somewhat less explicitly. When a regulator defines a product, complying with that definition can bring benefits or avoid costs, as described above. If product characteristics reflect trade secrets, the exclusivity conferred

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117. Lemley & Shapiro, *supra* note 115, at 1136–37.

118. *See* Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, & 35 U.S.C. (2012)).

119. Hemphill & Sampat, *supra* note 43, at 330 (finding an average effective lifespan of 12.2 years); Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAG. DECIS. ECON. 491, 491–502 (2007) (finding in a sample ranging from 1995 to 2005 average effective lifespans of 15.1 years for drugs with annual sales below \$50 million and 12.7 years for drugs with annual sales greater than \$500 million).

120. 35 U.S.C. § 271(e) (2012); *see* *Classen Immunotherapies, Inc. v. Biogen Idec*, 659 F.3d 1057, 1072 (2011) (holding that safe harbor applies before but not after approval).

by those trade secrets becomes correspondingly more important. For instance, when a secret manufacturing process is used to make a product, and unique product characteristics resulting from that manufacturing process are incorporated into regulatory definitions, that secret process carries the weight of regulatory compliance. Competitors seeking to comply with regulators must try to duplicate the secret process, which can range from practically impossible to merely very expensive.<sup>121</sup> This pattern might seem somewhat abstract and rare, but it occurs in the context of manufacturing biologics, as described in depth below.<sup>122</sup>

Trade secrets, unlike patents, lack the escape valve of duration. Trade secrets can continue indefinitely, which can extend regulatory strengthening for an indefinite time in problematic ways. As described below, biologics especially suffer from this problem.<sup>123</sup> One quasi-biologic product, Premarin, used to treat postmenopausal symptoms, has experienced a monopoly based on interactions between regulation and secrecy interactions for over seventy years, with no end in sight.<sup>124</sup>

In addition, the interaction between trade secrecy and regulation is often more opaque. While regulators in heavily-regulated industries may have access to trade secret data, competitors (by definition) do not, so understanding what characteristics of the regulated product result from trade-secret processes is challenging. Interactions between patents and regulation are explicit and sometimes known, so policy choices can take them into account. Interactions between trade secrecy and regulation, on the other hand, often fly below the policy radar, although recent scholarship has attempted to bring attention to them.<sup>125</sup>

The two aspects of regulatory industries described in this section interact at a practical level. Regulation can strengthen the effect of exclusivity and make the exclusive right closer to a true monopoly. And—significantly—in heavily regulated industries, this effect is likely to be more important on a social welfare level because those industries tend to have higher ancillary social costs and benefits.<sup>126</sup> Accordingly,

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121. Price, *supra* note 12, at 534–36.

122. *See infra* section III.

123. *See infra* section III.B.

124. Price, *supra* note 12, at 534–36.

125. *See generally* Price & Rai, *supra* note 11, at 1042–49.

126. David Levine has made a parallel point in the context of public infrastructure, arguing that it is fundamentally problematic for private firms to have trade secrets in matters of public infrastructure such as voting machines, breathalyzers, or educational standards. David S. Levine, *Secrecy and Unaccountability: Trade Secrets in Our Public Infrastructure*, 59 FLA. L. REV. 135, 164–70 (2007) (describing trade secrecy in publicly funded public infrastructure produced by

these issues are not merely theoretical, but have major practical implications. Although this Part has attempted to briefly describe these concerns and interactions in a conceptual fashion with brief illustrations, their operation in practice is, unsurprisingly, more complex. The next Part describes two examples of the impact of regulation on secrecy as an excludability incentive in the biopharmaceutical industry, and attempts to explain how the implications are socially problematic.

### III. BREAKDOWNS IN BIOPHARMACEUTICAL INNOVATION

The biopharmaceutical industry, including both traditional small-molecule drugs and larger biologics, is frequently presented as a success story of innovation policy. In particular, patents are largely credited as an important piece of the incentive structure for developing drugs.<sup>127</sup> Bringing a new drug to market, the story goes, is tremendously expensive, so exclusion and the possibility of monopoly pricing are needed to drive firms to develop new drugs.<sup>128</sup> Patents play an important role in this process, to the extent that unpatentable compounds are rarely developed.<sup>129</sup> With biopharmaceuticals, patents and products are often closely matched because a key patent will claim the drug itself.

The biopharmaceutical industry might then seem an odd example to observe the interplay between secrecy and innovation since the products—by regulatory and practical requirement—are fully disclosed, and are also almost invariably patented. Where, then, does secrecy fit into this picture? The answer, of course, is that the industry is not so simple as in the classic story. The industry does not just identify a single compound, patent that compound, and then sit back to watch monopoly profits roll in. Industry dynamics are, unsurprisingly, much more complex, and it is in these complexities, and the innovation underlying them, that secrecy comes into play.

In at least two areas in the biopharmaceutical industry, secrecy plays an important role, and in each of those areas secrecy can significantly hamper socially beneficial innovation. First, the secretive, idiosyncratic, and frequently stochastic way biologics are made hampers the development of biosimilars, the biologic quasi-equivalent of generic drugs. Second, the intersection between regulatory preferences for

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private firms); David S. Levine, *The People's Trade Secrets?*, 18 MICH. TELECOMM. & TECH. L. REV. 61, 75–77 (2011) (describing trade secrecy in privately funded public infrastructure).

127. See Roin, *supra* note 5, at 507–15.

128. *Id.* at 508.

129. *Id.* at 545.

stability and secrecy results in largely stagnant manufacturing process for small-molecule drugs, leading to major social welfare losses both from inefficiency and from quality lapses.

These two examples each have both practical consequences and deleterious effects on the development of fundamental knowledge about how drugs work and how they can best be made. Overall, while the central story of the biopharmaceutical industry may rightly be focused on patents and their (admittedly contested) success in driving the development of new drugs, these two important areas of the industry demonstrate that peripheral secrecy can lead to major social harm. In these situations, the policy preference for patents and disclosure over trade secrecy is unavailing; firms rely on secrecy because it provides better benefits for them, though the social cost of that choice is significant.

#### A. *Blocking Biosimilars*

Secrecy plays a major and problematic role in the production of biologics.<sup>130</sup> In particular, biologic manufacturing demonstrates the power of the interaction between secrecy and regulatory definitions. Because biologics are so closely defined by their manufacturing process, secrecy for those processes can block competition for the associated products.

Biologics differ significantly from small-molecule drugs. Small-molecule drugs, as the name implies, are relatively simple and can be chemically synthesized; these are compounds like statins, aspirin, and codeine. Biologics, on the other hand, are large biological macromolecules made by living cells;<sup>131</sup> these include mega-blockbuster drugs like Humira (\$8.5 billion in 2012 sales) and Enbrel (\$7.5 billion)

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130. For a detailed description of this interaction, see generally Price & Rai, *supra* note 11.

131. The label “biologic” also includes products of living cells other than therapeutic proteins, such as vaccines, blood products, and antivenoms. Biologics Price Competition and Innovation Act, 42 U.S.C. § 262(i) (2012). This section focuses on the production of therapeutic proteins, generally recombinant proteins produced in host cells, as such proteins are the leading edge of biologic development and the focus of both medical and innovation policy. Biologics can be regulated by the FDA’s Center for Biologics Evaluation and Research (CBER) or its Center for Drug Evaluation and Research (CDER), and can be governed by either the Federal Food, Drug, and Cosmetics Act (FDCA) for older drugs or by the Public Health Service Act (PHSA) for biologics developed after its enactment in 1944. See *Frequently Asked Questions About Therapeutic Biological Products*, UNITED STATES FOOD & DRUG ADMIN. (Dec. 15, 2014), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm113522.htm> [<https://perma.cc/ERN9-PDXV>].

and made up five of the top ten bestselling drugs of 2012.<sup>132</sup> The manufacturing processes for biologics are substantially more complex, and that complexity has pervasive effects on the market for and competition among those drugs.<sup>133</sup>

In contrast to the relatively straightforward processes by which small drugs are made, biologics are made through a complex path involving synthesis by living cells.<sup>134</sup> Critically for the purposes of regulation and innovation, the final biologics are quite path-dependent; that is, the exact contours of a biologic depend on exactly how that biologic is made.<sup>135</sup> Differences in production can change the final product, altering its effectiveness and its safety.<sup>136</sup> In one instance, producing a biologic in a different type of cell led to severe reactions to the new biologic.<sup>137</sup> Even changes in the container used to hold and administer the biologic can change the stability, activity, and immune response of the biologic.<sup>138</sup> Other changes, of course, have little effect, but which changes matter is largely unknown.

Accordingly, the FDA regulates the production of biologics quite strictly. Any manufacturing changes by the company must be accompanied by extensive evidence—based both in the company's experience and potentially in new scientific or clinical trials—that the new biologic is the same as the old.<sup>139</sup> More importantly, the complex nature and path dependence of biologics significantly complicates the process of developing competitors to biologics.

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132. Craig W. Lindsley, *The Top Prescription Drugs of 2012 Globally: Biologics Dominate, but Small Molecule CNS Drugs Hold on to Top Spots*, 4 AM. CHEM. SOC'Y CHEM. NEUROSCIENCE 905, 905 (2013).

133. Cost and innovation are also concerns in biologics manufacturing; manufacturing costs comprise about 14% of total sales for biologics manufacturers, and concerns raised about stagnation remain significant. Prabir Basu et al., *Analysis of Manufacturing Costs in Pharmaceutical Companies*, 3 J. PHARMACEUTICAL INNOVATION 30, 33 fig.1 (2008). However, the biosimilarity dynamic described below applies only to biologics, not small-molecule drugs, and is therefore the focus of this section.

134. Paul J. Declerk, *Biologics and Biosimilars: A Review of the Science and its Implications*, 1 GENERICS & BIOSIMILARS INITIATIVE J. 13, 13 (2012).

135. See Price & Rai, *supra* note 11, at 1033–35.

136. *Id.* at 1035–36.

137. Sabine Louët, *Lessons from Eprex for Biogeneric Firms*, 21 NATURE BIOTECHNOLOGY 956 (2003).

138. Basant Sharma, *Immunogenicity of Therapeutic Proteins. Part 2: Impact of Container Closures*, 25 BIOTECHNOLOGY ADVANCES 318, 319–23 (2007).

139. See *Guidance: Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products*, U.S. FOOD & DRUG ADMIN. (Apr. 1996), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm122879.htm> [<https://perma.cc/88QV-ZPQF>]; Price & Rai, *supra* note 11, at 1036.

For small-molecule drugs, once the original drug loses patent protection, generic versions of the drug typically enter the market rapidly.<sup>140</sup> These generics are chemically identical to the original—an identity easy to analytically verify—and are demonstrated to be bioequivalent; that is, they have the same effect on the body.<sup>141</sup> Generics are permitted to rely on the approval of the original drug, rather than being required to undergo their own independent, lengthy, and costly clinical trials.<sup>142</sup>

For biologics, on the other hand, currently available analytical techniques are insufficient to demonstrate that a competitor product is the same as the original biologic.<sup>143</sup> Instead, a follow-on firm must demonstrate that the new product is “highly similar” to the original biologic, without “clinically meaningful differences . . . in terms of the safety, purity, and potency of the product.”<sup>144</sup> To demonstrate this similarity, the follow-on firm must undertake analytical and clinical testing which can cost more than \$100 million, rather than the few millions typically required to demonstrate bioequivalence for a generic small-molecule drug.<sup>145</sup>

More challengingly, to create a similar biologic in the first place, the follow-on company must reverse-engineer the complex manufacturing process idiosyncratically developed by the first company.<sup>146</sup> This reversal is precisely the kind of costly duplicative research that innovation policy tries to avoid by encouraging inventors to move into the patent system. The initial development of a biologic involves many choices that have random factors, idiosyncrasies, and stochastic choices that nonetheless influence the identity and characteristics of the final product.<sup>147</sup> These choices are not typically deliberate, and frequently do not improve the resulting biologic.

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140. See generally Tracy L. Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 INT'L J. INDUS. ORG. 930, 938–39 (2008).

141. See 21 C.F.R. §§ 320.21–.63 (2014) (describing the procedures for determining the bioavailability or bioequivalence of drug products); *id.* § 320.1(e) (defining bioequivalence).

142. 21 U.S.C. § 355(j) (2012).

143. Price & Rai, *supra* note 11, at 1036–37.

144. 42 U.S.C. § 262(i)(2) (2012). A biosimilar may also be determined to be interchangeable—with the possibility of automatic pharmacy substitution—if it can be shown (1) to have the same clinical effect for each individual patient and (2) to pose no additional safety or efficacy risk when switching back and forth with the reference biologic over multiple uses. *Id.* § 262(i)(3).

145. Price & Rai, *supra* note 11, at 1048.

146. *Id.* at 1046–49.

147. Some choices may be deliberate and have partially known consequences; for instance, choosing to make a biologic in yeast rather than in mouse cells has predictable consequences for

However, when a follow-on company wishes to market a biosimilar, those twists and turns of manufacturing must largely be duplicated. Current analytical science lacks the tools to characterize a biologic fully, and also to understand how each measurable characteristic is important to the final product.<sup>148</sup> Therefore, a follow-on firm must try its best to match the manufacturing method of the first firm.<sup>149</sup> This effort may be effectively impossible—in which case no biosimilars may ever enter the market—or it may merely be very expensive and time-consuming. This means that innovator companies receive not only the time-limited protection of patents on the biologics themselves, they also are sheltered from competition indefinitely by the secrecy surrounding their manufacturing methods.<sup>150</sup> FDA regulation strengthens and calcifies this pattern by requiring precise matching to the original biologic as much as possible, even if some differences might not actually impact the drug's function.<sup>151</sup>

One particularly strong example of this pattern is the case of the drug Premarin, a product of natural conjugated estrogens made from the urine of pregnant mares.<sup>152</sup> The FDA explicitly defines Premarin according to

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how the biologic will be grown and must be purified. Other variations are random; for instance, the precise way that recombinant protein DNA incorporates into the host cell is largely uncontrollable and has variable consequences. *See id.* at 1033–35.

148. *Id.* at 1036–37.

149. Analogies may be made to the innovator firm's demonstrations of comparability after manufacturing changes, but those demonstrations are made with the benefit of extensive experience and the trade-secret data about manufacturing processes. Price & Rai, *supra* note 11, at 1036–37.

150. This juxtaposition raises the question: do these patents fail to satisfy the enablement standard? Under 35 U.S.C. § 112 (2012), a patent must enable a person having ordinary skill in the art to practice the invention; if a second firm cannot make the biologic based on that patent, is the patent valid? *See* Dmitry Karshtedt, *Limits on Hard-to-Reproduce Inventions: Process Elements and Biotechnology's Compliance with the Enablement Requirement*, 3 HASTINGS SCI. & TECH. L.J. 109, 133–37 (2011). The key distinction is that a patent may well enable such a person to create a biologic *as described in the patent*—that is, a protein having a certain amino acid sequence—without allowing that person to make the biologic *as defined by the FDA*—that is, a protein solution with a very specific set of measurable characteristics, made in a particular way. *See* Price & Rai, *supra* note 11.

151. For a description of this pattern in small-molecule drugs, see Janet Freilich, *supra* note 111, at 70.

152. *Wyeth v. Natural Biologics, Inc.*, No. Civ. 98-2469, 2003 WL 22282371, at \*1 (D. Minn. Oct. 2, 2003), *aff'd*, 395 F.3d 897 (8th Cir. 2005) (involving a trade secret misappropriation case brought by the manufacturer of Premarin against a competitor). Although Premarin, as a natural product, would be regulated as a biologic today, it was approved as a drug before the Public Health Service Act was passed. Accordingly, substitute versions of Premarin would be approved as generic drugs under the Food, Drug, and Cosmetics Act, 21 U.S.C. § 351(j) (2012), not biosimilars under the Public Health Service Act, 42 U.S.C. § 262(k) (2012). For a more detailed account of the Premarin trade secrecy case, see Price, *supra* note 12, at 534–36.

its production process, and has not approved any synthetic estrogens as generic substitutes for Premarin because the roles of the various estrogens involved are not fully understood.<sup>153</sup> The production process is kept as a trade secret, despite the existence of early patents on methods of estrogen extraction.<sup>154</sup> Though many competitors have tried to duplicate Premarin, they have all failed.<sup>155</sup> Accordingly, Premarin has been a monopoly product for over seven decades, with—by definition—no significant innovation in its production.<sup>156</sup>

Secrecy in biologics manufacturing tremendously undermines a deliberate policy of competition, with major consequences for the health of patients and the economics of the health market. Biosimilar development—when it occurs—is expected to cost up to \$100–150 million, rather than the few million dollars required to develop a generic small-molecule drug.<sup>157</sup> Consequently, biologics are expected to remain much more expensive, with drops of only 20–30 percent in price once competitive biosimilars enter the market.<sup>158</sup> And of course, as described above, many biologics may face no biosimilar competition at all.<sup>159</sup>

Secrecy in biologic manufacturing not only has profound economic and health consequences, it prevents the generation of fundamental knowledge that could increase our understanding of how biologics work and how to make them safely and efficiently.<sup>160</sup> Innovator biologic firms face scant incentives to develop fundamental knowledge about how exactly biologics (theirs or in general) are produced; they benefit from the indefinite protection provided by the combination of ignorance and

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153. Press Release, U.S. Food & Drug Admin., FDA Statement on Generic Premarin (May 5, 1997), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm169045.htm> [<https://perma.cc/3YMU-X8C5>].

154. Price, *supra* note 12, at 534–35 (citing *Wyeth*, 2003 WL 22282371, at \*1–2).

155. *Id.*

156. *Id.* at 535–36.

157. Price & Rai, *supra* note 11, at 1048.

158. *Id.* at 1028–29.

159. One more drastic way to deal with the health consequences of absent biologic competition might be to treat producers in important regulated industries as public utilities, and to more directly regulate corporate behavior. See Nicholas Bagley, *Medicine as a Public Calling*, 114 MICH. L. REV. 57 (2015) (suggesting regulating the medical industry under public utility law). This Article attempts to address the problem with less drastic measures, but should the problems persist, the public utility model presents possibilities for further intervention—with, of course, attendant political economy concerns.

160. This dynamic is cyclical; because the FDA requires tight matching to the original product, incentives are lowered to understand the medical significance of manufacturing differences—which in turn justifies the FDA's continued requirement for tight matching.

trade secrecy described above. Furthermore, innovator firms have incentives not to develop or share detailed knowledge with the FDA, out of fears that the FDA might require even more stringent matching to earlier characterizations of their own drug.<sup>161</sup> While follow-on companies have more significant incentives to develop analytical tools and may have experience copying products, they lack the broad experience with biologics' development possessed by the innovator firms. Overall, the incentives created by secrecy—or, more accurately, by secrecy's interactions with regulatory definitions and the market for biologics—actively discourage the production of new, generalizable knowledge and hamper the progress of cumulative innovation.

### B. *Making Small Drugs*

Trade secrecy and regulation also combine to create problems for the manufacturing of small-molecule drugs. We often brush aside the fact that drug manufacturers do, in fact, manufacture drugs. That is, in addition to conducting the research that results in the discovery of new drugs, and the clinical trials that demonstrate that those drugs are safe and effective, firms must also produce the drugs for distribution to the public.<sup>162</sup> Discussions of pharmaceutical innovation and economics, however, typically focus on the cost of developing new drugs and not on the challenges of actually making drugs.<sup>163</sup> This focus elides the real problems with pharmaceutical manufacturing, which is non-innovative, expensive, and of relatively poor quality.<sup>164</sup> These problems result from the combination of regulatory hurdles to innovation and inadequate intellectual property incentives.<sup>165</sup> A key piece of the latter is firms' reliance on trade secrecy instead of patent protection, and the consequent

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161. Price, *supra* note 12, at 535–36.

162. These functions may be split among multiple companies; not all drug companies discover, develop, make, and sell their own drugs. Indeed, large firms may acquire small firms for the discoveries those small firms have made, and may also license promising drugs as part of joint ventures. Similarly, firms may outsource some parts of drug manufacturing to contract manufacturing organizations (CMOs), rather than undertaking drug production themselves. See Ken Garber, *Biotech Industry Faces New Bottleneck*, 19 NATURE BIOTECHNOLOGY 184, 184–85 (2001). This potential for splitting the process does not result in significant changes to the overall innovation story; manufacturing still receives little scholarly attention, is still expensive and problematic, and still shows little innovation. See Price, *supra* note 12; Price & Rai, *supra* note 11.

163. See Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193 (2005); Roin, *supra* note 5; Bouchard, et al., *supra* note 79.

164. Price, *supra* note 12, at 497–509.

165. *Id.* at 509–39.

loss of cumulative innovation from information transfer across firms.<sup>166</sup> The dominance of trade secrecy, alongside a regulatory structure that creates incentives to avoid change, results in stagnation rather than innovation. This section briefly describes the problems of drug manufacturing, then discusses the problems in manufacturing innovation and the role of secrecy in limiting that innovation. This section argues that regulation and trade secrecy interact more simply and additively than the complex biologic interaction described above,<sup>167</sup> but also with large social costs.

Manufacturing is a high cost for drug companies, but the techniques they use are surprisingly non-innovative, frequently relying on plants and processes dating from the middle of the twentieth century.<sup>168</sup> The modernization of manufacturing in other industries has passed the drug industry by, with substantial consequences.<sup>169</sup> Moderate efficiency gains could lead to annual social welfare surpluses of between \$47 billion (if savings were used to reduce drug prices) and \$574 billion (if used to increase research-and-development budgets).<sup>170</sup> On a more human level, more innovative manufacturing and the accompanying closer control over production could cut down on the drug quality problems, including contaminations and shortages that have plagued the drug market.<sup>171</sup>

The lack of innovation in the manufacturing side of the drug industry results from two interacting factors. The first is regulatory. Like new drugs themselves, manufacturing techniques must be preapproved by the FDA; presenting an innovative technique as part of a New Drug Application is a chance for uncertainty and delay in an industry that fervently avoids both.<sup>172</sup> Making changes to approved techniques also faces procedural and substantive hurdles, creating a manufacturing mindset that a “product is approved and validated—do not change.”<sup>173</sup>

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166. *Id.* at 532–39.

167. *See supra* section III.A.

168. Price, *supra* note 12, at 500–01.

169. *Id.*

170. *Id.* at 505–06.

171. *Id.* at 506–09.

172. *Id.* at 512–14. Firms have avoided presenting new techniques to the FDA to avoid the possibility of delay in winning drug approval. *See* Testimony of Normal Winskill, Vice President for Manufacturing at Pfizer, at the FDA Science Board Meeting, 140–43 (Nov. 16, 2001), [http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3799t1\\_02.pdf](http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3799t1_02.pdf) [<https://perma.cc/6RJH-E7XX>] (describing Pfizer’s decision to avoid using a new, faster analytical technique in a New Drug Application to avoid the possibility of delays in FDA review).

173. THOMAS FRIEDLI, ET AL., OPERATIONAL EXCELLENCE IN THE PHARMACEUTICAL INDUSTRY 25 (2006) (stating that “[t]oo often in the past regulatory submission contained limited information

Overall, FDA regulatory oversight creates incentives against innovation in drug manufacturing.

The other key factor limiting this type of innovation is the pervasive—and related—choice of drug manufacturers to rely on trade secrecy instead of methods patents, which protect the methods of manufacturing a product.<sup>174</sup> Drug makers choose trade secrecy over patents for the eminently rational reasons described above.<sup>175</sup> Perhaps most importantly, if the FDA regulatory regime encourages techniques to stay constant over time, trade secrecy's indefinite duration is particularly attractive. Disclosure could potentially help competitors, and serves no particular immediate benefit for the firm. More potently, the scope of the protection can be quite narrow, needing to protect only a specific set of manufacturing processes. Broader patent rights would be challenging to enforce—as, in fact, are patent rights on the narrow process, because manufacturing processes typically occur in secret.<sup>176</sup> Discovering infringement in the first place is challenging, and once infringement is known, the costs of litigation are high.<sup>177</sup> This understandable choice of secrecy over patents and their attendant disclosure obligations decreases the opportunity for industry-wide cumulative innovation.<sup>178</sup>

Unfortunately, pharmaceutical manufacturing is an area where disclosure is highly desirable from a social standpoint, and potentially from the standpoint of industry as well. Lack of available information about manufacturing techniques severely dampens cumulative innovation.<sup>179</sup> Furthermore, intense secrecy reduces the incentives for some innovations; innovations with cost savings that are small but scalable may be cost-ineffective for a single firm to develop, but worthwhile across several firms. However, secrecy makes bargaining harder than disclosure, whether through patents or otherwise.<sup>180</sup> Thus, it

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concerning the specific root causes of those conditions. As a result, these conditions became regulatory commitments and plant operators were expected to always reproduce exactly those same sets of conditions. This type of operation can be considered a 'static manufacturing operation'').

174. Price, *supra* note 12, at 53239.

175. *See supra* section I.D.

176. *See* Price, *supra* note 12, at 526–27 (describing challenges in enforcing drug manufacturing patents); *id.* at 553–54 (describing the potential use of regulatory disclosure and FDA mediation to make patents easier to enforce and consequently more valuable).

177. *See supra* section I.C.

178. Price, *supra* note 1213, at 538.

179. *Id.* at 538–39.

180. Trade secrecy does help to solve Arrow's Information Paradox. Lemley, *supra* note 6, at 336–37. That Paradox posits that licensing information is limited when the information must be

is at least possible that the overall benefits to industry itself, setting aside the public benefits, exceed the costs of greater transparency. But industry's ability to realize these gains may be limited by distributional and collective-action problems.<sup>181</sup> The industry therefore remains in a stable but socially undesirable state, where firms across the board collectively rely on secrecy to protect the status quo, but where continuing stagnation results rather than productive innovation.

#### IV. REGULATORY DISCLOSURE

Regulation can have pernicious interactions with secrecy-based exclusivity, as described in the previous two Parts. However, the presence of a regulator also creates new possibilities for resolving those problems. Disclosure through the regulatory system is likely better to serve the goal of effective disclosure and provides other ancillary benefits, which could inure to the public, competitors in industry, and potentially even the first innovators themselves—though effects on first innovators are complex mixture of decreased secrecy protection coupled with other potential benefits.<sup>182</sup> For the reasons described above, disclosure in the patent system is frequently ineffective.<sup>183</sup> Regulatory disclosure resolves those issues. Essentially, where information is submitted to a regulator to obtain regulatory benefits, including market access or other regulatory competitive shelters,<sup>184</sup> that information could be disclosed publicly.

Such disclosure would obviously aid the goal of disclosure itself, but would also help solve the problematic combination of secrecy and regulatory boundaries by limiting trade secrecy in heavily regulated contexts. This Part first describes the basic policy proposal of regulatory disclosure. Second, it considers some of the implications of mandatory disclosure, including enablement of cumulative innovation, the

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disclosed to make the transaction attractive to the potential buyer. Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in NATIONAL BUREAU OF ECONOMIC RESEARCH, *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 609, 615 (1962). Trade secrecy helps protect the information from appropriation by the potential buyer even after disclosure. Lemley, *supra* note 6, at 336–37. However, because trade secrecy only protects information in the context of an existing confidence, it limits wider advertisement of secrets.

181. *See infra* note 204 and accompanying text. The precise nature of the political economy concerns of industry with respect to voluntary or mandatory disclosure are worth further study but are outside the scope of this work.

182. *See infra* section IV.B.

183. *See supra* section I.D.2.

184. *See generally* Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L. J. 299 (2015).

enhancement of oversight, increased worker mobility, and shifts toward patents and explicable knowledge. Third and finally, it addresses some political economy considerations and possible routes to implementation.

#### A. *Basic Framework*

Government regulators overseeing a heavily regulated industry are uniquely capable of operating and enforcing a meaningful disclosure regime. When the regulated firm seeks some benefit from the regulator—especially premarket approval, but also the maintenance of market presence or some other benefit<sup>185</sup>—the firm must convince the regulator that it deserves the benefit. In the context of small-molecule drug manufacturing, a pharmaceutical manufacturer seeking market approval must demonstrate to the FDA's satisfaction that its manufacturing process is replicable, high quality, and controlled.<sup>186</sup> Similarly, in the biologics context, the manufacturer must show the FDA that its process reliably produces a pure and therapeutically effective biologic; to the extent that the process defines the product, the firm must fully lay out its process to assist the FDA to understand the product seeking approval. In each case, such information is contained within the Chemistry and Manufacturing Controls section of the application for premarket approval, whether a New Drugs Application or a Biologics License Application.

The key aspect of these disclosures is that their purpose aligns closely with the structure of the regulatory regime. Firms have strong incentives to describe the details of their processes accurately; failing to convince the regulator forfeits either some regulatory benefits or, more typically, access to the market altogether. Penalties for nondisclosure or inaccurate disclosure can be severe, both for the product at hand and, since many firms are repeat players, for future firm interactions with the regulating agency.<sup>187</sup>

In addition to incentives for candid disclosure, regulators possess subject-matter expertise in evaluating that disclosure. Patent examiners have some scientific expertise in the area they examine, but are unlikely to possess the same depth of experience as agency reviewers charged

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185. See *supra* section II.A.

186. See, e.g., 21 U.S.C. § 355(b)(1)(D) (2012); 21 C.F.R. § 314.50(d)(1) (2014) (listing contents of the Chemistry and Manufacturing Controls section). Any subsequent manufacturing changes must be preapproved, concurrently approved, or reported, according to the significance of the change. 21 U.S.C. § 356 (2012).

187. See CARPENTER, *supra* note 83, at 673–84.

with substantive evaluation to ensure social welfare benefits from the regulated product. Put another way, while patent examiners need to check that a patent application tells a practitioner in the field enough to practice the invention, an FDA reviewer must ensure that the disclosed process would actually work, and needs to have both full disclosure and specific relevant expertise to make that determination.<sup>188</sup>

Accordingly, in heavily regulated industries, where the interaction between secrecy and regulation is problematic, the regulator could disclose those submissions required to achieve regulatory benefits. In the FDA context, for instance, the Chemistry and Manufacturing Controls section of a New Drug Application or Biologics License Application could be published when the Application is approved. This would provide clear disclosure to others—competitors or not—tied to the regulatory benefit sought from the regulator.<sup>189</sup>

### B. *Implications*

Regulatory disclosure has significant implications. Most obviously, first innovators will lose the powerful combination of trade secrecy with regulatory definitions as described above. This is the point of regulatory disclosure, but will certainly encourage substantial pushback. Industry innovators will argue that these incentives are necessary to drive them to innovate, and that removing this powerful protection will reduce

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188. 21 U.S.C. § 355(b)(1)(A); 21 C.F.R. § 314.50(d)(5) (requiring demonstration of safety and efficacy and listing the documentation in a New Drug Application necessary to satisfy that requirement). In contrast to FDA requirements, patent law does not strongly require that a patented invention actually function well; while an invention must demonstrate operable utility (that is, it must “work”), the burden is on the PTO to show that a person having ordinary skill in the art would reasonably doubt that the invention would function. *In re Swartz*, 232 F.3d 862, 864 (Fed. Cir. 2000); *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995). An invention can pass the operable utility bar even if it functions with low quality or efficiency; there is no commercial workability requirement. See *Ex parte McKay*, 200 U.S.P.Q. (BNA) 324 (P.T.O. Bd. App. 1975) (rejecting “practical considerations” as “the standard by which the statutory requirement of utility is to be measured”).

189. The details of such a plan would need substantial further elaboration, but a first step might look, perhaps counterintuitively, to patent law. Patent law’s enablement standard requires that an applicant provide sufficient information that an ordinarily skilled artisan would be able to make the product, as described in the patent, without undue experimentation. *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988); see *supra* note 150 (describing why patent law’s enablement requirement does not already solve the problem of inadequate disclosure in their circumstances). Regulatory disclosure might be held to a similar standard; the sponsor must provide sufficient information that an ordinarily resourced follow-on sponsor be able to match the regulatory definition of the product without undue experimentation. For some products, such as small-molecule drugs, this would require no more than what is disclosed now. For others, such as complex biologics, it would require more extensive disclosure, perhaps even deposition of unique cell lines.

innovation. A procedural response is that if these incentives are truly necessary, then they should be part of the explicit policy conversation—that is, the visible patent or regulatory exclusivity systems—rather than buried in opaque interactions. A more substantive response is that any cost to innovator companies should also be weighed against four possible positive effects that impact initial and later innovators as well as society more broadly. First, and certainly most important from an innovation policy/intellectual property standpoint, increased effective disclosure facilitates cumulative innovation both within firms and across them. Second, disclosure promotes oversight through the mechanism of transparency. Third, disclosure, by decreasing the importance of secrecy and associated non-disclosure and non-compete agreements, may help promote labor mobility. Fourth and finally, disclosure increases the benefits of patents, both by removing the option of trade secrecy and by increasing the ease of enforcement.

### 1. *Cumulative Innovation*

The central benefit from mandatory disclosure would be the furtherance of cumulative innovation. Though scholars argue about the importance of disclosure as a rationale for the patent system itself,<sup>190</sup> disclosure is undoubtedly a key component of cumulative innovation; without knowing the previous innovation, adding onto that innovation is impossible.<sup>191</sup> Thus, we should expect that a functional disclosure regime would increase later innovation.

Public disclosure should primarily facilitate inter-firm transfer of information, which is the standard model of cumulative innovation.<sup>192</sup> However, removing the possibility of secrecy should also aid intra-firm cumulative innovation. Measures taken to protect secret information can hinder cumulative innovation even within a firm: taking reasonable precautions to keep information secret can include compartmentalizing information and limiting its transfer between departments.<sup>193</sup> Mandatory disclosure to the outside world removes any need to compartmentalize information within the firm. Because both types of follow-on innovation

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190. See *supra* note 66, and sources cited therein.

191. See, e.g., Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSPECT. 29, 39 (1991).

192. *Id.*

193. See John Avellanet, *Securing Intellectual Property from the Inside Out*, in BEST PRACT. BIOTECHNOLOGY BUS. DEV. 37 (2008).

take place in contexts with high social costs and benefits, that innovation is likely to be especially socially valuable.<sup>194</sup>

## 2. *Oversight*

In addition, meaningful public disclosure would increase possibilities for oversight and transparency. Because social welfare impacts are high in regulated industries, oversight is particularly important, both by the regulator—hence its existence in the first place—and potentially by other actors. Transparency and disclosure enable oversight. Regulators can consult experts about potentially problematic methods, academics can independently examine data, and competitors can apply their own expertise to spot potential problems. In all of these instances, different actors, with different incentives, can perform some aspect of an oversight role.

In addition, the oversight burdens applied to typically overworked administrative agencies can be more widely spread. Current agency oversight is at times woefully under-resourced. FDA inspections of drug manufacturing facilities, for instance, occur only once every several years on average, though the FDA is working to increase that frequency.<sup>195</sup> Allowing other parties to perform at least some oversight—though, ideally, duplicative and complementary roles, not substitutions—could help improve oversight in general.

## 3. *Worker Mobility*

A third key implication from regulatory disclosure comes indirectly through its effect in decreasing trade secrecy. As Orly Lobel and others have noted, trade secrecy, and its frequent tying to non-compete agreements, reduces labor mobility and may reduce overall innovation.<sup>196</sup> These fears are bolstered by the doctrine of inevitable disclosure, which limits inter-firm transfer of workers whose new job will inevitably require that they use the trade secret knowledge acquired at their old job.<sup>197</sup> To the extent that regulatory disclosure decreases the

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194. See *supra* section II.B.

195. See Price, *supra* note 12.

196. See ORLY LOBEL, TALENT WANTS TO BE FREE: WHY WE SHOULD LEARN TO LOVE LEAKS, RAIDS, AND FREE RIDING (2013); On Amir & Orly Lobel, *Driving Performance: A Growth Theory of Noncompete Law*, 16 STAN. TECH. L. REV. 833 (2013); Mark J. Garmaise, *Ties That Truly Bind: Noncompetition Agreements, Executive Compensation, and Firm Investment*, 27 J.L. ECON. & ORG. 376 (2009).

197. See Suellen Lowry, *Inevitable Disclosure Trade Secret Disputes: Dissolutions of Concurrent Property Interests*, 40 STAN. L. REV. 519 (1988); Elizabeth A. Rowe, *When Trade Secrets Become*

possibility of trade secrecy in those industries, the incentive for firms to implement non-compete agreements is decreased. This at least has the potential to increase worker mobility and further innovation.<sup>198</sup>

#### 4. *Increased Patenting*

Mandatory disclosure does not mean that industry will cease to rely on excludability mechanisms altogether. Indeed, absent some policy choice otherwise, firms would still be able to rely on patent protection for their inventions, just not on trade secrecy. Innovations that were eligible for only trade secrecy before would be impossible to protect (save through regulatory mechanisms discussed above). However, innovations that were eligible for both patent protection and trade-secret protection would only be patentable. Accordingly, industry would be expected to patent some number of inventions that would otherwise be kept secret with the consequences expected and laid out in other scholarship for the choice of patents over trade secrecy.

Patents would be not only more valuable than no-longer-available trade secrecy, but also would be more valuable than in the current regime of patents without required disclosure. As described above, method patents are particularly hard to enforce in part because methods are kept secret, so infringement frequently goes unobserved.<sup>199</sup> If firms effectively disclose their methods, observing patent infringement becomes easier, which increases incentives to pursue patents in the first place.<sup>200</sup>

To the extent that firms can predict *ex ante* which types of innovations are likely to be patentable and which would be only protected by no-longer-available trade secrecy, they should be expected to allocate more resources to patent-eligible innovation. Because of patent law's requirements that the innovation be describable and, ideally, explicable, this may help develop fundamental knowledge, which will then be shared through both the imperfect patent disclosure and more effective regulatory disclosure.

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*Shackles: Fairness and the Inevitable Disclosure Doctrine*, 7 TUL. J. TECH. & INTELL. PROP. 167 (2005); Brandy L. Treadway, *An Overview of Individual States' Application of Inevitable Disclosure: Concrete Doctrine or Equitable Tool?*, 55 SMU L. REV. 621 (2002).

198. See generally LOBEL, *supra* note 196.

199. See Price, *supra* note 12, at 526–27; Jeffrey I. D. Lewis & Art C. Cody, *Unscrambling the Egg: Pre-Suit Infringement Investigations of Process and Method Patents*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 5, 7 (2002).

200. Price, *supra* note 12, at 554–55.

### C. Implementation

Regulatory disclosure of trade secrets comes with substantial interrelated concerns about implementation mechanisms, takings doctrine, and political economy. Regulatory disclosure is meant to be a real potential solution to real problems; that means that the practicalities of its implementation must be actively considered. This section briefly addresses some of those practicalities, although implementation would require substantially more study.

Should regulatory disclosure be mandatory or voluntary? A mandatory approach would solidify the benefits described above and ensure an equal playing field across the industry. However, mandatory disclosure might be harder to implement. In addition to political economy concerns, discussed below, a mandatory regime would raise Fifth Amendment Takings Clause concerns, particularly if applied retroactively.<sup>201</sup> Trade secrets have been recognized as property under state law, and are generally protected from agency disclosure under federal law.<sup>202</sup> Simply disclosing currently secret manufacturing methods, for instance, would then run afoul of current federal prohibitions and would likely constitute a taking requiring compensation—which could be quite substantial for trade secrets protecting exclusivity for a product. Prospective requirements that disclosure of trade secrets accompany an application for regulatory benefit, on the other hand, could avoid the takings problem but would leave untouched a large swath of currently indefinite trade secrets.<sup>203</sup>

One intriguing possibility for resolving this dilemma would be to tie disclosure to regulatory misfeasance or malfeasance. When firms run afoul of related regulations—for instance, failing to maintain quality

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201. A full analysis of the Takings Clause concerns is outside the scope of this work.

202. Price & Rai, *supra* note 11, at 1054–55. Under 21 U.S.C. § 301(j), the FDA is specifically prohibited from revealing trade secret manufacturing information under current law.

203. Even prospective disclosure requirements, if tied to the FDA's market approval regime, might constitute an unconstitutional condition. Under *Nollan v. California Coastal Comm'n*, 483 U.S. 825 (1987), and *Dolan v. City of Tigard*, 512 U.S. 374 (1994), property given up in exchange for government permission must be closely related and roughly proportional to the relevant social cost. However, the Supreme Court also noted in *Ruckelshaus v. Monsanto* in the related area of regulated pesticides, that:

[A]s 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.

467 U.S. 985, 1007 (1984). See also Price & Rai, *supra* note 11, at 1054–55 (discussing the Takings Clause concerns with mandatory disclosure in the biosimilars context).

standards in manufacturing or to prevent manufacturing-based shortages—the regulator could impose a disclosure requirement as part of the solution or penalty.<sup>204</sup> This tactic has been used extensively by the Office of the Inspector General of the Department of Health and Human Services in the context of False Claims Act<sup>205</sup> actions against health care providers, pharmaceutical companies, and medical device manufacturers,<sup>206</sup> where firms agree to ongoing corporate obligations to avoid the corporate “death sentence”<sup>207</sup> of exclusion from Medicare, Medicaid, and other federal health care programs.<sup>208</sup> Senator Elizabeth Warren has proposed a similar path for pharmaceutical firms, where settlements would require contributing revenues to NIH research<sup>209</sup> rather than disclosing information they already possess. This could also potentially obviate takings concerns.

Voluntary efforts at regulator-facilitated disclosure also resolve takings issues, but create the potential for gaming. Voluntary disclosure could be driven by incentives provided to firms, most likely in the form

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204. This does create the possibility that only some firms will disclose their innovations. Problematically, these firms would be likely to have quality problems and therefore make questionable models for cumulative innovation. There are at least three responses to this criticism. First, a large fraction of firms may stochastically come under this type of problem-solving jurisdiction at one point or another, so many firms would eventually disclose. Second, obligations imposed on a large fraction of the industry may shift the industry equilibrium to a disclosure norm. Third and finally, while having problematic firms disclose may not be ideal for cumulative innovation, it does serve the other goals described above; oversight and transparency are particularly important for underperforming firms, as is the possibility of redundant production in situations where socially valuable goods are vulnerable to quality problems or supply interruptions. See Janet Woodcock & Marta Wosinska, *Economic and Technological Drivers of Generic Sterile Injectable Drug Shortages*, 93 CLINICAL PHARMACOLOGY & THERAPEUTICS 170, 170 (2013) (noting shortages of sterile injectable drugs due to quality problems at sole manufacturers).

205. 31 U.S.C. § 3729 (2012).

206. See OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CORPORATE INTEGRITY AGREEMENT DOCUMENTS (2015), <https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp> [<https://perma.cc/W7VN-VYLT>] (listing 447 entities with Corporate Integrity Agreements, Certification of Compliance Agreements, and Settlement Agreements. These include large healthcare companies, biopharmaceutical companies, medical device manufacturers, hospitals, and individual practitioners).

207. Edward P. Lansdale, *Used as Directed? How Prosecutors Are Expanding the False Claims Act to Police Pharmaceutical Off-Label Marketing*, 41 NEW ENG. L. REV. 159, 181 (2006).

208. 42 U.S.C. § 1320a-7 (2012).

209. See Elizabeth Warren, “Support the Medical Innovation Act” (2015), [my.elizabethwarren.com/page/s/nihbill](http://my.elizabethwarren.com/page/s/nihbill) [<https://perma.cc/A6U2-9SPM>]; Ed Silverman, *Senator Wants Big Drug Makers That Break the Law to Fund NIH*, WSJ BLOGS – PHARMALOT (Jan. 22, 2015), <http://blogs.wsj.com/pharmalot/2015/01/22/senator-wants-big-drug-makers-that-break-the-law-to-fund-nih/> [<https://perma.cc/YP7Q-3VSF>].

of regulatory benefits such as agency-enforced exclusivity.<sup>210</sup> That is, if a firm discloses its secret methods, the agency could offer as a reward exclusivity for that method (or, potentially, some other exclusivity such as an extension of exclusivity for the product itself). Such exclusivity would have a limited duration and be explicit, resolving some of the problems with secrecy.<sup>211</sup> However, firms would be expected to game the system; those secrets worth more than the exclusivity would be kept secret, and those of lesser value would be disclosed, leading to a socially suboptimal outcome.

The political economy of choosing mandatory versus voluntary disclosure is more complicated than might be expected. On the one hand, mandatory disclosure means that firms may—intentionally—lose the strong protection that comes from combining exclusivity with regulatory definitions; this would seem likely to prompt strong protest. On the other hand, widespread secrecy is a strong barrier to cumulative innovation and also decreases investment in innovations that require widespread distribution to be economically feasible; secrecy can accordingly result in an industry-wide equilibrium of stagnation that is to no firm's benefit but that requires collective action to solve.<sup>212</sup> Regulatory disclosure mandates could break this equilibrium and shift to a higher-innovation equilibrium with increased quality and efficiency resulting. This view accords with at least some opinions in industry,<sup>213</sup> although the political economy of this choice may be different for different regulated industries.

Congress has already taken a step in the direction of mandated disclosure. The Biologics Price Competition and Innovation Act, which created the follow-on biologics pathway, includes provisions requiring a follow-on biologic applicant to provide the innovator company with its full application packet—disclosing the applicant's trade secrets—for the

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210. See generally Price, *supra* note 12; Price & Rai, *supra* note 11; Heled, *supra* note 184; Eisenberg, *The Role of the FDA in Innovation Policy*, *supra* note 4.

211. See Price, *supra* note 12, at 512–32 (discussing the limits of regulatory exclusivity); *id.* at 534–36 (discussing the problem of trade secrecy's potentially unlimited term).

212. One might ask why a collective action should persist in regulated industries with relatively few industry players and low amounts of certainty about the success of any particular product. See Joseph A. DiMasi, et al., *Clinical Approval Success Rates for Investigational Cancer Drugs*, 94 CLINICAL PHARMACOLOGY & THERAPEUTICS 329 (2013). However, the current maintenance of secrecy across industries belies this possibility. Furthermore, even if the industry players could be brought together, firms have incentives only to share information they have learned in the course of developing their processes, not the processes themselves.

213. Industry executive statements, MIT Center for Biomedical Innovation Summit: The Impact of Biosimilars and Biobetters on Biopharmaceutical Manufacturing (Nov. 15, 2012) (under the Chatham House Rules of the meeting, statements cannot be individually attributed).

purpose of enforcing the innovator's patent rights.<sup>214</sup> Although the disclosure is tightly circumscribed to avoid transfer of information between inventors, the fact remains that the Act mandates disclosure of trade secrets to the competitor most interested in those secrets.<sup>215</sup> While the Act reflects special congressional attention to follow-on biologics—and solicitude toward industry incumbents—it also demonstrates the possibility of a more integrated innovation policy in regulated industries, including a requirement of disclosure.

A final issue concerns international effects. If information currently kept secret is disclosed, that disclosure is almost certainly a disclosure to the world.<sup>216</sup> On the other hand, the offsetting benefits described here—principally regulatory exclusivity—are wholly domestic benefits. Accordingly, domestic firms may lose competitive advantages vis-à-vis international competitors. This is a real problem that must be addressed in the course of determining implementation details, but three possibilities exist that may curtail the problem. First, domestic benefits may be sufficient—or could be adjusted—to account for international competition; for instance, the United States pharmaceutical market is by far the world's largest,<sup>217</sup> and regulatory benefits in that context may outweigh the loss caused by disclosure of, for instance, manufacturing methods. Crucially, regulatory control over market access means that regulators can and do keep international competitors' products from the domestic market when enforcing regulatory exclusivity. Second, regulatory coordination among the largest markets, such as the European Union, the United States, and Japan, could maintain regulatory protection in large fractions of the relevant market.<sup>218</sup> Finally, to the extent that firms are able to patent innovations they would otherwise have kept secret, international patent protection can take the place of internationally effective secrecy.

The mechanics of implementing regulatory disclosure are undoubtedly complex, and will require input from agency and industry

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214. 42 U.S.C. § 262(l)(2)(A) (2012).

215. *Id.* §§ 262(l)(1)(B)–(D).

216. It is possible to imagine a more limited disclosure regime—for instance, the regulator could hold the disclosed information and only disclose to domestic competitors under confidentiality requirements—but such a limited regime would be difficult to enforce and would sacrifice many of the benefits of broader disclosure.

217. *See, e.g.*, EUROPEAN FED'N OF PHARM. INDUS. & ASS'NS, THE PHARMACEUTICAL INDUSTRY IN FIGURES: KEY DATA 2012, at 4 (2012), [http://www.efpia.eu/uploads/Modules/Documents/efpia\\_figures\\_2012\\_final-20120622-003-en-v1.pdf](http://www.efpia.eu/uploads/Modules/Documents/efpia_figures_2012_final-20120622-003-en-v1.pdf) [<https://perma.cc/5UMZ-U9WQ>].

218. Global regulatory coordination would completely solve the problem, but is almost certainly an impossible problem of political economy.

stakeholders, as well as academic study. Given the tremendous costs, and corresponding potential gains, associated with secrecy and innovation in regulated industries, the effort is eminently worthwhile.

## CONCLUSION

Intellectual property provides a key policy tool to drive innovation. But in heavily regulated industries, regulation plays a critical role in shaping how innovation proceeds. Regulation profoundly shapes the way intellectual property works; it strengthens it, and can push firms to choose secrecy over patents. That choice, however, creates problems by sharply limiting disclosure in regulated industries.

Disclosure is useful; it enables follow-on innovation, as well as enhancing transparency and oversight. The value of disclosure is especially high in industries with significant public benefits, like the heavily regulated biopharmaceutical industry, with its public health implications. Although this Article has focused on that industry, the insight that secrecy and strict regulation interact in socially problematic ways can be applied more broadly, such as in pesticides, nuclear power, or even military procurement. Each area demands careful and close consideration, but in general, the regulatory regimes of heavily regulated industries often can and—and perhaps should—be leveraged to drive additional disclosure, and to increase the innovation that follows.