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TRADE SECRETS IN BIOLOGIC MEDICINE: THE BOUNDARY WITH PATENTS

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Can something be both open and secret? That is the conundrum facing society as trade secret rights chafe against patent rights in cutting-edge, biologic medicine. The conflict is unsurprising. Trade secret has emerged as a relatively late bloomer among the family of intellectual property rights and only recently has begun to establish the boundaries of its own space, a process in which it will inevitably knock against other intellectual property doctrines already occupying their own domains. Nor is it surprising that the clash would arise in a fast-moving area of medical science. From insulin products, to cancer treatments, to mRNA vaccines, companies are staking the health of their companies on biologics.

There is a dearth of legal literature on the topic of trade secrets in the biologic space and almost nothing regarding how trade secrets interact with the patent system in that domain. These scientific and legal areas are sufficiently complex that even the most intrepid scholars fear to tread. This article explains in detailed and accessible language how the systems are working together to the detriment of society.

To address the problem, this article argues that a company receiving a patent on a drug product should be required to disclose the full range of trade secrets necessary to make that drug. As the descriptions below will explain, patent

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applicants are able to satisfy the patent requirement of providing sufficient disclosure that "one skilled in the art can make and use" the invention, without actually providing the information to do so. The surrounding regulatory systems intended to facilitate sharing of clinical trial data suffer the same problem.

As is frequently said in biologics, "the process is the product." In other words, the only way to define something derived from elements of living organisms is by describing the process of producing it. Thus, lack of process information is particularly problematic with biologics. Being faithful to the theoretical underpinnings of the intellectual property regimes requires a resolution of this problem and the establishment of a more effective boundary line between trade secrets and patents for biologic medicine.

I. INTRODUCTION

Can something be both open and secret at the same time? That is the conundrum facing society as trade secret rights chafe against patent rights in the cutting-edge area of biologic medicine.

The conflict is unsurprising. Trade secret has emerged as a relatively late bloomer among the family of intellectual property rights.[1] Evolving from "a quiet backwater doctrine"[2] to "the most pervasive form of intellectual property in the modern economy,"[3] trade secret law only recently has begun to establish the boundaries of its own space, a process in which it will inevitably knock against other intellectual property doctrines already occupying their own domains.[4]

Nor is it surprising that such a clash would arise most prominently in the area of biologic medicines, a cutting-edge, fast-moving realm of medical science in which products are derived from living sources, such as humans, animals, or microorganisms, and are often produced using specially engineered mammalian cells or microorganisms.[5] Numerous scholars have expounded on the glacial pace of legal change in comparison to the breathtaking speed of scientific advancement.[6] Thus, an emerging area of law and a fast-moving area of science, would inevitably create exquisitely complex legal issues. And legal quandaries—as with any other problems—do not go away when ignored, but merely sit in the corner growing larger as they wait for attention.

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[1] Consider that Congress passed federal legislation to protect Trade Secrets only in the last decade. The Defend Trade Secrets Act of 2016 was embedded into the existing Economic Espionage Act of 1995. *See* 18 U.S.C. §§ 1831–39. For other evidence of the rapidly emerging importance of Trade Secret law, *see generally* David S. Almeling, Darin W. Snyder, Michael Sapoznikow, Whitney E. McCollum & Jill Weader, *A Statistical Analysis of Trade Secret Litigation in Federal Courts*, 45 GONZ. L. REV. 291 (2010); David S. Almeling, Darin W. Snyder, Michael Sapoznikow, Whitney E. McCollum & Jill Weader, *A Statistical Analysis of Trade Secret Litigation in State Courts*, 46 GONZ. L. REV. 57 (2011).

[2] Robin Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Secret Overreach,* 22 YALE J.L. & TECH. 61, 64 (2020).

[3] *See* Peter S. Menell, *Tailoring a Public Policy Exception to Trade Secret Protection*, 105 CALIF. L. REV. 1, 3 (2017).

[4] *See* Charles Tait Graves & Sonia K. Katyal, *From Trade Secrecy to Seclusion,* 109 GEO. L.J. 1337, 1337 (2021) (identifying various nontraditional cases to demonstrate the extension of trade secrecy arguments into other areas of the law).

[5] *What Are "Biologics" Questions and Answers*, U.S. Food and Drug Administration (Feb. 6, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers; Ian Haydon, *Biologics: The Pricey Drugs Transforming Medicine*, Scientific American (Jul. 26, 2017), https://www.scientificamerican.com/article/biologics-the-pricey-drugs-transforming-medicine/.

[6] *See, e.g.*, DAVID FAIGMAN, LEGAL ALCHEMY: THE USE AND MISUSE OF SCIENCE IN THE LAW (1999); Ronal Dworkin, *Social Sciences and Constitutional Rights–the Consequences of Uncertainty*, 6 J.L. EDUC. 3, at 3 (1977); Roscoe Pound, *Law and the Science of Law in Recent Theories*, 43 YALE L. REV. 525 (1934); Oliver Wendell Holmes, *Law in Science and Science in Law*, 12 HARV. L. REV. 443 (1899); *see also* Steven Goldberg, *The Reluctant Embrace: Law and Science in America*, 75 GEO. L. J. 1341 (1987); Dean Hashimoto, *Science as Mythology in Constitutional Law*, 76 OR. L. REV. 111 (1997); Richard Lempert, *"Between Cup and Lip": Social Science Influences on Law and Policy*, 10 LAW & POLICY 167 (1988); Howard T. Markey, *Jurisprudence or "Juriscience"?*, 25 WM. & MARY L. REV. 525 (1984); J. Alexander Tanford, *The Limits of a Scientific Jurisprudence: The Supreme Court and Psychology*, 66 INDIANA L.J. 137 (1990); Charles Robert Tremper, *Sanguinity and Disillusionment Where Law Meets Social Science*, 11 LAW & HUM. BEHAV. 267 (1987); John Veilleux, Note, *The Scientific Model in Law*, 75 GEO. L.J. 1967 (1987).

The biologic sector is more than just a fascinating corner of the pharmaceutical industry. Even before mRNA vaccines for COVID-19 captivated the nation's attention, the entire pharmaceutical industry was tilting heavily towards biologic medicines.[7] From insulin products, to cancer treatments, to mRNA vaccines, companies are staking the health of their companies—not to mention the health of U.S. patients—on biologics. In doing so, the industry has brought the interactions between trade secrets and patents into stark relief.

The conflict unfolds in the following manner: Patent law requires that an inventor must provide disclosure of the newly created innovation to a sufficient degree that one who is skilled in the art can make and use it.[8] The concept of disclosure lies at the core of patent law and reaches back to the nation's conception. Into this realm of disclosure marches trade secret, the relative newcomer whose ethos is, to put it simply, secrecy. At its core, the requirements for protection of a trade secret include, unsurprisingly, that the information is not publicly known or readily available and that reasonable measures have been taken to maintain the information's secrecy.[9] Therein lies the inherent tension: Patent law demands openness while trade secret law demands secrecy. The two regimes pull in opposite directions.

Fifty years ago, courts confidently predicted that trade secret and patent laws would never conflict with each other. In the 1974 Kewanee decision, for example, the Supreme Court explained that the protections of trade secret are far weaker than patent law,[10] and predicted the following: "The possibility that an inventor who believes his invention meets the standards of patentability will sit back, rely on trade secret law . . . is remote indeed."[11]

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[7] Robin C. Feldman, *The Cancer Curse: Regulatory Failure by Success,* 21 COLUM. SCI. & TECH. L. REV. 1, 7 (2020) (demonstrating the shift to cancer biologics, including through measurements of the pipeline of late-stage trials; major pharmaceutical houses "pivoting to cancer," and companies spending heft sums to absorb smaller companies with promising cancer drugs) [hereinafter Feldman, *Cancer Curse*]; *see also* Dennis Roland, *Cancer-Drug Giant Roche Loses Edge as Rivals Grow*, WALL ST. J. (Apr. 28, 2019, 7:00 AM), https://www.wsj.com/articles/cancer-druggiant-roche-loses-edge-as-rivals-grow-11556449201. *See also* Jared Hopkins, *Pfizer Pivots to Cancer Drugs for Growth*, WALL ST. J. (Jan. 27, 2019, 10:00 AM), https://www.wsj.com/articles/pfizer-pivots-to-cancer-drugs-for- growth-11548601200.

[8] *See* 35 U.S.C. § 112(a) (2012) (Patent Act language providing that "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").

[9] JOHN G. SPRANKLING & THOMAS G. SPRANKLING, UNDERSTANDING TRADE SECRET LAW § 2.01 (2020) (citing Uniform Trade Secret Act § 1(4) (1985)); Robert G. Bone, *The (Still) Shaky Foundations of Trade Secret Law*, 92 TEX. L. REV. 1803, 1805 (2014) (outlining the evolution of modern principles, from common law to statutory codification).

[10] *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 489 (1974) (rejecting an assertion that Ohio law's trade secret protection for certain processes that did not satisfy the requirements of federal patentability was preempted by federal patent law by serving as an obstacle to the federal Patent Act).

[11] *Id.* at 490 (citation omitted).

The assumption made sense. Trade secret rights cannot be asserted against someone who independently reaches the same invention or against one who reverse engineers an item protected by trade secrets. Moreover, trade secret rights will be lost if the information becomes public. In contrast, the mighty patent right holds firm regardless of independent invention or public release. Who would give up a patent's all-powerful right to exclude for a hope of being able to huddle protectively around a secret and a prayer that no one else will figure it out on their own.[12]

Such confident predictions, however, have proven overly optimistic. The expansion of trade secrecy now threatens to trample over the territory of patents, undermining the statutory balance Congress struck in drafting the Patent Act and its surrounding regulatory regimes.[13] The problem is not that trade secrets are now more important than patents in the pantheon of protection; rather, it is the interplay between the two systems that prompts concern. Companies are able to magnify each system by mixing the systems together as a catalyst to create a power far greater than either can provide alone, and certainly greater than envisioned in the design of the patent system.

One might expect patent law to have established a boundary, a moat, a Rubicon of sorts that would set up a division between the two domains. And yet, patent law and related regulatory systems—specifically, the system Congress created for encouraging the entry of biosimilar and interchangeable medicines[14]—seem to be shrinking back from the secrecy onslaught. As these systems are being applied, they fail to establish an effective boundary line that would be faithful to the regime's theoretical underpinnings.

As Judge Learned Hand prophetically explained three-quarters of a century ago, "[I]t is a condition upon the inventor's right to a patent that . . . he must content himself with either secrecy or legal monopoly."[15] In the current environment, however, a firm can obtain patents while still protecting the information necessary for making and using the drug. Even while obtaining patents, critical manufacturing techniques, clinical trial protocols, and quality-control procedures all can be protected as trade secrets, a circumstance that can impede and discourage biosimilar market entry.

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[12] The right to exclude can be complicated in the case of overlapping patents, in which both parties have the right to exclude the other. *See* ROBIN FELDMAN, RETHINKING PATENT LAW (2012) (describing overlapping patents and explaining that "[d]espite popular misconceptions or at least very sloppy language, a patent does not grant the right to *do* anything" but merely the right to exclude others from doing something) (citations omitted).

[13] *See text accompanying notes 27–38, infra* (describing the Hatch-Waxman Act and Biologics Price Competition and Innovation Act regimes for encouraging entry of generic and biosimilar medicines).

[14] *See text accompanying notes 117–137, infra* (describing the Biologics Price Competition and Innovation Act).

[15] *See* Metallizing Engineering Co. v. Kenyan Bearing & Auto Parts Co., 153 F.2d 516, 520 (2d Cir. 1946), *cert. denied,* 328 U.S. 840 (1946).

Much ink has been spilled on the topic of patents and their effects on innovation.[16] Nevertheless, there is a dearth of legal literature on the topic of trade secrets in the biologic space, and almost nothing regarding how trade secrets interact with the patent system in that domain.[17] To fill this gap, the article will focus on examining how trade secrets interact with patents in the context of modern biologic medicine. Understanding this complex area of science, and the way in which the law interacts with it, lays the critical groundwork for engaging in jurisprudential reform.

Effective reform is within reach, and this article will suggest the following: A company that receives a patent on a drug product must disclose the full range of trade secrets necessary to make that drug. The assertion sounds simple enough, and yet, the world in which we live does nothing of the sort. As the descriptions below will explain, patent applicants are able to obtain the grant of a patent and satisfy the requirement of providing sufficient disclosure so that one skilled in the art can make and use the invention, without actually providing the information to do so.[18]

In the same vein, the relevant patent information should be identified as part of the approval process, along with other information necessary to carry out the intent of the regulatory regimes that provide for entry of biosimilars when patent protection expires. Society cannot encourage the entry of follow-on medications while simultaneously allowing companies to hide the necessary information.

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[16] To sample just a few seminal works, *see* Edmund W. Kitch, *The Nature and Function of the Patent System,* 20 J. L. & ECON. 268 (1977); Robert P. Merges and Richard R. Nelson, *On the Complex Economies of Patent Scope*, 90 COLUM. L. REV. 844 (1990); Mark A. Lemley, *The Economics of Improvement in Intellectual Property,* 75 TEX. L. REV. 1045 (1977); FREDERICK M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE, (1980).

[17] One bright spot is the work of Nicholson Price and co-author Arti Rai. *See* W. Nicholson Price II, *Regulating Secrecy*, 91 WASH. L. REV. 1769, 1801 (2016); W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologic Competition and Innovation*, 101 IOWA L. REV. 1023, 1034-35 (2016) [hereinafter Price & Rai, *Manufacturing Barriers*]. For literature regarding patents and biologics, rather than how trade secrets interact with patent in that domain, *see, e.g.,* Victor L. Van de Wiele et al., *Barriers to US Biosimilar Market Growth: Lessons From Biosimilar Patent Litigation*, 40 HEALTH AFF. 1198, 1198 (2021) ("To facilitate more timely biosimilar entry, policy makers should consider limits on patent prosecution, compulsory public patent listing, and enhanced antitrust enforcement."); Simona Rose & Tracea Rice, *The Biosimilar Action Plan: An Effective Mechanism for Balancing Biologic Innovation and Competition in the United States?*, 51 U. PAC. L. REV. 539, 557 (2020) ("[O]riginator biologic manufacturers are notorious for engaging in complex patent litigation tactics and other gaming strategies to further impede biosimilar market entry. . . . [B]ecause of government controlled pricing and more limited patent protection for biologics, there are over fifty-four biosimilars presently marketed in Europe at an average discount of 80%."); Jeffrey Wu & Claire Wan-Chiung Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 CHI. KENT J. INTELL. PROP. 93 (2020) (describing patent thickets in the biologics industry).

[18] This legal interpretation allows biologic companies, for example, to withhold information that follow-on drugs such as biosimilars would need—thereby imposing additional costs on challengers. The biologic company also can file different forms of patents with the information originally withheld, just as the original patent is expiring, obtaining many additional years of monopoly protection. *See text accompanying notes 141–142, infra.*

As a backdrop, Section II provides a tour of the legal landscape, including patent law, the Hatch-Waxman and Biosimilars Act regimes, and trends in the American legal history of trade secrets. Section III introduces the biologics industry, providing an overview of the ways in which the legal regimes unfold for that industry. Section IV explores the clash of patents and trade secrets with biologic medicine, including the curious phenomenon in which patent law and related regulatory systems seem to be shrinking back from the secrecy onslaught. This section also considers and rejects the possibility that with the recent federalization of trade secrets, Congress intended to preempt the Patent Act. Section V offers a cradle to grave view of development of a biologic product, examining the types of trade secret rights that can be asserted to protect information, including manufacturing processes, clinical trial data, and quality-control procedures. Section VI describes how trade secrets inhibit other policy tools capable of improving competition in the biologics industry, including the Biosimilars Act, march-in rights, 28 U.S.C. § 1498, and the TRIPS waiver. Section VII describes ways in which these interwoven pieces of legislation can be brought into proper alignment together and explains that Congress, regulatory agencies, and the courts each have pathways available to take the necessary steps.

II. CORE CONCEPTS OF PATENT AND TRADE SECRET LAW

The following section describes the doctrines of patent law and the related regulatory regimes that are particularly salient to biologic medicine. The section then explores the history and development of relevant trade secret doctrines, contrasting those with the theoretic underpinnings of patents.

A. A Patent Must Teach

Numerous Supreme Court opinions have explained that the goal of patent law is not the moral rights of inventors or some form of societal due, but rather the benefit to the public.[19] We suffer the "embarrassment of an exclusive patent," as

[19] *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980) (quoting Kewanee Oil Co. v. Bicron Corp. 416 U.S. 470, 480 (1974) and noting that, "[t]he authority of Congress is exercised in the hope that "[the] productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens"'); Mazer v. Stein, 347 U.S. 201, 219 (1954) ("The economic philosophy behind the [patent and copyright] clause is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare"); Woodbridge v. United States, 263 U.S. 50, 61 (1923) (explaining that "[t]he public . . . is a most material party to, and should be duly considered in, every application for a patent, securing to the individual a monopoly for a limited time, in consideration for the exercise of his genius and skill," so as to further the "large public policy to promote . .. science and the useful arts"); Graham v. John Deere Co., 383 U.S. 1, 9 (1966) ("The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge."); Brenner v. Manson, 383 U.S. 519, 534–36 (1966) ("The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public [and therefore, a patent] is not a reward for the search, but compensation for its successful conclusion."); *see also* Robin Feldman, *Intellectual Property Wrongs*, 18 STAN. J. OF L., BUS. & FIN. 250 (2013) (explaining that from the store of

Thomas Jefferson so memorably wrote, only because we believe the grant of that patent will bring benefit to the public as a whole.[20] And as a unanimous Supreme Court noted in *Bonito Boats*, certain requirements of patentability "embody a congressional understanding, implicit in the Patent Clause itself, that free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception . . . . [T]he ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure."[21]

In this context, patent law requires that an inventor must provide disclosure of the newly created innovation to a sufficient degree that one who is skilled in the art can make and use it.[22] Disclosure is frequently described as the "quid pro quo" for receiving the precious patent grant.[23] The Court has sometimes described disclosure as the price paid for receipt of the patent grant and sometimes as the goal of the patents.[24] Either way, disclosure lies at the heart of the patent system.

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things that would ordinarily be freely available for anyone in the public to enjoy, we remove some for a limited time, dedicating them to the use of a few, in the hopes that such dedication will redound to the benefit of all); WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS 42–43 (1890) (seminal patent treatise of the late 1800s explaining that, "[t]he duty which the state owes to the people to obtain for them, at the earliest moment, the practical use of every valuable invention in the industrial arts is .. . a higher and more imperative duty than which it owes to the inventor"); *cf.* Kendall v. Winsor, 62 U.S. 322, 329 (1858) (explaining that in encouraging invention, "the rights and welfare of the community must be fairly dealt with and effectively guarded"). For a discussion of the historic utilitarian basis of U.S. patent law as opposed to a moral rights notion, see Douglas G. Baird, *Common Law Intellectual Property and the Legacy of International News Service v. Associated Press*, 50 CHICAGO L. REV. 411, 416 (1983) (contrasting the Anglo-American reliance on the "incentive rationale" with "continental systems," which prioritize creators' rights, at least in the case of copyrights, "out of respect for the labors of the individual artist"); *see also* Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? - Reevaluating the Patent "Privilege" in Historical Context*, 92 CORNELL L. REV. 953 (2007).

[20] *See* 13 THOMAS JEFFERSON,WRITINGS OF THOMAS JEFFERSON 335 (Andrew A. Lipscomb & Albert Ellery Bergh, eds., Memorial Ed. 1904) (describing patents as the activity of "drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not").

[21] *See* Bonito Boats, v. Thundercraft, 489 U.S. 141, 151 (1989).

[22] *See* 35 U.S.C. § 112(a) (2012) (Patent Act language providing that "[t]he 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").

[23] *See, e.g.*, Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484-85 (1974); A patent, of course, is no guarantee of a return, and many patent holders receive little value either directly from revenue or indirectly by serving to building a portfolio to defend territory around an innovation. Nevertheless, a patent provides an extraordinary opportunity to create value by excluding others.

[24] *Compare* Bonito Boats at 151 ("the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure") *with* Eldred v. Ashcroft, at 787 (dicta in copyright case describing patent disclosure as not the goal but the price of a patent as following: "This is understandable, given that immediate disclosure is not the objective of, but is *exacted from*, the patentee. It is the price paid for the exclusivity secured. See *J.E.M. Ag Supply,* 534 U.S., at 142, 122 S.Ct. 593. For the author seeking copyright protection, in contrast, disclosure is the desired objective, not something exacted from the author in exchange for the copyright").

Beyond the Court's analyses, patent scholars and practitioners grant disclosure a central role in the patent system. Practitioners speak of patents as "teaching" something—a decidedly awkward linguistic formulation for those not steeped in patent lingo. Most scholars frame disclosure as the bargain a patent holder enters into, although other roles for disclosure emerge in the literature,[25] and, as many scholars have pointed out, the modern patent system is deeply flawed in its ability to deliver on the promise of the disclosure language.[26] Nevertheless, regardless of how many hats disclosure must wear or how well it wears them, disclosure holds a prominent position in patent law—one that is visible in all corners of the field, from statute to slang.

B. Related Regulatory Regimes: Hatch-Waxman and the Biosimilars Act

The disclosure orientation of patent law is echoed in the design of the Hatch-Waxman legislation, which created a system for encouraging the rapid entry of generic drugs as soon as patent protection expires.[27] A key aspect of the legislation ensures that generic companies have access to data that original manufacturers provide to the FDA as part of the approval process. The economic logic is the following: The lure of a monopoly period from a patent on the drug allows the original company to engage in the time and expense of clinical trials. Generic drug companies enter the market after the patent has expired, and cannot receive their own patents. Thus, generic companies lack the requisite incentives to engage in clinical trials. Nor would repeat clinical trials necessarily be in society's best interests. Not only would these trials waste societal resources, they might also trample ethical boundaries by asking some patients in a trial to forgo a medicine already proven to work, in order to demonstrate that the medication works.

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[25] Other roles for the disclosure doctrines of patent law include helping downstream innovation, *see, e.g.*, Katherine Strandberg, *What Does the Public Get? Experimental Use and the Patent Bargain,* 2004 WIS. L. REV. 81, 111 (2004); providing a notice function, *see, e.g.*, Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON 265 (1977); and ensuring that the patent holder actually has an invention in hand, *see, e.g.*, Robin Feldman*, The Inventor's Contribution,* 9 UCLA J.L. & TECH. 6, 32 (2005) (discussing various roles that the disclosure doctrines of enablement and written description can play). *See* Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 146 (2006).

[26] *See, e.g.*, Nicholson Price, *Regulating Secrecy*, *supra* note 17, at 1782–1783; Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 542 (2009); Benjamin N. Roin, The Benjamin N. Roin, The Disclosure Function of the Patent System (or Lack Thereof), 118 HARV. J.L. & TECH. 2007, 2025 (2005)); Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709, 745 (2012); Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 545, 546–47 (2012).

[27] Drug Price Competition and Patent Term Restoration ("Hatch-Waxman") Act, Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified as amended in sections of 21 U.S.C. and 35 U.S.C.); *see generally* ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 26–33 (2017) (describing design and mechanics of Hatch-Waxman Act). The system also contains incentives to encourage generic companies to challenge patents that are invalid or invalidly applied to a particular drug. *See id.*

In light of these challenges, the legislation allows generic drug manufacturers to piggy-back on the safety and efficacy information submitted by the original drug maker.[28] Rather than repeating the clinical trials that produced the information, a generic drug maker can reference the data submitted and then demonstrate that its generic version is bioequivalent to the original drug.

As part of the compromises struck within the Act, an original drug maker receives a five-year period in which no generic company can reference the clinical trial data in applying for FDA approval.[29] The period is shortened to four years if a generic company files for approval and challenges patents underlying the drug as invalid or invalidly applied.[30] As with the patent system, Hatch-Waxman facilitates the open exchange of information in the context of safety and efficacy information.

The entrance of generic drugs steeply erodes brand drug prices,[31] enabling increased access for patients who could not afford the drug at the brand prices. Although by no means a perfect system, Hatch-Waxman has saved U.S. consumers and taxpayers trillions of dollars by facilitating generic market penetration.[32]

Hatch-Waxman, however, regulates only small-molecule drugs such as aspirin, antihistamines, and statins. Large-molecule biologic drugs—think insulin, Humira, and Spikevax—are regulated instead by the Biologics Price Competition and Innovation Act ("BPCIA" or "Biosimilars Act").[33] Just as Hatch-Waxman created a simplified pathway for market entry of generic small-molecule drugs, so the BPCIA aimed to create a simplified pathway for market entry of "biosimilars," which are what the BPCIA (and hence this Article) call the generic versions of large-molecule biologic drugs.[34] In the U.S., however, biosimilars

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[28] 21 U.S.C. § 355(j).

[29] Sometimes known as a "data exclusivity," the five-year period in which no other company can reference the safety and efficacy data is available only in regard to drugs that constitute an entirely new chemical entity. *See* Robin Feldman, *Regulatory Property: The New IP,* 40 COLUM. J.L. & ARTS 53, 61–62 (2016).

[30] *See id.* at Appendix A.

[31] *See* Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation* 9–10 (Nat'l Bureau of Econ. Rsch., Working Paper No. 16431, 2010), www.nber.org/papers/w16431.pdf (finding that entrance of several generics can bring brand drug price down by 90% within months).

[32] Evan Hoffman, *Competitive Dynamics of the Generic Drug Manufacturing Industry*, 52 BUS. ECON. 68, 68–69 (2017) (estimating total consumer savings secured by generic drugs at over $1 trillion between 2005 and 2015 because of growth in prescription of generics from 55% of all prescribed drugs in 2005 to 88.7% in 2015).

[33] Patient Protection and Affordable Care Act of 2010 §§ 7001–02, 42 U.S.C. § 262(k).

[34] As its name suggests, a biosimilar is a highly similar version—but not an exact copy—of the reference product, which is biologic that it is approved to replace. *See Biosimilar and Interchangeable Products*, U.S. FOOD & DRUG ADMIN. (Oct. 23, 2017), https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products; 42 U.S.C. § 262(i)(2)(A), (B) (defining "biosimilar" as "highly similar to the reference product notwithstanding minor differences in clinically inactive components" and without "clinically meaningful differences between the biological product and the reference product in terms of the

have not created the robust competition for large-molecule drugs that generics created for small-molecule drugs. The market for biosimilars in the U.S. also has languished in comparison to Europe. Many fewer biosimilars have been approved in the U.S., in comparison to Europe, and fewer still have advanced to market.[35] A tepid biosimilar industry, consequently, has failed to insulate the U.S. from the high cost of biologic drugs,[36] which account for an outsized and increasing share of prescription drug spending. Biologic drugs accounted for just 2% of all drug prescriptions written in 2019, yet they were responsible for more than a third of net drug spending in the U.S.[37] As a result, biologics since 2014 have caused 93% of the growth in total prescription drug spending.[38]

There are several reasons meaningful biosimilar competition has yet to materialize in the U.S.[39] Key among these is the role of trade secrets in this landscape. An analysis of the interplay between patents, the Biosimilars Act, and trade secrets requires an examination of the principles of trade secret law.

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safety, purity, and potency of the product"). "Reference biologic" or "reference product" refers specifically to the original, approved biologic against which the biosimilar is compared by the FDA and to which the biosimilar is therapeutically equivalent. *See* U.S. FOOD & DRUG ADMIN., CONSIDERATIONS IN DEMONSTRATING INTERCHANGEABILITY WITH A REFERENCE PRODUCT: GUIDANCE FOR INDUSTRY 6 (2019).

[35] *See* GENERICS AND BIOSIMILARS INITIATIVE, HOW DO THE BIOSIMILAR MARKETS IN THE US AND EUROPE COMPARE? (Feb. 19, 2021) (noting that as of January 2021, 69 biosimilars had been approved in Europe, almost all of which were marketed soon after approval while only 29 biosimilars had been approved in the U.S. and only 18 of those had launched), https://gabionline.net/reports/How-do-the-biosimilar-markets-in-the-US-and-Europe-compare#:~:text=There%20are%20currently%2069%20biosimilars,5%5D%2C%20see%20Table%201; Ioana Gherghescu & Maria Begoña Delgado-Charro, *The Biosimilar Landscape: An Overview of Regulatory Approvals by the EMA and FDA*, 13 PHARMACEUTICS 48, 48 (2021) (noting that, through 2019, EU has approved 65 biosimilars, of which 55 are on market, while U.S. has approved only 26 biosimilars, of which 11 are on market); *see also* Joel Lexchin, *Affordable Biologics for All*, 3 JAMA NET. OPEN e204753 (2020) (noting that European biosimilars also average better market penetration).

[36] *See* Richard Frank et al., *Biosimilar Competition: Early Learning*, 31 HEALTH ECON. 647, 647 (2022) (observing 4–10% decrease in price for each biosimilar that entered the market).

[37] Lexchin, *supra* note 35 (biologics account for 2% of prescriptions but 37% of net drug spending); Dana P. Goldman and Tomas Philipson, *Biosimilars competition helps patients more than generic competition,* STAT NEWS (Oct. 8, 2021), https://www.statnews.com/2021/10/08/biosimilars-competition-helps-patients-more-than-generic-competition/ (biologics account for 2% of prescriptions but 43% of overall drug spending).

[38] *Id.*

[39] Other explanations proposed for the sluggish biosimilar industry in the U.S. include the development time required to replicate a complex molecule, the high cost of clinical trials and—once biosimilars are approved—patent litigation settlements that delay biosimilar market entry. *See generally* Preston Atteberry et al., *Biologics Are Natural Monopolies (Part 1): Why Biosimilars Do Not Create Effective Competition*, HEALTH AFF. (Apr. 15, 2019), https://www.healthaffairs.org/do/10.1377/forefront.20190405.396631/; Mike Z. Zhai et al., *Why Are Biosimilars Not Living up to Their Promise in the US?*, 21 AMA J. ETHICS E668-78 (2019), https://journalofethics.ama-assn.org/article/why-are-biosimilars-not-living-their-promise-us/2019-08#:~:text=The%20high%20cost%20of%20biologics%20remains%20a,to%20patient%20access%20and%20adherence.&text=Although%20biosimilars%20will%20likely%20remain,is%20introduced%20into%20the%20market.

C. Trade Secrets Are Silent

To offer a brief overview of trade secret concepts, information must satisfy three criteria to qualify as a trade secret. The information must confer a competitive advantage, not be publicly known or readily ascertainable, and the information's owner must have taken reasonable measures to maintain the information's secrecy.[40] Trade secrets differ from patents in the scope and duration of protection they offer.[41] Although patent protection is time-limited,[42] trade secret protection never expires, continuing as long as the information remains a secret.[43] In further contrast to the patent system, others are free to use information protected as a trade secret if they reverse-engineer or independently discover the protected information.[44] Outside parties are only restricted from misappropriating a trade secret, which is generally defined as disclosure or use of trade secrets through improper means, including "theft, bribery, misrepresentation, breach or inducement of a breach of a duty to maintain secrecy, or espionage through

[40] *See* SPRANKLING & SPRANKLING, *supra* note 9, § 2.01 (citing Uniform Trade Secret Act § 1(4) (1985)); *see* Robert G. Bone, *The (Still) Shaky Foundations of Trade Secret Law*, 92 TEX. L. REV. 1803, 1805 (2014) (outlining evolution modern principles, from common law to statutory codification). California is an outlier in that it requires that the information isn't publicly known while the Uniform Trade Secrets Act language adopted in most states specifies publicly known or readily ascertainable for this element. *Compare* the 1985 version of the Uniform Trade Secrets Act § 1(4)(i) (the information "derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use") *with* the California Code of Civil Procedure § 3426.1(d)(1) ("Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use"). For a discussion of other variations in trade secret protection among the states, even after drafting of the Uniform Trade Secrets Act, see Grant Cole, *Secrets, Sovereigns, and States: Analyzing State Government's Liability for Trade Secret Misappropriation*, 28 J. INTELL. PROP. L. 131, 143 (2020) (citing Sid Leach, *Anything but Uniform: A State-By-State Comparison of Differences in the Uniform Trade Secrets Act*, SNELL & WILMER L.L.P. (Oct. 23, 2015), https://www.swlaw.com/assets/pdf/news/2015/11/06/How%20Uniform%20Is%20the%20Uniform%20Trade%20Secrets%20Act%20-%20by%20Sid%20Leach.pdf).

[41] *See* Robert G. Bone, *A New Look at Trade Secret Law: Doctrine in Search of Justification*, 86 CALIF. L. REV. 241 (1998) (arguing that trade secrets are anomalous among other forms of intellectual property).

[42] *See* 35 U.S.C. § 154(a)(2) (describing length of patent term).

[43] Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, 61 STAN. L. REV. 311, 352 (2008) ("Trade secrets, by contrast, are protected for an indefinite term, until they are no longer secret."); W. Nicholson Price II, *Expired Patents, Trade Secrets, and Stymied Competition*, 92 NOTRE DAME L. REV. 1615, 1615 (2017) ("Trade secrets, unlike patents, can persist indefinitely; some last for many decades.").

[44] Uniform Trade Secrets Act § 1 *cmt.* ("Proper means include: […] 1. Discovery by independent invention; […] 2. Discovery by 'reverse engineering', that is, by starting with the known product and working backward to find the method by which it was developed."); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 476 (1974) (noting that trade secret "does not offer protection against discovery by fair and honest means, such as by independent invention . . . or by so-called reverse engineering, that is, by starting with the known product and working backward to divine the process which aided in its development or manufacture"); *see also* Sharon K. Sandeen, *The Evolution of Trade Secret Law and Why Courts Commit Error When They Do Not Follow the Uniform Trade Secrets Act*, 33 HAMLINE L. REV. 493, 512 (2010) (discussing *Kewanee*) [hereinafter Sandeen, *Evolution*].

electronic or other means." [45] The following section describes the history and evolution of trade secret law into the modern behemoth it has become.

1. Trade Secrets: Early Caselaw and the First Restatement

Building on a foundation laid by British caselaw,[46] early American trade secret law emerged from two leading decisions: *Vickery v. Welch* and *Peabody v. Norfolk*. *Vickery,* generally accepted to be the first American trade secret case, helped elucidate a core tenet that continues to distinguish trade secrets from other intellectual property: The value of a trade secret stems from the fact that the protected information is not publicly known.[47] *Peabody* solidified the idea that trade secret rights are not enforceable against the entire public and that one can lawfully sidestep trade secret protections by independently discovering or developing the protected information.[48]

Peabody's language embodied both what is known as a "property view" and what is known as a "confidentiality view" of trade secret law.[49] A property view regards trade secrets as a form of intellectual property for which the owner may seek legal recourse when improper external disclosure or use diminishes the economic value of the information.[50] Under the property view, trade secrets have

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[45] Uniform Trade Secrets Act § 1(1)(2). Misappropriation also includes disclosure or use of trade secrets in specified situations in which the violator should have known that the piece of information was a confidential trade secret, regardless of whether an explicit contract existed between the parties. *See id.*

[46] *See, e.g.*, Yovatt v. Winyard, 37 Eng. Rep. 425, 425–26 (1820) (enjoining former employee of veterinary practice who, against his employer's wishes, learned to make veterinary medicines and used this information in his own business pursuits); Morison v. Moat, 68 Eng. Rep. 492, 498 (noting that basis of other trade secret cases "has been referred to property, in others to contract, and in others again, it has been treated as founded upon trust or confidence."). Both cases outlined early principles of trade secret jurisprudence. *Yovatt* defined a breach of trust as the primary act of wrongdoing in a trade secret violation, giving primacy to the confidentiality view in early trade secret law. *Yovatt* also established injunctive relief, still used today, as a legitimate remedy for trade secret violations. *Morison* anticipated the modern conception of trade secrecy by recognizing the property view as well as the confidentiality view.

[47] *See* Vickery v. Welch, 36 Mass. 523, 527 (1837) (holding that sole heir of chocolate recipe breached contract when he publicized protected information, despite arguing that protecting information was anticompetitive trade practice); *see also* Hamilton Mfg. Co. v. Tubbs Mfg. Co., 216 F.401, 407 (C.C.W.D. Mich. 1908) (holding that no trade secret violation existed if information at stake was publicly ascertainable).

[48] Peabody v. Norfolk, 98 Mass. 452, 458 (1868) ("If he invents or discovers, and keeps secret, a process of manufacture, whether a proper subject for a patent or not, *he has not indeed an exclusive right to it as against the public, or against those who in good faith acquire knowledge of it*" (emphasis added)).

[49] *Peabody*, 98 Mass. at 458 (holding that inventor of manufacturing process who maintains it as trade secret "has a property in it, which a court of chancery will protect against one who in violation of contract and breach of confidence undertakes to apply it to his own use, or to disclose it to third persons."); *see also Morison*, 68 Eng. Rep. at 498. The two views are not mutually exclusive. In fact, most courts and scholars rely on a combination when analyzing trade secret cases today. *See* SPRANKLING & SPRANKLING, *supra* note 9, § 1.05 ("Modern trade secret law is best viewed as an amalgam of the… [confidentiality] and property approaches.").

[50] SPRANKLING & SPRANKLING, *supra* note 9, § 1.05.

the same legal justification as other forms of intellectual property such as patents: They incentivize firms to take on the often expensive and time-consuming process of innovation.[51]

In contrast, a confidentiality view sees trade secret protections through the lens of commercial ethics.[52] This perspective focuses on the wrongfulness of conduct causing a loss of confidentiality, such as an employee's divulgence of protected information to a rival firm, or a firm's corporate espionage that procures a competitor's secrets.[53] Those who adopt the confidentiality view use terms such as "improper methods," "crime," "tort," and "breach of confidence" in discussing how one may improperly obtain a trade secret because such terms describe the civilly and criminally wrongful means of accessing protected information.[54] The confidentiality view, in other words, prioritizes how the information is acquired or used over the nature of the information itself. *Peabody* embraced both conceptualizations, holding that one who holds a trade secret "has a property in it, which a court of chancery will protect against one who in violation of contract and breach of confidence undertakes to apply it to his own use, or to disclose it to third persons."

From these common-law origins, the first step towards codification of trade secret law was the Restatement (First) of Torts ("First Restatement") in 1939.[55] The First Restatement provided general guidelines for evaluating trade secret cases, including the most rudimentary principles of trade secrets: The protected information must confer a competitive advantage on its owner, and the owner must take reasonable measures to maintain the secrecy of the information. [56] Beyond these principles, the First Restatement included a comment setting forth a six-factor test for determining whether information is protected as a trade secret.[57]

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[51] *See* Robert D. Cooter & Uri Y. Hacohen, *Progress in the Useful Arts: Foundations of Patent Law in Growth Economics*, 23 YALE J.L. & TECH. 191, 191 (2020); *see also* Arnold Plant, *The economic theory concerning patents for inventions*, 1.1 ECONOMICA 30, 36 (1934); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484–85 (1974) (recognizing value of patents alongside—not in lieu of—trade secrets); Lemley, *supra* note 43, at 331 (explaining that trade secrecy fills in gaps left by patent law).

[52] *See* SPRANKLING & SPRANKLING, *supra* note 9, § 1.03; Lemley, *supra* note 43, at 318.

[53] SPRANKLING & SPRANKLING, *supra* note 9, § 1.03.

[54] *Id.* § 1.03.

[55] That trade secrecy principles were included in the Restatement of Torts rather than the Restatement of Contracts demonstrated that, in line with *Peabody* and *Morison*, relationships of trust and confidentiality did not have to be contractually recognized in order for a breach of trust or confidentiality to occur.

[56] RESTATEMENT (FIRST) OF TORTS §§ 757–59 (AM. L. INST. 1939); Lemley, *supra* note 43, at 316.

[57] *Id.* § 757, cmt. b ("The six-factor test for determining whether information qualifies as trade secret protected is as follows: (1) The extent to which the information is known outside of the business; (2) The extent to which it is known by employees and others involved in the business; (3) The extent of measures taken to guard the secrecy of the information; (4) The value of the information to the business and to competitors; (5) The amount of effort and money expended in developing the information; and (6) The ease or difficulty with which the information could be properly acquired or duplicated by others.").

Notably, the last two factors deviated from earlier definitions of trade secrets by directing courts to consider both the degree of difficulty, in terms of financial or resource investment, required to develop the information and the ease or difficulty with which the information could be properly acquired or duplicated.[58] The addition of these two factors significantly altered the kinds of information that could receive trade secret protection.[59]

The First Restatement's articulation of trade secret principles attempted to standardize the common law. Nevertheless, the confusing implications of several then-contemporary rulings, beginning with *Erie Railroad Co. v. Tompkins*, prompted legislation that would fully standardize trade secret law across the enacting jurisdictions.[60] In *Erie*, the Supreme Court ruled that, absent a federal question, federal courts in diversity cases must apply state statutory or state common law; the "federal general common law" developed through decisions in federal courts could not be used to decide diversity cases.[61] This holding posed a problem for trade secret litigation between diverse parties because the common law of trade secrets and unfair competition often varied from state to state, if applicable decisions existed at all.[62] Thus, after *Erie*, the outcome of a federal diversity case involving trade secrets could hinge on which state's law was applied.

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[58] *Id.*

[59] Depending on the circumstances, the addition of the two new factors could either expand or limit trade secret protections. Information that marginally fails to satisfy one of the first four factors might still obtain trade secret status if its development was expensive; at the same time, inexpensively developed information that satisfied the first four factors might still fail to qualify because of the "effort and money" test. The First Restatement also expanded trade secret protections by specifying certain situations in which a party should be held liable for trade secret misappropriation even without a breach of confidence in the traditional sense. *See* Sandeen, *Evolution*, *supra* note 44, at 501 (noting that misappropriation includes acquisition of trade secret information through "improper means" (e.g., acquisition through theft or burglary) in addition to disclosure by third party or accidental acquirer if information's protected status was reasonably obvious).

[60] *See* Sandeen, *Evolution*, *supra* note 44, at 503 (arguing that *Erie* prompted formal trade secret legislation).

[61] Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78 (1938) ("Except in matters governed by the Federal Constitution or by acts of Congress, the law to be applied in any case is the law of the state. And whether the law of the state shall be declared by its Legislature in a statute or by its highest court in a decision is not a matter of federal concern. There is no federal general common law."); *see also* Sharon K. Sandeen, *The* Erie/Sears/Compco *Squeeze:* Erie's *Effects on Unfair Competition and Trade Secret Law*, 52 AKRON L. REV. 423, 424 (2018) [hereinafter Sandeen, *Squeeze*] ("For almost 150 years from the adoption of the Federal Judiciary Act of 1789 until the Court's decision in *Erie* in 1938, the federal judiciary had developed a body of federal jurisprudence that applied (if not created) what the federal courts thought was the 'general common law.' Then, with one decision, that body of jurisprudence was rendered moot."); Camilla A. Hrdy, *Erie, Remedies, and Trade Secrets*, 10 CONLAWNOW 237, 238 (2018) (noting that even in cases where no state statute pertains, state common law still supplants federal general common law principles); Sandeen, *Squeeze*, at 428-29 (noting pre-*Erie* development of federal general common law related to trade secrets and unfair competition).

[62] *See* Sandeen, *Evolution*, *supra* note 44, at 503–04.

Decisions after *Erie* created additional need for standardization of trade secret law. In *Sears, Roebuck & Co. v. Stiffel Co.* and *Compco Corp. v. Day-Brite Lighting, Inc.*, the Supreme Court held that the unfair competition laws of Illinois were preempted by federal patent law.[63] Although neither *Sears* nor *Compco* expressly dealt with trade secrets, the state unfair competition laws invalidated in those cases encompassed trade secret misappropriation. That invalidation foreclosed an important means of addressing trade secret misappropriation and heightened the existing confusion regarding how such misappropriation should be handled.[64]

The combined effect of the so-called "*Erie*/*Sears*/*Compco* squeeze" left states in a difficult bind.[65] *Erie* had already established that, absent a federal question, a federal diversity case must be decided under state statutory or state common law.[66] *Sears* and *Compco*, however, barred states from employing state unfair competition law to address trade secret violations.[67] In a sense, *Sears* and *Compco* created greater problems for trade secret litigation than did *Erie*. *Sears* and *Compco's* holdings that federal patent law preempts state unfair competition law applied in both state-court and federal-court cases; *Erie's* abolition of federal general common law in diversity applied only in federal-court cases.[68]

A decade after the *Sears* and *Compco* decisions, *Kewanee Oil Co. v. Bicron Corp.*, helped ease the "squeeze" and paved the way for the first genuinely standardizing trade secret legislation.[69] In *Kewanee*, the Supreme Court held that

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[63] Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 231 (1964) (holding that federal patent laws preempt state unfair competition laws); Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234, 237–38 (1964) (holding that when article or information is not protected by patent or copyright, state unfair competition law may not bar copying of article or information).

[64] Enacted in 1987, the Illinois Trade Secrets Act, for example, displaces state unfair competition laws that provided remedies for trade secret misappropriation. *See* 765 ILL. COMP. STAT. ANN. 1065/8(a) (West 2022) ("Except as provided in subsection (b), this Act is intended to displace conflicting tort, restitutionary, unfair competition, and other laws of this State providing civil remedies for misappropriation of a trade secret.").

[65] *See* Sandeen, *Evolution*, *supra* note 44, at 507.

[66] *Erie*, 304 U.S. at 78.

[67] Ciro A. Gamboni, *Unfair Competition Protection after* Sears *and* Compco, 55 TRADEMARK REP. 964, 969–70 (1965), *noted in* Sandeen, *Squeeze*, *supra* note 61, at 440.

[68] *See* Sandeen, *Squeeze*, *supra* note 61, at 440–41. *Erie* did not outlaw federal common law altogether; uniquely federal matters such as disputes between states, disputes in admiralty, and disputes over the rights and obligations of the federal government are resolved by federal common law, both in federal court and in state court. *See, e.g.*, J.F.P. Offshore, Inc. v. Diamond, 600 So.2d 1002, 1004 (Ala. 1992) (resolving state-court admiralty case under federal common law (citing Texas Indus., Inc. v. Radcliff Materials, Inc., 451 U.S. 630, 641 (1981))); Martha A. Field, *The Scope of Federal Common Law*, 99 HARV. L. REV. 881, 897 (1986) ("Just as Erie Railroad v. Tompkins was designed to ensure that in proper cases state law would apply regardless of the forum, so the application of federal common law should not in theory differ according to whether a state or federal court has jurisdiction over a dispute."); *see also* Jay Tidmarsh, *A Theory of Federal Common Law*, 100 NW. U. L. REV. 585, 615 (2006) (noting that federal common law can displace state statutory or common law when case is tried in state court).

[69] *See infra* note 73; *Kewanee*, 416 U.S. at 470 (holding that federal patent laws did not preempt Ohio's trade secret laws); *see also* Sandeen, *Squeeze*, *supra* note 61, at 448–49. Without

Ohio's trade secret laws were not preempted by federal patent law, explaining that preemption was necessary only if the state laws addressing trade secrets directly clashed with federal patent law.[70] *Kewanee* thus cleared states to pass laws protecting trade secrets.[71] But that was not all. *Kewanee* also regarded trade secret law as providing an incentive for innovation independent of the incentive provided by patents.[72] Finally, *Kewanee's* descriptions of trade secrets and their misappropriation ultimately informed the definitions that would appear in the state Uniform Trade Secrets Act.[73]

2. Standardizing Trade Secrecy: From the State Uniform Trade Secrets Act to the Federal Defend Trade Secrets Act

Responding to problems in the common law of trade secrecy, the National Conference of Commissioners on Uniform State Laws[74] promulgated the Uniform Trade Secrets Act in 1979.[75] Although the Act is not itself a legally binding

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Kewanee, the Uniform Trade Secrets Act, which states enacted on an individual basis, may have faced the same problems as state unfair competition laws under *Sears* and *Compco*. *Kewanee* thus paved the way for the states to enact trade secret legislation.

[70] *Kewanee*, 416 U.S. at 480 ("The patent law does not explicitly endorse or forbid the operation of trade secret law. However, as we have noted, if the scheme of protection developed by Ohio respecting trade secrets 'clashes with the objectives of the federal patent laws,' […] then the state law must fall. To determine whether the Ohio law 'clashes' with the federal law it is helpful to examine the objectives of both the patent and trade secret laws.").

[71] Sandeen, *Squeeze*, *supra* note 61, at 449 ("The Court's 1974 decision that Ohio's common law of trade secrecy was not preempted by U.S. patent law solved the preemption problem in part, allowing efforts to craft a uniform trade secrets act to resume in late 1975."). The logic of the decision was echoed again in the Court's decision in *Aronson v. Quick Point,* holding that patent law did not preempt a state contract law decision enforcing agreement to pay royalties even after the patent had been rejected. *See* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 266 (1979).

[72] *See Kewanee*, 416 U.S. at 484 (describing three classes of trade secrets: (1) those that could reasonably qualify for patent protection, (2) those that are unpatentable, and (3) those where it is unclear whether invention is patentable).

[73] *See* Sharon K. Sandeen, *Kewanee Revisited: Returning to First Principles of Intellectual Property Law to Determine the Issue of Federal Preemption*, 12 MARQ. INTELL. PROP. L. REV. 299, 317–18, 332–33 (2008) (noting that *Kewanee* presents two categories of trade secret violations that are reflected in Uniform Trade Secrets Act's definitional language). Sandeen also notes that the limitations placed on the subject matter of trade secret information by the Uniform Trade Secrets Act were in large part derived from *Kewanee*.

[74] The organization is now known as the Uniform Law Commission.

[75] *Trade Secret*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/trade_secret#:~:text=The%20Uniform%20Trade%20Secrets%20Act,Columbia%20have%20adopted%20the%20UTSA. The Uniform Trade Secrets Act was amended in 1985 to refine its remedies for trade secret misappropriation. An amendment to § 7 replaced "liability" with "remedy" to prevent claims of trade secret misappropriation from precluding additional breach-of-contract claims. An amendment to § 3 allowed reasonable royalties as a remedy even when unjust enrichment and monetary harm cannot be proved. And an amendment to § 2(b) allowed damages and reasonable royalties as remedies against good-faith trade secret violators only in the event of exceptional circumstances. *See* Sandeen, *Evolution*, *supra* note 44, at 535–38.

document, some version of the Uniform Trade Secret Act has since been adopted by almost every state legislature.[76]

The Uniform Trade Secret Act standardized the definitions of trade secret and misappropriation, as well as crafting guidelines for injunctive relief and other remedies.[77] Although the Uniform Trade Secret Act's definitions of misappropriation and improper means largely reflected existing common-law definitions,[78] the Uniform Trade Secret Act altered protectable subject matter considerably. First, the Uniform Trade Secret Act eliminated the First Restatement's requirement that a trade secret be "continuously used in one's business."[79] Second, the Uniform Trade Secret Act permitted "negative information" (i.e., information about failure) to have trade secret protection. For example, if a pharmaceutical company fails to develop an effective anti-inflammatory drug for rheumatoid arthritis, the process by which the firm failed is protected information. The publication of such information, after all, may facilitate the drug development process for other firms, thereby removing a competitive advantage for the firm that failed.[80] Before the Uniform Trade Secret Act, courts did not typically regard negative information as eligible for trade secret protection.[81] Finally, the Uniform Trade Secret Act removed the First Restatement's fifth factor of its six-factor test, which offered consideration based on "the amount of effort and money expended in developing the information"

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[76] Grant Cole, Note, *Secrets, Sovereigns, and States: Analyzing State Government's Liability for Trade Secret Misappropriation*, 28 J. INTELL. PROP. L. 131, 137, 137 n.33 (2021). Massachusetts' adoption of the Uniform Trade Secrets Act in 2018 left North Carolina and New York as the only non-enacting states. *See Trade Secrets Act: Enactment History*, UNIFORM LAW COMMISSION, https://www.uniformlaws.org/committees/community-home?communitykey=3a2538fb-e030-4e2d-a9e2-90373dc05792 (last visited Oct. 8, 2022, 6:05 PM).

[77] *See* TRADE SECRETS, INTERFERENCE WITH CONTRACTS, AND RELATED MATTERS, 1974 A.B.A. SEC. PAT., TRADEMARK & COPYRIGHT L. COMMITTEE REP. § 402, *as reprinted in* Sandeen, *Evolution*, *supra* note 44, at 514–15.

[78] The Uniform Trade Secrets Act defines misappropriation as disclosure or use of trade secrets through improper means, or disclosure or use of trade secrets in specified situations in which the violator should have known that the piece of information was a confidential trade secret, regardless of whether an explicit contract existed between the parties. Improper means, according to the Uniform Trade Secrets Act, includes "theft, bribery, misrepresentation, breach or inducement of a breach of a duty to maintain secrecy, or espionage through electronic or other means." Uniform Trade Secrets Act § 1(1)(2). However, unlike the common law, the Uniform Trade Secrets Act authorizes a preliminary injunction for threatened or potential harm. Uniform Trade Secrets Act § 2(a) ("Actual or threatened misappropriation may be enjoined."); *see, e.g.,* SPRANKLING & SPRANKLING, *supra* note 9, § 7.02 (citing Winter v. Natural Res. Defense Council, Inc., 555 U.S. 7, 20 (2008)).

[79] Uniform Trade Secrets Act § 1 *cmt*.

[80] *See infra* Section III for other examples in today's pharmaceutical industry of negative information that is protected as a trade secret.

[81] SPRANKLING & SPRANKLING, *supra* note 9, at § 2.04 ("'[T]he secret to be protected should be positive, not negative. . . . [E]quity will not protect knowledge as to mistakes to be avoided.'" (quoting Materials Develop. Corp. v. Atl. Advanced Metals, Inc., 172 U.S.P.Q. 595, 606 (Mass. Super. Ct. 1971))).

when determining trade secrets.[82] Rulings following the Uniform Trade Secrets Act are consistent with the Uniform Trade Secret Act's expansion of the kinds of information eligible for trade secret protection.[83]

The Uniform Trade Secret Act also embraces the property view to a greater extent than did the common law.[84] First, the term "owner of [a] trade secret" in the Uniform Trade Secret Act presupposes that trade secrets are a kind of intellectual property.[85] Second, the expansion of the injunction remedy for merely threatened or potential misappropriation reflects a heightened concern for the competitive value of trade secrets.[86]

The Uniform Trade Secret Act was not the only indicator of this shift. In *Ruckelshaus v. Monsanto,* the Supreme Court found that the Constitution's Takings Clause applied to trade secrets on the grounds that Missouri's state law recognized trade secrets as private property.[87] Going beyond the standard property view,[88] therefore, the Court's ruling compared trade secrets to "more traditional forms of property."[89]

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[82] RESTATEMENT (FIRST) OF TORTS § 757 cmt. b (AM. L. INST. 1939); UNIF. TRADE SECRETS ACT § 1(4); *see* Sandeen, *Evolution*, *supra* note 44, at 521–23 ("From the perspective of trade secret law, the mere fact that someone went to the time, trouble, and expense to gather information-or even to create it-does not make it a protectable trade secret."). In some circumstances, removing the "sweat of the brow" doctrine could serve to *limit*—not expand—trade secret protection if information received protection primarily because it required great time or expense to create.

[83] *See, e.g.*, Learning Curve Toys, Inc. v. PlayWood Toys, Inc., 342 F.3d 714, 729 (7th Cir. 2003) ("We fail to see how the value of PlayWood's concept would differ in any respect had Clausi spent several months and several thousand dollars creating the noise-producing track. Accordingly, we conclude that PlayWood's lack of proof on this factor does not preclude the existence of a trade secret."); Novell Inc. v. Timpanogos Rsch. Grp. Inc., No. 970400339, 1998 WL 177721, at *28 (D. Utah Jan. 30, 1998) (holding that use of negative knowledge by employees in external business practice constituted trade secret violation).

[84] *See* SPRANKLING & SPRANKLING, *supra* note 9, § 1.05 ("Over time, the importance of the . . . [confidentiality] view has waned, as the property view has expanded."); *e.g.,* E. I. Du Pont De Nemours Powder Co. v. Masland, 244 U.S. 100, 102 (1917) ("The word 'property' as applied to trademarks and trade secrets is an unanalyzed expression of certain secondary consequences of the primary fact that the law makes some rudimentary requirements of good faith. Whether the plaintiffs have any valuable secret or not the defendant knows the facts, whatever they are, through a special confidence that he accepted. *The property may be denied, but the confidence cannot be*." (emphasis added)).

[85] Uniform Trade Secret Act § 1 *cmt*.

[86] *See generally* UNIF. TRADE SECRETS ACT; *see also* Lemley, *supra* note 43, at 325 (citing Lynn C. Tyler, *Trade Secrets in Indiana: Property vs. Relationship*, 31 IND. L. REV. 339, 339 (1998)); SPRANKLING & SPRANKLING, *supra* note 9, at § 1.05 ("The gradual adoption of the UTSA by state legislatures expanded the influence of the property view. Although in form the act tries to strike a middle ground between the competing theories, its substantive provisions emphasize the property approach.").

[87] Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984) holding that, for purposes of Takings Clause, trade secrets could be considered property despite their intangibility).

[88] *See, e.g.,* Lemley, *supra* note 43, at 313.

[89] Ruckelshaus v. Monsanto Co., 467 U.S. 986, 987, 1002–03 (1984). The Justices noted, "we are mindful of the basic axiom that '"[p]roperty interests ... are not created by the Constitution. Rather, they are created and their dimensions are defined by existing rules or understandings that

To be sure, *Ruckelshaus*, whose reasoning is not without detractors,[90] specified only a narrow set of conditions under which a trade secret might constitute property for purposes of the Takings Clause.[91] Moreover, despite this relative shift in focus,[92] trade secret law continues to synthesize both approaches to this day.[93]

Five years after *Ruckelshaus*, the Supreme Court weighed in on clashes between federal and state law intellectual property protection once again in the 1989 case of *Bonito Boats*.[94] The *Bonito Boats* decision held that the federal Patent Act preempted a Florida state law providing protection for boat hull design innovations that failed to satisfy the requirements of patentability. In distinguishing the Court's earlier decision to uphold the state trade secret law in *Kewanee*, the Court explained that the *Kewanee* decision had rested on the conclusion that trade secret protection did not conflict with federal patent law because trade secrets provided far weaker protection.[95] With Florida's boat hull regulation, the Court concluded that Florida's protection substantially impeded public use of unprotected ideas, running afoul of preemption doctrines.[96] This line of cases, from *Sears,* to *Compco,* to *Bonito Boats,* demonstrates early stirrings of concerns over whether trade secrets could threaten to interfere with patent protection.

The history of trade secret law requires one, final chapter to reach today's setting. In this final stretch, federal legislation has picked up where the state Uniform Trade Secrets Act left off. Specifically, the 1996 Economic Espionage

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stem from an independent source such as state law."'" *Id.*, at 1001 (citing Webb's Fabulous Pharmacies, Inc. v. Beckwith, 449 U.S. 155, 161 (1980) (quoting *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972)).

[90] *See, e.g.,* Thomas W. Merrill, *The Landscape of Constitutional Property*, 86 U. VA. L. REV. 885, 938–39 (2000) (criticizing *Ruckelshaus* Court's justification for considering trade secrets to be constitutional property as "extremely confusing" and reliant on "smoke and mirrors").

[91] Despite holding that publication of confidential pesticide data during a limited period of time constituted a "taking" under the 5th Amendment, *Ruckelshaus* stopped well short of holding that *all* regulatory disclosures of trade secrets are takings. *See Ruckelshaus*, 467 U.S. at 1007 ("as long as Monsanto 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.").

[92] *See* SPRANKLING & SPRANKLING, *supra* note 9, at § 1.05 ("The Supreme Court's 1984 decision in Ruckelshaus v. Monsanto Co. reflected the ascendancy of the property theory The gradual adoption of the UTSA by state legislatures expanded the influence of the property view. Although in form the act tries to strike a middle ground between the competing theories, its substantive provisions emphasize the property approach.").

[93] *See id.* at § 1.05.

[94] *See* Bonito Boats, v. Thundercraft, 489 U.S. 141, 143 (1989).

[95] *See id.* at 155 (explaining that "the *Kewanee* Court emphasized that '[t]rade secret law provides far weaker protection in many respects than the patent law.' This point was central to the Court's conclusion that trade secret protection did not conflict with either the encouragement or disclosure policies of the federal patent law. The public at large remained free to discover and exploit the trade secret through reverse engineering of products in the public domain or by independent creation" (citation omitted)).

[96] *See* Bonito Boats, 489 U.S. at 157 (citing *Sears* and *Compco*).

Act ("EEA") and the 2016 Defend Trade Secrets Act ("DTSA")[97] have further standardized and codified trade secret law.[98]

The Economic Espionage Act allows the federal government to prosecute an alleged trade secret violation[99] in response to possible espionage by foreign governments and other entities.[100] The Defend Trade Secrets Act extends the Espionage Act to allow trade secret owners, in addition to the government, to sue in federal court for misappropriation.[101] The Defend Trade Secrets Act also equips the federal government with additional enforcement measures against trade secret violations.[102] Finally, the Defend Trade Secrets Act provides definitions for trade secrets, misappropriation, and improper means that closely resemble those in the Uniform Trade Secret Act.[103]

As we enter the third decade of the millennium, the replacement of the common-law patchwork of state trade secret laws with statutory standardization and increased federalization have bulked up the power of the trade secrets regime. Although a few Supreme Court cases indicated early stirrings of concern about potential clashing between patents and trade secrets, the problem looms particularly large in the realm of biologic medicine. The following section will describe biologic medicines and examine the role trades secrets play in protecting information in the biologic domain.

III. THE BIOLOGICS LANDSCAPE

Biologics, which are large-molecule drugs sourced from living organisms, differ[104] from the small-molecule drugs that once dominated the pharmaceutical

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[97] Economic Espionage Act of 1996, 18 U.S.C. §§ 1831–39 (1996); Defend Trade Secrets Act of 2016, Pub. L. No. 114–153, 130 Stat. 376 (2016).

[98] Although the Uniform Trade Secret Act represented an important step towards greater uniformity, the versions of the U adopted by each state vary. *See* Matthew D. Kasner, *Third Time's the Charm: Remedying the Lack of Uniformity and Predictability in Trade Secret Law,* 87 BROOKLYN L. REV. 749, 751 (2022).

[99] 18 U.S.C. §§ 1831–32.

[100] *See generally* Spencer Simon, *The Economic Espionage Act of 1996*, 13 BERKELEY TECH. L.J. 305 (1998); *see, e.g.,* United States v. Yu Qin, 688 F.3d 257 (6th Cir. 2012).

[101] 18 U.S.C. § 1836.

[102] *See* David S. Levine & Christopher B. Seaman, *The DTSA at One: An Empirical Study of the First Year of Litigation Under the Defend Trade Secrets Act*, 53 WAKE FOREST L. REV. 105, 116-17 (2018). The Defend Trade Secrets Act includes provisions for an ex parte seizure remedy and for the protection of whistleblowers. The ex parte seizure provision permits a court to order the seizure of property, without notice to the property owner, to prevent disclosure of a trade secret that is the subject of the action. The whistleblower provision shields an individual from liability for disclosing a trade secret to the government when the individual is reporting a violation of law. *See id.* at 119 (citing 18 U.S.C.A. § 1833(b) (West 2018)). The Defend Trade Secrets Act in these ways expanded the remedies available to address trade secret violations.

[103] *Id.* at 116–17.

[104] The BPCIA defines a "biological product"—more commonly known as a "biologic"—as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure

industry. The biologic category encompasses a variety of drug products, including vaccines, monoclonal antibodies, insulin, and other therapeutic proteins.[105]

The dollar value of biologic drug sales in the U.S. increased 50% between 2014 and 2018 alone.[106] Moreover, although most of the drugs marketed and new molecular entities approved each year continue to be small-molecule drugs, most of the top money-making drugs are biologics.[107] And biologic drugs account for a disproportionate share of American prescription drug spending, costing patients an average of 20 times more per day than do small-molecule drug prescriptions.[108]

In contrast to small-molecule drugs, which are chemically synthesized according to a repeatable step-by-step recipe, biologic production involves purifying cell lines that are genetically modified from living organisms.[109] Small-molecule production tends to be straightforward and easily transferable (i.e., from a brand company to a generic competitor), with minimal variation in the end product.[110] In contrast, the FDA allows biologic producers to have some variation between batches of the end product out of necessity.[111] In fact, the challenge of exactly replicating a biologic drug serves to locate the definition of a

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of a disease or condition of human beings." 42 U.S.C. 262(i)(1). Note that this statutory definition does not rely on molecular weight, but that industry definitions use molecular weight to distinguish between "small" and other molecules. Although the upper weight limit for "small" molecules varies, many put it at 1,000 Daltons. *See, e.g.*, Niamh Coleman & Jordi Rodon, *Taking Aim at the Undruggable*, ASCO Educational Book (2021), https://ascopubs.org/doi/full/10.1200/EDBK_325885 (noting that FDA-approved cancer drugs fall into two categories—small-molecule drugs and biologics—and defining former as "those with composite molecular mass < 1,000 daltons").

[105] *See Biosimilar and Interchangeable Products*, U.S. FOOD & DRUG ADMIN. (Oct. 23, 2017), https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products [hereinafter FDA Biosimilars].

[106] Alex Brill & Benedic Ippolito, *The Economics of Biologic Drugs: A Further Response To Bach et al.*, HEALTH AFF. (Aug. 8, 2019), https://www.healthaffairs.org/do/10.1377/forefront.20190807.554429/full/.

[107] Eric Sagonowsky, *The Top 20 Drugs by Worldwide Sales in 2020*, FIERCEPHARMA (May 3, 2021), https://www.fiercepharma.com/special-report/top-20-drugs-by-2020-sales (citing data establishing that, of the 20 drugs with highest dollar-value sales worldwide in 2020, 60% were biologics, accounting for 62% of total spending); Patricia Van Arnum, *Blockbuster Muscle: Small Molecules or Biologics?*, DCAT VALUE CHAIN INSIGHTS (Sept. 1, 2021), https://www.dcatvci.org/features/blockbuster-muscle-small-molecules-or-biologics/#:~:text=The.

[108] Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469, 469 (2013) ($45/day for biologics compared to $2/day for small-molecule drugs); AMERICAN JOURNAL OF MANAGED CARE/CENTER FOR BIOSIMILARS, *The Cost of Biologics and Biosimilars* (Jan. 24, 2018), https://www.centerforbiosimilars.com/view/the-cost-of-biologics-and-biosimilars (average daily cost to patients is $45/day for biologics and $2/day for non-biologics). Industry analyses believe that such growth will persist. *See, e.g., Biologics Market Growth – At a CAGR of 8.4% by 2028*, BIOSPACE (Feb. 28, 2022), https://www.biospace.com/article/biologics-market-growth-at-a-cagr-of-8-4-percent-by-2028-/.

[109] Michael A. Carrier & Carl J. Minniti Fland, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 1, 5–8 (2018).

[110] *Id.* at 6–7.

[111] FDA Biosimilars, *supra* note 105.

biologic instead in the details of its manufacturing process. Hence, as frequently said in the biologics field, "the process is the product."[112]

The complexity of biologics, moreover, creates manufacturing challenges that do not exist in small-molecule production.[113] Consider proteins, which are made of a primary structural level (consisting of an amino acid sequence) and secondary, tertiary, and quaternary structural levels (representing larger three-dimensional structures).[114] An amino acid sequence is simple to replicate, but unanticipated structural variations can arise at any of the three other levels—as can adverse patient reactions due to these variations.[115] Such unforeseen developments may arise during stages of production, purification, or post-production maturation.[116] Producing a biologic, as a result, is vastly more difficult, time-consuming, and expensive compared to a small-molecule drug.[117]

The high cost and de facto exclusivity enjoyed by early biologics due to the difficulty of creating and manufacturing a follow-on product encouraged passage of the Biologics Price Competition and Innovation Act ("BPCIA" or "Biosimilars Act"). The complexities of biologic production—and attendant concerns for biosimilar safety and equivalence—are reflected in the biologic/biosimilar regulatory regime. Analogous to the Hatch-Waxman Act, the Biosimilars Act offers a pathway to ease the entry of lower-cost biosimilars after patent and regulatory exclusivities expire—but with important distinctions.[118]

First, the Biologics Act gives biologics a longer period of data exclusivity than Hatch-Waxman gives small-molecule brand drugs. The Biologics Act provides 12 years of data exclusivity. No other company can apply for FDA

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[112] *See, e.g.,* Raj K. Puri, *FDA's Perspectives on Quality and Non-clinical Evaluation of Cell/Tissue-based Products,* Center for Biologics Evaluation and Research, U.S. Food and Drug Administration (Aug. 26, 2010), https://www.pmda.go.jp/files/000153661.pdf (presenting to the Pharmaceuticals and Medical Devices Agency 5th International Symposium on Biologics in Tokyo); *see also NCI Initiative Aims to Boost CAR T-Cell Therapy Clinical Trials, National Cancer Institute* (Apr. 23, 2020), https://www.cancer.gov/news-events/cancer-currents-blog/2020/car-t-cell-nci-manufacturing-clinical-trials; H. Report. No. 106-556, at 41 (2000), as reprinted in 2022, https://www.congress.gov/106/crpt/hrpt556/CRPT-106hrpt556.pdf; Yaniv Heled, *The Case for Disclosure of Biologics Manufacturing Information*, 47 J. MED. & ETHICS 54, 56 & n.40 (2019); Carrier & Minniti, *supra* note 109, at 7.

[113] FDA Biosimilars, *supra* note 105.

[114] Carrier & Minniti, *supra* note 109, at 7.

[115] *Id.*

[116] *Id.*; *see also infra* text accompanying notes 175–179 (describing Eprex).

[117] *See* Lexchin, *supra* note 35, at 22 ("Research and development costs for biologics are higher than those for small molecule drugs ($391 million vs $309 million)"); Favour Danladi Makurvet, *Biologics vs. Small Molecules: Drug Costs and Patient Access*, MEDICINE IN DRUG DISCOVERY 1, 4 (2021) (estimating average production or manufacturing cost for biologic at 12 times greater than for small-molecule drug). Developing a biosimilar also vastly exceeds the cost required to bring a small-molecule generic to market—by one analysis, $100 to 250 million compared to a mere $1 to 4 million for a small-molecule generic. Blackstone & Fuhr, *supra* note 108, at 470–71.

[118] 42 U.S.C. § 262(k)(7)(A); *see generally* Robin Feldman, *The Cancer Curse: Regulatory Failure by Success*, 21 COLUM. SCI. & TECH. L. REV. 1, 20 (2020) (arguing that biologics receive greater protection than do small-molecule brand drugs).

approval for the first four years, even if they use their own data and if patents on the original drug are invalidated. For the remaining eight years, another company could apply for FDA approval but would not be allowed to rely on any data from the original drug.[119] In contrast, Hatch-Waxman mandates that no generic application can be submitted for 4 to 5 years after the brand drug is approved.

Next, although both regulatory pathways enable the follow-on applicant to use the brand product's original safety and efficacy data, the proof requirements are different. The small-molecule generic simply needs to show bioequivalence to the brand drug.[120] The biosimilar, however, must prove that it is "highly similar" to the biologic product and that it displays "no clinically meaningful differences." Satisfying these two standards generally requires the performance of additional clinical trials.[121]

Unlike small-molecule generics,[122] FDA approval does not necessarily bring biosimilars within the automatic substitution laws that permit pharmacists to substitute a generic or biosimilar for the brand, when filling a prescription for a brand drug.[123] Only by garnering an interchangeability designation can biosimilars qualify for automatic substitution, and develop the robust market presence, enjoyed by all approved small-molecule generics.[124] To attain the coveted "interchangeability" designation, the biosimilar must offer yet additional proof, supplying additional clinical data.[125] Specifically, the biosimilar must perform a

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[119] *See* Robin Feldman, *Regulatory Property: The New IP,* 40 COLUM. J.L. & ARTS 53, 84 (2016).

[120] *Id.*

[121] *See* FDA Biosimilars, *supra* note 105.

[122] 21 U.S.C. §§ 355(j)(2)(A)(i)–(v).

[123] In some cases, automatic substitution laws permit the pharmacist to substitute a generic or biosimilar without patient consent or physician notification. While all states have some version of automatic substitution law, many have additional requirements like patient consent or physician notification, especially for interchangeable biosimilar substitution. *See generally* Chana A. Sacks et al., *Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions*, 181 JAMA INTERNAL MED. 16 (2021) (surveying variations in automatic substitution laws by state).

[124] *See* Anita Afzali et al., *The Automatic Substitution of Biosimilars: Definitions of Interchangeability are not Interchangeable*, 38 ADV. THER. 2077, 2077 (2021).

[125] *See* U.S. FOOD & DRUG ADMIN., *CONSIDERATIONS IN DEMONSTRATING INTERCHANGEABILITY WITH A REFERENCE PRODUCT: GUIDANCE FOR INDUSTRY* (2019) (describing various types or amounts of clinical data needed to support interchangeability designation, depending on reference biologic's complexity). "Biosimilar" is defined *supra* at note 34. A biological product is "interchangeable" if it "is biosimilar to the reference product" and "can be expected to produce the same clinical result as the reference product in any given patient," and, "for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch." 42 U.S.C. § 262(k)(4)(A), (B). If a biological product is "interchangeable," then "it may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product." 42 U.S.C. § 262(i)(3). *See* Lauren F. Friedman, *An Innovation That Could Transform the Drug Industry Faces a Major Hurdle*, Business Insider (Apr. 29, 2015 2:38 PM), https://www.businessinsider.com/biosimilars-bio equivalence-and-interchangeability-2015-4.

"switching study," so-called because trial participants switch between the original biologic and the biosimilar to confirm that both produce the same clinical effects.[126] Switching studies, however, may be difficult to justify ethically, as they expose patients to potential harm simply to show that one drug option is not less efficacious or more dangerous than the other (i.e., without the expectation of providing additional clinical benefit).[127] As of 2022, only two biosimilars have been approved by the FDA as interchangeable.[128]

Finally, the Biosimilars Act deviates significantly from Hatch-Waxman with respect to the procedure through which follow-on products may challenge brand patents, a procedure known as the "patent dance."[129] The Hatch-Waxman Act requires small-molecule drug manufacturers to identify, in their new drug applications ("NDAs"), the patents associated with their drug for which "a claim of patent infringement could be reasonably asserted" and to amend their applications to add any patents obtained between filing and approval.[130] For any patent issued after the drug's approval, small-molecule companies are required to submit information for such patents within 30 days after the patent's issuance.[131] The FDA is then required to list these patents in a public registry called the Orange Book and to update this listing every 30 days.[132] This Hatch-Waxman regime of patent disclosure allows follow-on manufacturers, prior to drug development, to be aware of the existing patents on a drug and when those patents will expire. Such advance knowledge allows follow-on manufacturers to assess risk, including any possible infringement claims, and to "design around" or otherwise prepare for market entry.[133]

Unlike the Hatch-Waxman Act, the Biosimilars Act in its original form did not require biologics to list their patents in a public registry. Even as amended in

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[126] *See* Heled, *supra* note 112, at 57 (describing "switching studies"); Carrier & Minniti, *supra* note 109, at 15–16 (outlining how switching studies may be used to substantiate interchangeability).

[127] *See* Heled, *supra* note 112, at 58.

[128] Press Release, U.S. Food & Drug Admin. *FDA Approves Cyltezo, the First Interchangeable Biosimilar to Humira* (Oct. 18, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-cyltezo-first-interchangeable-biosimilar-humira ("Cyltezo is the second interchangeable biosimilar product approved by the agency and the first interchangeable monoclonal antibody."); Press Release, U.S. Food & Drug Admin. *FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes* (July 28, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes.

[129] *See generally* Yang Li, Note, *Does it Still Take Two to Tango? A Modern Interpretation of the BPCIA Patent Dance*, 9 N.Y.U. J. INTELL. PROP. & ENT. L. 107, 113–14 (2019); Alejandro Menchaca, *The Inner Workings of the BPCIA Patent Dance*, AM. J. MANAGED CARE: CTR. FOR BIOSIMILARS (Jul. 24, 2021), https://www.centerforbiosimilars.com/view/the-inner-workings-of-the-bpcia-patent-dance.

[130] 21 U.S.C. § 355(b)(1)(A)(viii), (B).

[131] 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53 (2019).

[132] 21 U.S.C. § 355(j)(7)(A)(iii).

[133] Stacie Ropka et al., *Opinion: Purple Book Patent Listings are Only a First Step*, AM. J. MANAGED CARE CTR. FOR BIOSIMILARS (May 8, 2021), https://www.centerforbiosimilars.com/view/opinion-purple-book-patent-listings-are-only-a-first-step.

2020, the Biosimilars Act requires public listing only if a biosimilar has provided its application to the biologic and if the biosimilar and biologic have not otherwise agreed to sidestep the publication requirement.[134] Thus, even following that 2020 amendment, the first biosimilar must initiate and undertake drug development "in the dark"—i.e., without the benefit of any public listing of the patents protecting the biologic, and thus without any reliable way to "design around" or to assess the risk of possible infringement claims. In short, in comparison to the disclosure regime in Hatch-Waxman, the Biosimilars Act limits the information that is made available to the first biosimilar, and further enables the biologic and any biosimilar jointly to limit what information is made available to subsequent biosimilars.[135] Despite these differences, both regimes are designed to provide pathways for smoothing the approval and entry of follow-on medicines as soon as patents expire by using the clinical data from the original drug company and providing efficient pathways for resolving any patent disputes.

IV. THE CLASH OF THE TITANS

The following section explores the clash of patent and trade secret rights, describing the expansion of trade secrets into the patent domain in a manner that frustrates the basic openness of the patent system. The section also analyzes potential pre-emption issues at this complex intersection of two federal statutory systems, one of which relies on state law systems.

A. Patent Shrinks Back in the Onslaught of Trade Secrets

Numerous commentators have spoken at length about modern biopharmaceutical manufacturers relying on trade secrecy to protect manufacturing process information,[136] including in the context of COVID-19.[137] Data from multiple surveys of drug manufacturers reinforce this conclusion, with one study revealing that trade secrets are considered about twice as effective at protecting manufacturing processes as patents.[138] This preference for trade secrecy

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[134] *See generally* Menchaca, *supra* note 129.

[135] *See generally* Feldman, *Cancer Curse*, *supra* note 7, at 20–21 (noting that BPCIA provides opportunities for strategic games by biologics manufacturers).

[136] *See, e.g.,* Levi, Eric Lawrence, *Using data exclusivity grants to incentivize cumulative innovation of biologics' manufacturing processes*, 66 AM. U.L. REV. 911 (2016). Diependaele, Lisa, Julian Cockbain, & Sigrid Sterckx, *Similar or the Same? Why Biosimilars are not the Solution*, 46.3 J. OF LAW MEDICINE & ETHICS 776, 781 (2018); Bruce S. Manheim, Jr., Patricia Granahan & Kenneth J. Dow, *Follow-On Biologics: Ensuring Continued Innovation in The Biotechnology Industry*, 25 HEALTH AFF. 394, 397 (2006); W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 532-38 (2014) [hereinafter Price, *Making Do*]).

[137] Allison Durkin et al., *Addressing the Risks That Trade Secret Protections Pose for Health and Rights*, 23 HEALTH HUM. RIGHTS 129, 133 (2021).

[138] Price & Rai, *Manufacturing Barriers*, *supra* note 17, at 1046 (discussing the results of drug manufacturer surveys from 1994 and 2008; Wesley M. Cohen, Richard Nelson, and John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why US Manufacturing Firms Patent (or Not)*, National Bureau of Economic Research Working Paper 7752 (2000).

manifests in the written text of patents in a number of forms, all of which reflect insufficient manufacturing method disclosure given the purposes of our patent system. As one commentator has noted, companies might submit claims on manufacturing processes that contain a range of values for such critical facets of drug batch manufacture as temperature and concentration.[139] Alternatively, a company might submit claims that include an extremely wide variety of possible means of manufacture, even the type of host cell (eukaryotic, prokaryotic, mammalian, insect) in which a drug might be produced.[140] Both methods, while claiming the veneer of manufacturing disclosure, still force follow-on drugmakers to go through the time consuming and expensive process of reverse engineering the biologic manufacturer's specific form of the drug, which the biologic manufacturer's disclosure is meant to provide to them in exchange for a limited time monopoly. The lack of sufficient manufacturing method disclosure in early patents allows biopharmaceutical companies to maintain trade secrecy indefinitely,[141] to patent manufacturing methods years later (even after FDA approval) in an attempt to extend monopoly pricing power,[142] or a combination of the two.

For example, a biologic company can rely on trade secrets to keep the information secret throughout the patenting process, with the result that biosimilar companies must spend as much as a decade of experimentation to reverse engineer how to make the invention. Along the way, the biologic inventor can choose to file new patents on the processes that should have been originally disclosed, extending the years of protection on the original drug, and delaying the time when less expensive biosimilars get to market.

Given the recent federalization of trade secret rights with passage of the Defend Trade Secrets Act, one must ask whether Congress actually intended such a result. In particular, perhaps Congress intended that trade secrets would overshadow patents, and any lament over trade secret's encroachment on patent territory simply harkens back to a different time and place. Moreover, intellectual property regimes frequently are not exclusive, and if a writer or inventor satisfies the dictates of more than one form of intellectual property, both types of protection may be granted. For example, software can be covered by copyright and patent protection; an elaborate corporate design can be covered by trademark and copyright.

The current protection for biologic medicines, however, presents a direct clash between patents and trade secrets. An item cannot both remain secret and disclosed at the same time, and thus, the invention cannot serve both masters. And yet, we have reached a point at which the systems are moving on a collision

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[139] *See* Jayson Singh Sohi, 17 INTELL. PROP. L. BULL. 157, 164 (2013); *see also* (Patent US 8,663,945 B2 (providing an example).

[140] *See* Patent US 8,343,737 B2; *also see* discussion of Enbrel, infra.

[141] *See* discussion of Premarin, *infra*.

[142] Arti K. Rai, and W. Nicholson Price, II, *An administrative fix for manufacturing process patent thickets*, 39 NAT. BIOTECH. 20, 21 (2021).

course. How then should the legal system resolve a conflict between these two regimes?

Both constitutional law and statutory interpretation doctrines apply when laws appear to conflict with each other. When the question involves two federal legislative regimes—as in the case of the federal Patent Act and the federal Defend Trade Secrets Act—courts will assume that Congress actually knew what it was doing. Thus, multiple pieces of legislation will be interpreted under the assumption Congress understood the nuances of each and intended for both to operate in harmony, absent clear language to the contrary.

With passage of the Defend Trade Secrets Act, however, Congress did provide language expressly noting its intent. In a section of the Act titled, "Rules of Construction," Congress declared that "[n]othing in the amendments made by this section shall be construed . . . to preempt any other provision of law."[143] Thus, federal trade secret law should not be read to preempt the Patent Act, Hatch-Waxman Act, or the BPCIA—all of which existed when Congress passed the Defend Trade Secrets Act. One could then assume that Congress intended that the Defend Trade Secrets Act should be interpreted so as not to interfere with other existing federal laws, given that the Act does not preempt any of them.

The relationship between federal and state trade secrets provides additional complexity, however. Just as the Defend Trade Secrets Act does not preempt other federal laws, so too it does not preempt any state laws. State law regimes exist in tandem, and those who hold trade secrets can sue for misappropriation of their rights under both federal and state statutes, with potential variations among them.[144] In particular, although the Defend Trade Secrets Act definition of a trade secret is modeled after the modern state Uniform Trade Secret Act, which has been adopted by almost all of the states, differences exist among the definitions adopted by the states.[145]

A preemption analysis also would have to consider whether the Patent Act preempts any state trade secret laws. Federal preemption of state statues is grounded in the Supremacy Clause of the Constitution, which provides that, federal law "shall be the supreme law of the land . . . anything in the constitution or laws of any state to the contrary notwithstanding."[146] Modern legal systems frequently operate as a matter of concurrent jurisdiction with overlapping powers between state and federal laws.[147] Nevertheless, state laws can run afoul of

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[143] Defend Trade Secrets Act of 2016, Pub. L. No. 114–153, 130 Stat. 376, section 3(f).

[144] *See* Feldman & Graves, *Naked Price, supra* note 2, at 65.

[145] *See* Grant Cole, *Secrets, Sovereigns, and States: Analyzing State Government's Liability for Trade Secret Misappropriation*, 28 J. INTELL. PROP. L. 131, 137 & n.33 (2020). Massachusetts' adoption of the Uniform Trade Secrets Act in 2018 left North Carolina and New York as the only non-enacting states. *See* Uniform Law Commission – Enactment History (*https://www.uniformlaws.org/committees/community-home?CommunityKey=3a2538fb-e030-4e2d-a9e2-90373dc05792*).

[146] *See* U.S. CONST. art. VI, cl. 2.

[147] *See generally* Ernest A. Young, *"The Ordinary Diet of the Law": The Presumption Against Preemption in the Roberts Court,* 2011 SUP. CT. REV. 253 (describing historic and modern

preemption analysis either through express preemption (federal legislation states that it is preempting state legislation), field preemption (federal legislation so occupies the field that Congress must have intended to leave no room for the states),[148] or conflict preemption (state law makes it impossible to comply with both the state and federal scheme or state law serves as an obstacle to "the accomplishment and execution" of the federal scheme).[149] Much of the discussion and debate in modern caselaw concerns conflict preemption, which is where a discussion of Patent Act preemption of current trade secret doctrines would fall.

Specifically, if trade secret laws are being asserted to allow biologic medicine inventors to refuse to provide full information on how to make and use the drug products they claim as an invention,[150] that interpretation presents at least an obstacle to the disclosure expressly required by the Patent Act and deeply embedded in patent theory and history—and perhaps even posing an impossibility to carrying out the requirements of the Patent Act.

The same is true for the related regulatory regime of the Biosimilars Act. If inventors are asserting trade secret laws to prevent the FDA from disclosing information required for the operation of the Biosimilars Act (such as clinical trial protocols, safety and efficacy data, and quality control procedures)[151] that assertion of trade secrets poses an obstacle to the Biosimilars Act.

Congress passed the Defend Trade Secrets Act in 2016, years after the 2010 passage of the Biosimilars Act and centuries after the first Patent Act in 1790. Thus, from a federal perspective, if Congress intended that the federal Defend Trade Secrets Act would be consistent with prior acts of the congressional body,[152] Congress cannot have intended that trade secret holders could refuse to provide information in a patent through the assertion of federal trade secret law.

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preemption law); Robin Feldman, *Federalism, First Amendment, and Patents: The Fraud Fallacy,* 17 COLUM. SCI. & TECH. L.J. 30, 32, 69 (2015) (citing sale of securities, banking, food and drug, and immigration laws as examples).

[148] *See, e.g.,* PG&E v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 204 (1983) (citing Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 152 (1982)).

[149] Oneok, Inc. v. Learjet, Inc., 575 U.S. 373, 377 (2015) (describing obstacle preemption). For general discussion of the three bases for preemption, *see generally* Young, *supra* note 147; Jeanne C. Fromer, *The Intellectual Property Clause's Preemptive Effect*, *in* INTELLECTUAL PROPERTY AND THE COMMON LAW 265, 271–72 (Shayamkrishna Balganesh ed., 2013); Mark A. Lemley, *Beyond Preemption: The Law and Policy of Intellectual Property Licensing*, 87 CAL. L. REV. 111, 137–138 (1999). For a discussion of debates raging in modern preemption caselaw, including Justice Thomas' skepticism that obstacle preemption provides a valid basis for preempting state law, see Feldman, *Federalism, supra* note 147, at 66–69.

[150] Such disclosure should include the detailed information and know-how necessary for those skilled in the art to create and perfect the manufacturing processes. For a discussion of the necessary information that may be claimed as a trade secret, see *infra* Section V.

[151] For a discussion of these types of information and how they are being withheld from FDA disclosures under the Biosimilars Act, see *infra* Section V.

[152] *See text accompanying notes 143–144*, *supra* (discussing the implications of language in the federal Defend Trade Secrets Act that the provisions of the Act "shall not be construed . . . to preempt any other provision of the law").

From a state law perspective, if state trade secret laws were interpreted to allow drug companies to decline to provide necessary information in a patent application, on the grounds of trade secret, the state laws operate as an obstacle to the execution of the federal scheme. In this case, the obstacle would not just be an example of one scheme undermining the incentives or the workings of another, it would be a direct undermining of the "execution" of the federal act.[153]

One could argue further that by preventing fulfillment of the disclosure mandated in the Patent Act, a trade secret law so interpreted would rise to the level of creating a physical impossibility for compliance with both the federal and state scheme. After all, under the Patent Act, a patent "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. . . ."[154] The inability to satisfy the basic statutory requirements of the Patent Act would make that interpretation far more troubling than if a different law were to operate in a manner that undermined the goals of the Act.

Beyond the esoteric heights of preemption doctrine, the law is simply being misapplied. When patent examiners allow patent applications to move forward without full information and the courts uphold the resulting patents, these legal processes have lost sight of the basic requirement for disclosure in the Patent Act.

Much confusion exists in the caselaw concerning whether a biologic patent that describes one way to produce a product can reach all methods of producing that product, including methods beyond the state of the art at the time of the invention.[155] As fascinating as those questions may be, this is a far simpler problem: How can a patent applicant fail to provide the full range of information necessary to even create the product in the first place.

Part of the problem may stem from misdirection as a result of changes in the so-called "best mode" doctrine. In addition to language requiring that a patent applicant disclose information sufficient that one skilled in the art can make and use the invention, the disclosure section of the Patent Act also includes language requiring that an inventor disclose the preferred way of making the invention, known as the "best mode."[156]

The notion of ensuring that the inventor does not withhold the best information reaches back to the Patent Act of 1870,[157] which specified that one accused of patent infringement could defend on the grounds that the patent "was

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[153] *See* Oneok v. Learjet, 135 S. Ct. 1591, 1595 (2015) (describing obstacle preemption).

[154] 35 U.S.C. § 112(a) (2012).

[155] For a discussion of the tension in the caselaw, see Robin Feldman, *Rethinking Rights in Biospace,* 79 S. CAL. L. REV. 1 (2015).

[156] *See* 35 U.S.C. § 112(a) (2012) (requiring that the inventor "set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention").

[157] Patent Act of 1870, sec. 26, 16 Stat. 198–201, 201 (1870) (revised by Patent Act of 1952, ch. 950, 66 Stat. 792 (codified as amended in scattered sections of 35 U.S.C.)).

made to contain less than the whole truth."[158] That language formed the basis of what would become the requirement to disclose the best mode.[159]

Prior to the America Invents Act of 2011,[160] failure to satisfy the best mode requirement constituted a defense to patent infringement. A spirited debate occurred prior to and during the passage of the Act concerning whether to eliminate the best mode requirement, focusing in part on foreign inventors whose home jurisdictions might not require a best mode disclosure.[161] Other complaints concerned the difficulty of managing the requirement of proving intent to deceive—perhaps a holdover from the historic language of the "whole truth defense"—and the burden of such an inquiry on all litigation parties, particularly smaller inventors. Congress chose a Solomonic compromise: Best mode language would remain in the disclosure section of the Patent Act.[162] However, the section specifying defenses to a charge of patent infringement would specifically note that failure to satisfy best mode would not constitute a basis for invalidating the patent.[163] In other words, inventors are required to disclose the best mode, but failure to disclose it has no real cost.

In theory, patent examiners could choose to bring a disciplinary action within the Patent Office processes and threaten to revoke a patent attorney's license to appear before the Patent Office for failure to comply with best mode. Nevertheless, given human nature, overworked patent examiners might understandably choose to focus little attention on this requirement, and the requirement appears to be honored largely, if not entirely, in the breach.[164]

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[158] *See* Patent Act of 1870, sec. 61, 16 Stat. 208 (1870) (revised by Patent Act of 1952, ch. 950, 66 Stat. 792 (codified as amended in scattered sections of 35 U.S.C.)).

[159] Sohi, *supra* note 139, at 160 (chronicling the history of the best mode statutory language and noting that the "whole truth defense" formed the backbone of the modern best mode requirement).

[160] Leahy-Smith America Invents Act, Pub. L. No. 112–129, 125 Stat. 284 (2011) (codified in various sections of 35 U.S.C.).

[161] *See, e.g.*, THE ADVISORY COMM'N ON PATENT LAW REFORM, A REPORT TO THE SECRETARY OF COMMERCE 100–103 (1992) (recommending elimination of best mode); Jerry R. Selinger, *In Defense of Best Mode,* 43 CATHOLIC U.L. REV. 1071 (1994) (recommending preservation of best mode).

[162] The language changed slightly with the Act in certain ways, notably in using gender-neutral language. *Compare* (language following the America Invents Act requiring that an inventor, "set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention") *with* (language prior to the America Invents Act requiring that an inventor, "set forth the best mode contemplated by the inventor of carrying out his invention").

[163] 35 U.S.C. §282 (2012) amended by Pub. L. 112–129 § 20(g), (l), 125 Stat. 334, 335 (2011).

[164] U.S. Dept. of Commerce, Patent and Trademark Office, Manual of Patent Examining Procedure § 2165.03 (8th ed. Rev. 6, 2007). The Patent Office manual for examination prior to the America Invents Act expressed skepticism about an examiner's ability to identify if best mode was concealed. "The examiner should assume that the best mode is disclosed in the application. It is extremely rare that a best mode rejection properly would be made in [the patent examination process]. The information that is necessary to is rarely accessible to the examiner"); *see also* Sohi, *supra* note 139, at 164–165 (discussing problems with expecting examiners to catch best mode deception).

Best mode, however, is not the only disclosure language. The basic, core Patent Act language requiring sufficient disclosure to make and use the invention remains unchanged. Thus, regulatory or judicial interpretations that decline to follow the dictates of disclosure in the context of biologic medicine are falling far short of the language of the Act. As one scholar has explained, although biologic medicine inventors currently are permitted to satisfy the disclosure requirements by offering approximations or ranges for a variety of elements, including temperature, molecular composition, concentration and reaction agents, despite the fact that such approximations do not actually show one skilled in the art how to make the product.[165]

V. SO WHAT'S THE BIG SECRET?

From cradle to grave, trade secrets feature prominently in the life cycle of a biologic drug, from initial synthesis, to the scaling-up of production, to clinical trials, to the ensuring of consistent quality post-approval. First, and arguably most important, is the detailed information and know-how necessary to create and perfect the manufacturing processes. These processes, all protectable by trade secret doctrine, include fundamental steps of biologic synthesis such as cell line selection and the development of a culture medium.[166] In the absence of this knowledge, it may be impossible to produce a therapeutically equivalent, much less one that will be deemed interchangeable,[167] Thus, companies that are trying to enter the biosimilars market face a far greater challenge than those trying to enter the generics market. The more exacting requirements of the Biosimilars Act and the importance of trade secret-protected, process details to the production of biologic medicines combine to make biosimilar entry vastly more difficult.[168] Unlike small molecule drugs, the information disclosed in the patents isn't nearly enough.

Second, drug companies have long claimed clinical trial protocols[169] and data (i.e., safety and efficacy data) as trade secrets,[170] restricting their dissemination

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[165] *See* Sohi, *supra* note 139, at 158.

[166] *See* Price II & Rai, *Manufacturing Barriers*, *supra* note 17, at 1034–35 (highlighting complexity of biologic manufacturing processes).

[167] Not all approved biosimilars are "interchangeable" with their reference biologic. *See supra* at 24–25 & notes 105, 125; U.S. FOOD & DRUG ADMIN., BIOLOGICAL PRODUCT DEFINITIONS. For a discussion of the additional testing that must take place before the FDA will grant a biosimilar an interchangeability designation, see *supra* text accompanying notes 125–127.

[168] One should note that even without the issue of trade secret information, biologic drugs are much more difficult to produce than small molecule drugs.

[169] *See infra* note 220 (pharmaceutical company assertions that clinical trial protocols and related information are trade secrets).

[170] *See infra* note 221 (pharmaceutical company assertions that clinical trial data are trade secrets).

beyond the FDA.[171] These clinical trials, of course, permit a biologic to enter its next major phase: FDA approval and market entry.[172]

Third, once a biologic has gained FDA approval, trade secrets can also protect FDA-mandated quality-control procedures for production of the biologic. By sequestering approved quality-control practices as trade secrets, the biologic can create another expense for, and thus another barrier to, biosimilar development.

A. Trade Secret Protection in Manufacturing: "The Process is the Product"

Often protected as trade secrets, the minutiae of the processes by which a biologic drug is manufactured affect the safety and efficacy of the biologic, a concern that is absent from small-molecule drug production. The relatively simple chemical structure of small-molecule drugs can often be drawn by hand. In contrast, the size and complexity of biologics, which are cultivated using living tissue, prevent their exact replication or characterization.[173] Instead, standardization of biologic drugs is ensured through the process by which the biologic is manufactured. As is often noted with respect to biologic medicines, "the process is the product."[174]

In addition, a minor alteration in a biologic's manufacturing process can produce profound and even dangerous changes to the drug. For example, to reduce contamination risk, manufacturers of the anemia treatment Eprex replaced one of the inactive chemical compounds in which the drug was formulated, stored, and shipped.[175] This ostensibly innocuous change sparked a severe immune response in many Eprex patients, ultimately worsening the anemia that the drug was designed to mitigate.[176] The impact of this minor adjustment to Eprex shows how difficult it is for a biosimilar to re-create, or create an alternative to, a biologic's manufacturing processes. Moreover, trying to produce a therapeutic equivalent to a biologic when the details of the biologic's manufacturing information are unknown presents a Sisyphean task.[177]

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[171] In fact, although some courts have found that clinical trial data and other information *fail* to qualify for trade secret protections, the FDA refuses to disclose information that meets its broader category of "confidential commercial information," which includes but is not limited to trade secrets. *See infra* text accompanying notes 241–246.

[172] Costs and hence entry barriers are raised further by the requirement that a biosimilar perform "switching studies" in order to obtain an interchangeability designation. For a discussion of "switching studies," see Heled, *supra* note 112, at 57.

[173] *See* Heled, *supra* note 112, at 56. "Characterization" refers to an understanding or description of a molecule's physical and chemical properties. *See, e.g., Pharmaceutical Physical/Chemical Characterization Services*, EUROFINS, https://www.eurofins.com/biopharma-services/product-testing/services/biopharma-product-testing-services/method-development/characterization/characterization-for-pharmaceutical-products/.

[174] *See* Heled, *supra* note 112, at 56 & n.40.

[175] *See* Li, *supra* note 129, at 113–14; Erika Lietzan, *A Solution in Search of a Problem at the Biologics Frontier*, 2018 U. ILL. L. REV. ONLINE 19, 25 (2018) (also describing Eprex).

[176] *Id.* at 114.

[177] *Id.*

Biologic manufacturers may prefer to rely on trade secret rights to protect manufacturing processes that are highly specific and therefore unlikely to be independently discovered or reverse-engineered. If the principal benefit of a patent (i.e., to exclude competitors from using an invention for a period of time) can be obtained without having to engage in the quid pro quo of patent disclosure a drug-maker is likely to maintain and assert trade secret protection rather than file for a patent. Trade secrets, after all, endure beyond a patent's 20 years.[178] Moreover, disclosing a highly specific manufacturing process in a patent application leaves open the possibility that a biosimilar competitor may circumvent the biologic's patent protection with a slightly altered process (but only if, as the Eprex example above illustrates, the altered process can still produce a therapeutically equivalent biosimilar).[179]

Regulators also may unwittingly incentivize more extensive use of trade secrets: Drug-makers sometimes avoid disclosing new manufacturing technologies in their NDAs or biologics license applications because the FDA's unfamiliarity with these technologies can translate to costly approval delays.[180] Thus, a drug-maker may find it more expeditious to keep a novel manufacturing process secret than to disclose it in a patent.[181]

What information precisely are biologic firms seeking to protect? Under the wide umbrella of "manufacturing processes," many specific actions required to generate a successful biologic can each be protected as a trade secret. Trade secret protections can cover basic laboratory processes for initial biologic development, including information pertinent to: protein or hormone structure;[182] the culture or

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[178] *See* Price, *Expired Patents*, *supra* note 43, at 1615 (noting that trade secrets do not expire).

[179] Eric Lawrence Levi, *Using Data Exclusivity Grants to Incentivize Cumulative Innovation of Biologics' Manufacturing Processes*, 66 AM. U. L. REV. 911, 947 (2017) (noting that patenting manufacturing processes leaves open risk of other competitors designing around specified patent claim); Karl F. Jorda, *Patent and Trade Secret Complementariness: An Unsuspected Synergy*, 48 WASHBURN L. J. 1, 18 (2008).

[180] *See* Price, *Making Do*, *supra* note 136, at 512–13 (describing FDA's institutional resistance to new technologies).

[181] The Orange Book contains information about FDA-approved small-molecule drugs and their generic equivalents, including patent protections, regulatory exclusivities, and other approval information. *See* U.S. FOOD & DRUG ADMIN., ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm (last visited Oct. 5, 2022). The Purple Book is the FDA's analogous dataset for biologic drug products. *See* U.S. FOOD & DRUG ADMIN., PURPLE BOOK DATABASE OF LICENSED BIOLOGIC PRODUCTS, https://purplebooksearch.fda.gov/ (last visited Oct. 5, 2022).

[182] *E.g.,* Merckle GmbH v. Johnson & Johnson, 961 F. Supp. 721, 727 (D.N.J. 1997) (asserting that public information about protein's structure and formulation disqualifies trade secret protections). *Cf.* Salsbury Lab'ys, Inc. v. Merieux Lab'ys, Inc., 735 F. Supp. 1555, 1569 (M.D. Ga. 1989), *aff'd as modified*, 908 F.2d 706 (11th Cir. 1990) (choice of strain used for poultry vaccine protected as trade secret).

conditions optimal for a process[183] or cell growth;[184] methods for making a specific type of medium;[185] and the use of agents to facilitate certain steps or reactions such as purification,[186] concentration,[187] and inhibition.[188] Subsequently, trade secrets also feature in guarding the steps needed to convert laboratory bench-work into viable manufacturing,[189] and, following commercialization, the scaling-up and scaling-out of production.[190] The variety of biologic drug types—and the complexity of their production—translates to a variety of processes for which a firm may seek protection, including trade secret protection.

Trade secrets also protect the testing protocols and purity analysis techniques used to verify consistent biologic production.[191] These can be challenging to replicate. Given that biosimilar drug companies will have to engage in clinical trials—which generic companies can forgo—such missing information can delay and increase the costs of biosimilar drug development.

It is also important to emphasize that the lists above are not exhaustive of all biologic manufacturing processes that may qualify for trade secret protection. That, of course, is the challenge of evaluating the extent of things that are secret. From the perspective of one standing outside a company and looking in, one does not necessarily know all the items that are claimed—or could be claimed—as a trade secret. The youth of the biologics industry, as well as the recent vintage of trade secret law, limits the number of trade secret claims that have been tested and described in a court setting.

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[183] *E.g.,* Merck & Co. v. SmithKline Beecham Pharms. Co., No. C.A. 15443-NC, 1999 WL 669354, at *12-13 (Del. Ch. Aug. 5, 1999) (basing finding of trade secret misappropriation in part on fact that defendant's conditions (e.g., multiplicity of infection, ratio of infectious virions to cells in culture) for vaccine production inexplicably matched those used by plaintiff), *aff'd*, 746 A.2d 277 (Del. 2000), and *aff'd*, 766 A.2d 442 (Del. 2000); Genentech, Inc. v. JHL Biotech, Inc., No. C 18-06582 WHA, 2019 WL 1045911, at *3 (N.D. Cal. Mar. 5, 2019) ("The claimed trade secrets generally relate to . . . information regarding the development and selection of a formulation for those four biologics and Tecentriq (another Genentech biologic)").

[184] Price & Rai, *Manufacturing Barriers*, *supra* note 17, at 1046.

[185] *Id.* at 1046; *cf. Salsbury Lab'ys, Inc.*, 735 F. Supp. at 1569 (use of unique medium for poultry vaccine protected as trade secret).

[186] Price & Rai, *Manufacturing Barriers*, *supra* note 17, at 1046.

[187] *Cf. Salsbury Lab'ys, Inc.*, 735 F. Supp. at 1569 (use of agent to adjust concentration of organism in poultry vaccine production protected as trade secret).

[188] *Cf. id.* (use of inhibitor in poultry vaccine production protected as trade secret).

[189] Merck , 1999 WL 669354, at *15 (Del. Ch. Aug. 5, 1999) ("The changes needed to convert a known laboratory process into a manufacturing process can constitute protectable trade secrets.").

[190] *See* ZAIN RIZVI, PUB. CITIZEN, SHARING THE NIH-MODERNA VACCINE RECIPE 16-19 (2021) (describing trade secrets protecting information for increasing Covid-19 vaccine production ("scaling up") and for setting up production in additional factories ("scaling out")).

[191] *E.g., Genentech*, 2019 WL 1045911 at *3 ("The claimed trade secrets generally relate to Genentech's . . . validated analytical methods to test and ensure the stability, potency, purity, identity, and quality of the four biologics"); *cf.* Upjohn Co. v. Freeman, 906 S.W.2d 92, 101 (Tex. App. 1995) ("The record does, however, contain evidence supporting the trial court's finding that the portion of the discovery documents that contain Upjohn's protocols in testing and analyzing Halcion (small-molecule drug) contain trade secrets.").

Although the minutiae of the manufacturing processes listed above may sound granular or ancillary, applying trade secrets to any of these manufacturing steps can have profound consequences for a drug market. To take one example of the extent to which trade secret protections on manufacturing processes can impair biosimilar production, consider the endurance of the drug Premarin's hold on the market. Premarin is a hormone replacement therapy for menopausal symptoms that is derived from the urine of pregnant mares.[192] Originally approved in 1942, Premarin continues—80 years later—to enjoy a market free of equivalent competitors. In 2016, Premarin sales totaled nearly $1 billion,[193] driven in part by aggressive list price growth.[194] Today, Premarin still lacks an equivalent follow-on product.[195] Alternatives to Premarin include synthetic or plant-based bioidentical estrogen replacement therapies (i.e., hormone products that are molecularly identical to what the body produces).[196] These bioidentical options are not approved as generic equivalents to Premarin and have failed to discipline its price.[197]

Premarin owes its exclusivity to the trade secrets protecting the manufacturing process that enables a proper characterization of Premarin's active ingredient.[198] Wyeth, Premarin's manufacturer, has carefully guarded the "Brandon Process," which derives estrogen from pregnant mares' urine. The process is guarded so carefully that details were not even written down until required by Canadian regulations.[199]

The details are sufficiently critical that, as with many biologics, the FDA expressly defines Premarin by its process.[200] To date, no prospective competitor has succeeded in replicating processes for extracting and purifying estrogen from pregnant mares' urine, notwithstanding that patents on Premarin's estrogen extraction methods expired in the 1970s.[201] The entry barrier posed by Premarin's

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[192] For historic reasons, some complex molecules derived from biologic products are listed in the FDA's so-called Orange Book of small-molecule drugs, rather than the so-called Purple book listing biologic products.

[193] Matej Milukic, *Top 20 health products for women in the U.S. based on revenue in 2016*, STATISTA (Oct. 2017), https://www.statista.com/statistics/312282/revenue-from- top-20-women-health-products-in-the-us/.

[194] *See, e.g.,* Tracy Staton, *10 big brands keep pumping out big bucks, with a little help from price hikes*, FIERCEPHARMA (May 7, 2014, 8:00 AM), https://www.fiercepharma.com/sales-and-marketing/10-big-brands-keep-pumping-out-big-bucks-a-little-help-from-price-hikes (noting 257% list price increase in 2012).

[195] *See* Price, *Making Do*, *supra* note 136, at 534.

[196] Jane Allin, *FDA-Approved Alternatives to Premarin Derivatives – are they safer?*, TUESDAY'S HORSE (Nov. 10, 2015), https://tuesdayshorse.wordpress.com/2015/11/10/fda-approved-alternatives-to-premarin-derivatives-are-they-safer/.

[197] *Id.*; Wyeth v. Natural Biologics Inc., 2003 WL 22282371, at *1 (D. Minn. Oct. 2, 2003) (noting that Premarin sales quadrupled in the decade that synthetic alternatives debuted on market).

[198] *See* Price, *Making Do*, *supra* note 136, at 534; *supra* note 173 (defining characterization).

[199] *Wyeth*, 2003 WL 22282371 at *3–4.

[200] *See* Price, *Making Do*, *supra*, note 136, at 536.

[201] *See id.* at 534–35 (describing "Brandon Process," named for Wyeth's manufacturing plant in Brandon, Manitoba).

trade secrets is more than hypothetical: In 2003, a district court permanently enjoined a competitor from developing a generic Premarin, finding that the competitor misappropriated trade secrets disclosed to it by a former Wyeth consultant in order to recreate the Brandon Process.[202] Trade secrets, thus, can confer a permanent monopoly on complex molecules that are defined by the intricacies of their production. In contrast, if Premarim had been protected by patents that fully disclosed the information necessary to make the product, follow-on versions could have entered the market 40 years ago.

Despite the protective power of trade secret law, and despite the limitations of patent protection (such as a patent's fixed duration), patents do offer certain advantages over trade secrets as a means of guarding manufacturing information. For example, drug companies frequently engage in a strategic behavior known as evergreening, in which additional patents and exclusivities are added to expand the length or strength of a drug's protection.[203] Even if some of those patents are likely to be overturned in court, the effort needed to challenge them can serve as a deterrence to competitors. For example, best-selling rheumatoid arthritis drug, Humira, an evergreening poster child, carries more than 200 patents related to its manufacturing processes.[204]

It is not uncommon for a drug's manufacturing process to be protected by a combination of patents and trade secrets. For example, the manufacturer of the biologic medicine Humira, recently sued biosimilar producer Alvotech for misappropriating trade secrets related to the drug's production, despite the fact that the drug is protected by an array of manufacturing process patents.[205]

Furthermore, a drug-maker may leverage both patents and trade secrets by not disclosing the "best mode" of producing a biologic in its composition patent. Instead, the biologic drug-maker could seek manufacturing patents for some processes required to produce the biologic, while keeping the optimal manufacturing process a trade secret.[206] Deploying both patents and trade secrets can better fortify biologics against prospective biosimilar competition.[207]

This complementary approach to protecting manufacturing processes shows that the information disclosed by manufacturing patents often fails to enable

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[202] *See* Wyeth, *supra* note 197, at *26–28.

[203] Robin Feldman, *May Your Drug Price Be Evergreen*, 5(3) Journal of Law and the Biosciences 590, 596 (2018) (defining evergreening as a process by which pharmaceutical companies artificially extend "the life of a patent or other exclusivity by obtaining additional protections to extend the monopoly period").

[204] Price, *Making Do*, *supra* note 136, at 527.

[205] Nicholson Price, *Regulating Secrecy*, *supra* note 17, at 1801; *cf.* Norbrook Laboratories Ltd. v. GC Hanford Mfg. Co., 297 F. Supp. 2d 463, 472 (N.D.N.Y. 2003) (describing how misappropriation of manufacturing trade secrets by former employee was uncovered only by accident during discovery for defamation lawsuit against same employee); Price, *Making Do*, *supra* note 136, at 527. *AbbVie*, 2021 WL 4593490 at *2.

[206] *See* Price, *Expired Patents*, *supra* note 43, at 1618 (describing biologics' technique of combining patent and trade secrecy protections as "safety valve," and noting that patents effectively need not disclose invention's "best mode" after America Invents Act of 2011).

[207] *Id; see generally* Jorda, *supra* note 179.

biosimilar development.[208] Besides the fact that not disclosing an invention's best mode does not suffice to invalidate a patent,[209] drug-makers may avoid including in their patents detailed manufacturing information that proves irrelevant to their final product. Because drug-makers file for patents early in drug development, it is not uncommon for the biologic approved years later to rely on revised manufacturing processes that are different from those described in the patent.[210] Moreover, a biologic manufacturer is not incentivized to disclose detailed production information, lest the FDA require the approved biologic to hew more closely to that earlier-disclosed information.[211] Chemical composition patents, consequently, may be substantiated with limited or irrelevant manufacturing process claims.[212] Conversely, a drug-maker may claim an extensive portfolio of manufacturing processes, many of which are useless to enabling future biosimilars.[213] Enbrel's composition patent, for example, describes hundreds of techniques and materials that may be used to express the active protein, but only a small subset of these would yield a compound biosimilar to Enbrel.[214] Faced with those hundreds of descriptions, a prospective biosimilar manufacturer would find it next to impossible to identify the precise technique and materials that would yield the correct product.

Even if a manufacturing process patent does enable development of a biosimilar, the trade secrets that safeguard crucial specifics or know-how may preclude a biosimilar from obtaining the elusive and valuable designation of "interchangeability."[215] Apart from enabling a biosimilar to come within state automatic substitution laws,[216] that designation confers a competitive benefit: The first biosimilar that is deemed interchangeable with a reference biologic obtains a one-year exclusivity period, during which no other biosimilar for that reference

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[208] *Cf.* Jorda, *supra* note 179, at 21 ("manufacturing process details are, even if available at the time of filing, not a part of the statutorily required enablement and best mode disclosure of a patent. Case law leaves no doubt that disclosure of manufacturing details or production specifications is not required.").

[209] *Id.*; *see also* Frank W. Eucalitto, *Best Mode or (Trade) Secret Mode? The Evisceration of the Best Mode Requirement and its Impact on the Biotechnology Industry*, 33 QUINNIPIAC L. REV. 199, 208–13 (2014) (describing how passage in 2011 of America Invents Act, which eliminated failure to disclose invention's best mode as ground to invalidate patent, especially benefited patent-holders in biotech and pharma industries).

[210] *See* Price & Rai, *Manufacturing Barriers*, *supra* note 17, at 1050.

[211] Price, *Regulating Secrecy*, *supra* note 17, at 1798–99.

[212] *See, e.g.,* 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, 140–46 (describing Amgen v. Hoechst, in which the Federal Circuit affirmed infringement of composition patent for a range of protein patterns that disclosed only one production method).

[213] Price & Rai, *Manufacturing Barriers*, *supra* note 17, at 1050–51 (describing Enbrel).

[214] *Id.*

[215] Interchangeability is discussed *supra* at 117–137 and note 34 (explaining that although all small-molecule generics qualify for state automatic substitution laws, only those biosimilars that are designated as interchangeable qualify). S*ee generally* Sacks et al., *supra* note 123; Afzali, *supra* note 124.

[216] *See supra* note 215.

biologic can qualify as interchangeable.[217] Thus, much potential profit may hinge on knowing the specifics of biologic production—details often developed after patent applications are filed.[218]

B. Clinical Trial Data and Protocols

Besides manufacturing processes, trade secret doctrine may also protect the clinical trial data required to obtain regulatory approval.[219] Specifically, drug-makers claim as trade secrets both the clinical study protocols used to test drugs under development[220] and the data they produce (e.g., safety and efficacy data).[221] Drug-makers have even emphasized that the mere existence of certain trials must also be concealed.[222]

FDA decisions to approve new drugs are based on the results of clinical trials, but the agency does not release the complete set of clinical evidence that substantiates its decisions, publishing only a high-level "summary review" of pertinent studies.[223] Although manufacturers are obligated to report clinical trial

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[217] 42 U.S.C. § 262(k)(6)(A).

[218] *See* Price, *Expired Patents*, *supra* note 43, at 1623.

[219] Trade secret protections for clinical trial data apply to small-molecule and biologic drugs alike.

[220] *E.g.*, Pfizer, Inc. v. ICI Americas, Inc., No. 7785, 1984 WL 8262, at *4 (Del. Ch. Nov. 21, 1984) ("[Laudadio] is apparently well aware that such information, *i.e.*, the results of the clinical testing of sorbinil to date, does fall within the category of trade secrets belonging to Pfizer and that he has a contractual obligation not to disclose it to Pfizer or anyone else. *What the case is about is Laudadio's knowledge of the best ways to conduct the clinical testing of an aldose reductase inhibitor. Pfizer contends that this know-how also constitutes trade secrets belonging to it*." (emphasis added)). The court disagreed that clinical testing methods qualified as trade secrets. *Pfizer,* 1984 WL 8262, at *10; Hoffmann-La Roche Inc. v. Yoder, 950 F. Supp. 1348, 1351, 1360 (S.D. Ohio 1997).

[221] *E.g.*, King Pharms., Inc. v. Eon Labs, Inc., No. 04-CV-5540 DGT, 2010 WL 3924689, at *12 (E.D.N.Y. Sept. 28, 2010) ("The challenged excerpts describe *Elan's decision to conduct a bioequivalence study; the results of that study*; Elan's internal communications regarding a review of clinical studies that had already been conducted; and other evidence regarding Elan's awareness of prior research relating to metaxalone Elan has again failed to demonstrate that these portions contain any secret, proprietary information, the disclosure of which would injure Elan competitively." (emphasis added)); *In re* Zyprexa Prod. Liab. Litig., No. MDL1596JBWASC, 2005 WL 2237793, at *1 (E.D.N.Y. Apr. 7, 2005) ("Eli Lilly and Company maintains that its Clinical Trial Data and the format in which it is maintained on Lilly's computer systems is highly confidential, proprietary information that constitutes trade secrets."); Hemostemix, Inc. v. Accudata Sols., Inc., No. CV 20-881-RGA, 2021 WL 1198137, at *9 (D. Del. Mar. 30, 2021) ("Plaintiff counters that it has sufficiently alleged that Aspire wrongfully obtained and used its trade secrets, including Aspire's improper acquisition of the Midpoint Analysis [clinical trial data report] and its actions to obstruct Plaintiff's access to the clinical trial data I agree with Plaintiff."); *cf* Upjohn Co. v. Hygieia Biological Labs., 151 F.R.D. 355, 358 (E.D. Cal. 1993) (finding that data necessary for approval of veterinary vaccines qualify as trade secrets).

[222] Barbara Mintzes et al., *Clinical Trial Transparency: Many Gains but Access to Evidence for New Medicines Remains Imperfect*, 116 BRIT. MED. BULL. 43, 46 (2015).

[223] Christopher J. Morten & Amy Kapczynski, *The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccine*, 109 CAL. L. REV. 493, 504-05 (2021); *see, e.g.*, CTR. FOR DRUG EVALUATION & RSCH. U.S. FOOD & DRUG ADMIN., APPLICATION NUMBER: 200603 SUMMARY REVIEW (2010).

data—regardless of outcomes—on ClinicalTrials.gov within one year of the study's conclusion, disclosure requirements are incomplete because they mandate the posting of no individual-level data and only partial metadata (e.g., study enrollment criteria) and summary data. In practice, moreover, many trial results are posted after the reporting deadline, or never at all.[224] This may be particularly true of failed clinical trials.[225] Similarly, although drug-makers sometimes voluntarily release summary safety and efficacy data,[226] a clinical study's individual-level patient data and its metadata are usually kept secret.[227]

Trade secret protections inhibit outside auditors from auditing clinical study data and findings. Independent verification of clinical study data helps establish greater confidence in the FDA approval process and ensure consumer safety, and can inform what therapeutic options are included in health plan formularies.[228] Moreover, the need for external data auditing may be heightened by the latent conflicts of interest in the many clinical trials administered or designed by drug companies.[229] Sometimes, public pressure will induce drug-makers to disclose trade secrets such as clinical study protocols—as did Covid-19 vaccine manufacturers after insistent outcry—but disclosure is not the norm.[230] The drugs whose complete clinical trial data would be most useful to audit, of course, may be those whose data a manufacturer is least inclined to release voluntarily. Examples of drugs worth auditing may include expensive drugs with cheaper therapeutic alternatives or drugs that were narrowly or contentiously approved by

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[224] Morten & Kapczynski, *supra* note 223, at 504, 516; *see also* Charles Piller, *FDA and NIH let clinical trial sponsors keep results secret and break the law*, SCIENCE (Jan. 13, 2020), https://www.science.org/content/article/fda-and-nih-let-clinical-trial-sponsors-keep-results-secret-and-break-law (describing study that found 31.6% of clinical trials in 2018-2019 failed to report their results to ClinicalTrials.gov).

[225] *Cf.* Erick H. Turner et al., *Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy*, 358 N. ENGL. J. MED. 252 (2008) (97% of successful antidepressant clinical trials were reported in medical literature, compared to just 33% of those with negative results).

[226] *See, e.g.,* Durkin, *supra* note, at 137 (noting that, after public pressure, Covid-19 vaccine manufacturers released their secret clinical study protocols).

[227] *See* Morten & Kapczynski, *supra* note 223, at 511–14 (describing different data types and their current availability); Mintzes et al., *supra* note 222, at 44.

[228] *Cf.* Shane P. Stenner et al., *ePrescribing: Reducing Costs Through In-Class Therapeutic Interchange*, 7 APPL. CLIN. INFORM. 1168 (2016) (finding that, in addition to substituting therapeutically equivalent generics, substantial drug savings (about $18 per person per year) can result from substituting other therapeutic alternatives within that drug class, whose clinical interchangeability requires extensive clinical evidence to establish).

[229] *See* Kristine Rasmussen et al., *Collaboration between academics and industry in clinical trials: cross sectional study of publications and survey of lead academic authors*, 363 BRIT. MED. J. k3654 at 1 (2018) (finding that 87% of phase III/IV clinical trials involved industry funders in their design).

[230] Durkin, *supra* note, at 137. The initial obfuscation of Covid-19 protocols may have fueled vaccine hesitancy. *See Vaccine Confidence Needs Radical Transparency*, 586 NATURE 8 (2020); NATALIE RHODES ET AL., TRANSPARENCY INT'L., FOR WHOSE BENEFIT? TRANSPARENCY IN THE DEVELOPMENT AND PROCUREMENT OF COVID-19 VACCINES 9 (2021).

the FDA (i.e., when the FDA advisory panel did not recommend the drug's approval).[231]

Keeping the protocols, data, and existence of failed clinical studies secret[232] may serve to increase drug development costs.[233] Data about other drug-makers' failures can inform which drug candidates a firm chooses to advance through expensive clinical testing, and for which indications. Secret failures, on the other hand, may leave other drug-makers to waste millions on futile and redundant trials.[234] Drug companies frequently invoke the costs of failed drug development and clinical trials to justify high drug prices, on the basis that "[p]harmaceutical companies and the rest of the scientific community can learn from these failures to improve the research process."[235] Stowing these failures away flies in the face of such logic.

Similarly, patients may needlessly enroll in clinical studies that, based on the outcomes of past unreported studies, may be unlikely to work, a prospect that raises ethical concerns. For example, imagine a terminal cancer patient who is offered a place in one of two phase III trials, each for a different oncology therapeutic. Trial A tests a first-of-its-kind drug. Trial B tests a drug that failed to show efficacy for the patient's condition in a similar study the year prior, a study that went unreported and whose data remained concealed by trade secret claims. (Because the potential market is large, the company decides it is worth the cost to attempt another study.) The drug in Trial A is produced by a smaller, upstart firm without previous experience in the oncology arena, while Trial B's manufacturer is a household name with several prior cancer blockbusters. Without knowing that the drug in Trial B failed to show efficacy in a previous study, the patient may unhesitatingly choose to enroll in Trial B. The information gap created by

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[231] *See, e.g.,* Bill Chappell, *3 Experts Have Resigned From An FDA Committee Over Alzheimer's Drug Approval*, NPR (Jun. 11, 2021), https://www.npr.org/2021/06/11/1005567149/3-experts-have-resigned-from-an-fda-committee-over-alzheimers-drug-approval (describing how members of FDA advisory committee resigned after agency approved Aduhelm); Charles Seife, *FDA Documents Reveal Depths of Internal Rancor over Drug's Approval Process*, UNDARK (Aug. 2, 2017), https://undark.org/2017/08/02/fda-eteplirsen-janet-woodcock/, *reprinted in* Morten & Kapczynski, *supra* note 223, at 526 (describing saga of eteplirsen's approval, which saw FDA overrule its scientific advisers); *see also* Joshua M. Sharfstein et al., *Blueprint for Transparency at the U.S. Food and Drug Administration: Recommendations to Advance the Development of Safe and Effective Medical Products*, 45 J.L. MED. & ETHICS 7 (2017) (advocating for greater clinical trial data transparency by FDA in approval process).

[232] For a discussion of trade secrecy law's protection for such "negative information," see *supra* Section II.C.2.

[233] Durkin, *supra* note 137, at 133.

[234] *See generally* Thomas J. Moore, *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016*, 178 JAMA INTERN. MED. 1451, 1451 (2018) (estimating median cost of clinical trial required for new drug approval to be $19 million).

[235] JOHNSON & JOHNSON, TRANSFORMING LIVES, ADVANCING HOPE: 2019 JANSSEN U.S. TRANSPARENCY REPORT 11 (2019), https://transparencyreport.janssen.com/_document/janssen-2019-transparency-report?id=0000017f-4bb2-ddcd-ad7f-7fbb03bf0001.

obfuscating the existence and outcomes of clinical trials has the potential to undercut ethical medical care.[236]

While many details of manufacturing processes may qualify for trade secret protection,[237] the same cannot be said for clinical trial data. Courts have stated that safety and efficacy data gleaned from clinical trials do not constitute trade secret protection.[238] In the same vein, the European Medicines Agency—which has approved and helped bring to market more biosimilars than has the FDA[239]—has found that clinical study reports or protocols do not constitute trade secrets.[240] Unlike legitimate trade secrets, moreover, it is "logically impossible" to independently discover or reverse-engineer the data produced by a particular clinical trial.[241]

The FDA's failure to challenge drug manufacturers' expansive understanding of trade secrets bears some responsibility for limiting the availability of clinical trial data.[242] FDA regulations implementing Exemption 4 of the Freedom of Information Act ("FOIA") exempt from disclosure not only trade secrets but also the much broader category of confidential commercial information.[243] Under those regulations, all confidential commercial information submitted to the FDA, such

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[236] S*ee* Gabriele Spina Ali, *TRIPS and Disclosure of Clinical Information: An Intellectual Property Perspective on Data Sharing*, 20 J. WORLD INTELL. PROP. 24, 30–31 (2017); *cf. Informed Consent*, AM. MED. ASS'N, https://www.ama-assn.org/delivering-care/ethics/informed-consent (highlighting ethical importance of providing patient with relevant medical information about all treatment options).

[237] *See, e.g.*, Wyeth v. Natural Biologics, Inc., 2003 WL 22282371 at *2 ("[T]he Brandon Process is neither generally known nor readily ascertainable, derives independent economic value from secrecy, and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy."); Merckle GmbH v. Johnson & Johnson, 961 F. Supp. 721, 730–31 (D.N.J. 1997) ("Neither party contests that the type of information at issue here (i.e., the process for making rHuEPO) is worthy of trade secret protection.").

[238] *See* Morten & Kapczynski, *supra* note 223, at 534; *e.g.,* Pub. Citizen Health Rsch. Grp. v. FDA, 964 F. Supp. 413, 416 (D.D.C. 1997) ("The record as it stands does not present a clear picture as to the competitive injury, if any, that would result from releasing the [study] protocol."); Pub. Citizen Health Rsch. Grp. v. FDA, 704 F.2d 1280, 1286 (D.C. Cir. 1983) (holding that safety and efficacy data from clinical trials for intraocular lenses were not trade secrets); *but see* Erika Lietzan, *A New Framework for Assessing Clinical Data Transparency Initiatives*, 18 MARQ. INTELL. PROP. L. REV. 33, 47 (2014) (citing A.L. Labs., Inc. v. Philips Roxane, Inc., 803 F.2d 378, 381 (8th Cir. 1986)) (arguing that definitions of trade secrets encompass health and safety testing information).

[239] Gherghescu & Delgado-Charro, *supra* note 35, at 48.

[240] Mintzes, *supra* note 222, at 46.

[241] *See* Lietzan, *supra* note 238, at 56–57.

[242] *See* Morten & Kapczynski, *supra* note 223, at 523 (describing FDA's deference to drug-makers' own designations of confidential information).

[243] 5 U.S.C. § 552(b)(4) (exempting from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential"); 21 U.S.C. § 20.61(b) (FDA's implementing regulation, which provides: "Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.").

as clinical trial data, cannot be disclosed by anyone in the agency.[244] In particular, the FDA rarely verifies whether information that drug companies designate as confidential commercial information actually meets the appropriate regulatory definition.[245]

The deference with which the FDA treats drug company safety and efficacy data wholly ignores the fact that the companies already enjoy a lengthy data exclusivity period during which no biosimilar may use the original product's data to file an application.[246] For the first four years after a biologic's approval, no biosimilar applications may even be filed.[247] Arguably, the data exclusivity period is not just an incentive to biologic drug companies: it is also, in substance, a form of compensation for the public disclosure of the company's clinical data.[248]

Unfortunately, Supreme Court jurisprudence supports an interpretation of the confidential commercial information as a broad category, one that is vastly broader than trade secrets. In *Food Marketing Institute v. Argus Leader Media* ("FMI"), the Court interpreted Exemption 4 to permit rejection of Freedom of Information Act requests for information "customarily and actually treated as private by its owner," not just information whose disclosure would cause "substantial competitive harm."[249] By narrowing the category of information obtainable by a Freedom of Information Act request, the *Food Marketing Institute* case effectively authorizes drug companies to control what data can be disclosed—a significant power considering the lack of scrutiny with which the FDA determines whether information should be confidential.[250]

Treating clinical trial data as trade secrets affects small molecule drugs as well as biologics. Nevertheless, the greater complexity of biologic medicines and the additional requirements necessary for biosimilar approval in comparison to small molecule drugs makes secrecy particularly problematic. As a result, the secrecy of clinical trial data provides an additional opportunity for blocking, delaying, or disincentivizing competitive entry.

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[244] Morten & Kapczynski, *supra* note 223, at 522; *see, e.g.*, Pub. Citizen Health Rsch. Grp. v. FDA, 704 F.2d 1280, 1290–91 (D.C. Cir. 1983) (holding that clinical trial data was CCI protected under FOIA Exemption 4 despite not meeting trade secrecy qualifications).

[245] *See* Morten & Kapczynski, *supra* note 223, at 523–25 (citing 21 C.F.R. § 20.61(b)).

[246] 42 U.S.C. § 262(k)(7)(A).

[247] 42 U.S.C. § 262(k)(7)(B).

[248] *Cf.* Heled, *supra* note 112, at 67 (arguing that, in return for release of biologics' manufacturing information, 12-year exclusivity enjoyed by biologics provides compensation that is "more than just").

[249] 139 S. Ct. 2356, 2358 (2019).

[250] *See generally* Morten & Kapczynski, *supra* note 223, at 520–27 (describing shortcomings of FOIA as lever to promote disclosure of clinical trial data). The *FMI* holding applies to FOIA requests filed before the 2016 amendments to FOIA. *See id.* at 524–25 & n.170. There is an open question, unresolved by *FMI*, as to whether those amendments—particularly the requirement that an agency seeking to withhold information in response to a FOIA request must establish that it "reasonably foresees that disclosure would harm an interested protected by" the FOIA exemption at issue—limited each agency's ability to withhold information as CCI. *See id*. (citing 5 U.S.C. § 552(a)(8)(A)(i)(I)).

C. Quality-Control Processes

Biologic companies also can impede biosimilar development by claiming trade secret protection for the quality-control processes that are required to secure regulatory approval. For example, biologics manufacturers can treat as trade secrets their Current Good Manufacturing Processes quality-control measures taken to ensure the "identity, strength, quality, and purity of drug products."[251] Trade secrets therefore raises a substantial hurdle to the development of Current Good Manufacturing Processes. Intended to provide flexible, goal-oriented standards, the FDA's Current Good Manufacturing Processes guidance documents are understood by industry to endorse the use of specific technologies, effectively reducing the number of allowable manufacturing and quality-control technologies.[252] If there is currently a best way of doing something in the eyes of the FDA, and that best way is kept secret, those who are trying to satisfy the requirement are at a significant disadvantage. Thus, Current Good Manufacturing Processes—especially when given inflexible readings by industry practice—impose an additional hurdle for biosimilars to clear as they attempt to circumvent or recreate a biologic's production.

As a result of these problems, biosimilars must not only develop manufacturing processes without the benefit of crucial biologic details and know-how, but also redundantly devise new measures to ensure regulatory compliance. Although Current Good Manufacturing Processes and other quality-control processes may sound ancillary, one manufacturing plant reported that, of the 250 days required to complete a batch of medications, quality-assurance and control activities consumed 237 of those days.[253] Thus, using trade secrets to safeguard Current Good Manufacturing Processes further raises the very biosimilar development costs that the Biosimilars Act sought to lower.[254]

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[251] *Facts about Current Good Manufacturing Practices (CGMPs)*, U.S. FOOD & DRUG ADMIN. (JUN. 1, 2021), https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps; *e.g.,* Genentech, Inc. v. JHL Biotech, Inc., No. C 18-06582 WHA, 2019 WL 1045911, at *3 (N.D. Cal. Mar. 5, 2019) at *3 ("The claimed trade secrets generally relate to Genentech's . . . manufacturing and operation protocols, including *GMP-compliant procedures*." (emphasis added)); *see generally* Katherine E. Perrelli & Erik W. Weibust, *Tips for Ensuring Your Competitors Do Not Steal the Valuable Fruits of Your Research and Development*, SEYFARTH SHAW (Mar. 28, 2014), https://www.tradesecretslaw.com/2014/03/articles/trade-secrets/tips-for-ensuring-your-competitors-do-not-steal-the-valuable-fruits-of-your-research-and-development/. Individualized quality- control and testing processes can satisfy CGMP requirements (i.e., CGMP regulations are flexible standards rather than prescriptions); manufacturers may therefore employ any of various methods to comply with CGMP requirements.

[252] *See* Price, *Making Do*, *supra* note 136, at 514–15.

[253] *Id.* at 503–04.

[254] *Cf.* Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power Over Price*, 96 YALE L.J. 209 (1986) (coining phrase "raising rivals' costs" to describe how limiting rival's supply of goods or product inputs can function as anticompetitive conduct). This theory might also apply in the context of biosimilar approval as biologic firms restrict the flow of information in order to raise the cost of biosimilars' approval.

As with manufacturing processes, drug-makers have reason to protect their quality-control and testing procedures with trade secret doctrine and not with patents. A safe harbor protects a non-patentee that uses patented information in the service of drug development activities "reasonably related" to obtaining regulatory approval, such as from the FDA.[255] Courts have specifically interpreted such activity to include biosimilarity testing.[256] In other words, a rival drug-maker can use a biologic's patents to develop—but not commercialize—a biosimilar.[257] Given that patents may not effectively protect biologic drug-makers' testing and quality-control processes from biosimilars seeking approval, biologic drug-makers may prefer to rely on trade secret doctrine instead.[258]

In addition to raising biosimilar development costs, the expansion of trade secret protections in this arena likely has other drawbacks. Innovation may be harmed given that the assertion of trade secrets limits both collaboration between drug-makers and the flow of publicly available information.[259] Moreover, requiring biosimilars to independently develop quality-control procedures that differ from those used to safeguard biologics may fuel concerns from consumers that biosimilars are less safe than biologics or are regulated less stringently.[260]

VI. CONSEQUENCES OF OVERLOOKING TRADE SECRETS

A. Unbalancing the Biosimilars Act

As the biologic analog to the Hatch-Waxman Act, the Biosimilars Act attempts to facilitate biosimilar entry without sacrificing the interests of the original biologic company. In particular, the Act was designed to produce incentives for both biologics and biosimilars to take on the burdens of innovating and competing. These incentives include giving generous exclusivity periods to

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[255] 35 U.S.C. § 271(e)(1).

[256] *See, e.g.,* Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348, 1359 (Fed. Cir. 2012) (finding that generic's use of brand drug's patented testing processes in support of its FDA application is covered by Hatch-Waxman's safe harbor).

[257] *See* Amgen Inc. v. Hospira Inc., 944 F.3d 1327, 1339-41 (Fed. Cir. 2019) (affirming jury's finding that some batches of biosimilar did not qualify for safe harbor because patented manufacturing processes were not used only for FDA approval purposes). Although a biologic's manufacturing processes could help a biosimilar prepare a drug batch for approval, the biosimilar would be unable to use these patented processes to produce its biosimilar for commercial purposes. That inability may be of little consequence to the biosimilar, as testing processes may not be necessary after approval.

[258] *See* Price, *Making Do*, *supra* note 136, at 529–31 (explaining that safe harbor provision weakens innovation incentives for manufacturing and testing techniques).

[259] *Id.* at 502–03; *cf.* Laura G. Pedraza-Fariña, *Spill Your (Trade) Secrets: Knowledge Networks as Innovation Drivers*, 92 NOTRE DAME L. REV. 1561, 1577–78, 1584 (2017) (arguing that, in industries—like pharmaceuticals—with strong collective innovation and knowledge-sharing networks, costs of trade secrecy are likely to outweigh benefits); *but see* Mark F. Schultz, *Trade Secrecy and Covid-19* 14–16 (Geneva Network Working Paper, 2021) (arguing that trade secrecy does not chill innovative partnerships and instead promotes trust between firms).

[260] *See, e.g.,* Ira Jacobs et al., *Patient Attitudes and Understanding about Biosimilars: An International Cross-Sectional Survey*, 10 PATIENT PREF. & ADHER. 937 (2016) (survey finding that fewer than half of patients believe switching to biosimilars is safe).

biologic drug-makers[261] and allowing biosimilars to use the safety and efficacy data of the first biologic, provided the biosimilar demonstrates "no clinically meaningful differences."[262] The assertion of trade secrets disrupts the bargain struck in the Biologics Act by effectively extending the lifespan of a biologic's market monopoly past the expiration of patents and exclusivities.[263] This problem contributes to the lack of robust biosimilar competition in the United States.[264]

Thus, the current assertion of trade secrets reconfigures the statutory incentives to innovate and compete. Trade secrets can provide biologic companies with total market dominance for years past the biologics' statutory allotment, as well as foist higher development costs on biosimilars and impeding biosimilar interchangeability.[265] Without access to biologic manufacturing information, biosimilar companies that are unable to replicate the biologic's composition are left to target clinical comparability instead.[266] Clinical comparability involves developing a new cell line and performing clinical trials in the hopes of demonstrating nearly identical therapeutic effects to the reference biologic's.[267]And, of course, there are even more trials and more expense if the biosimilar seeks interchangeability status. The necessity for redundant work upsets the balance contemplated by the Biologics Act, tipping the scales against biosimilar drug-makers.

B. Undermining March-in Rights, Section 1498, TRIPS Waiver, and Operation Warp Speed

The Biosimilars Act is not the only regulatory regime undermined by the modern application of trade secrets in the context of biologic medicine. That failure has undermined other legislative and regulatory scaffolding including march-in rights, compulsory licensing under Section 1498, and the Covid-19 vaccine effort known as "Operation Warp Speed"—all of which are tools that can facilitate affordable access to biologic medications.

1. March-in Rights

Prior to passage of the Bayh-Dole Act in 1980, the federal government retained the right to patent and grant licenses for any inventions developed with government funding.[268] The government, however, had a rather lack-luster history

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[261] *See* 42 U.S.C. § 262(k)(7)(A). Biologics' 12-year exclusivity period has drawn criticism for being too long. *See, e.g.,* Lexchin, *supra* note 35, at 1 ("there is no difference in the median premarket development time between biologics and small molecule drugs that would justify the 12 years of data exclusivity that the former group received in 2010.").

[262] 42 U.S.C. § 262(i)(2)(B).

[263] *See, e.g.*, Section I.C.1. (describing Premarin).

[264] *See* Gherghescu & Delgado-Charro, *supra* note 35, at 48. For other explanations of the tepid biosimilar industry in the U.S., *see* supra text accompanying notes 117–137.

[265] *See supra* text accompanying notes 139–142, 166–167, 177–179, 215, 233–234, and 254.

[266] *See* Heled, *supra* note 112, at 56.

[267] *Id.*

[268] 5 U.S.C. § 203(a). Initially only *non-profit* government contractors could receive patent

of managing to license such inventions. In an effort to facilitate translation of government-funded inventions into products for the benefit of society, the Bayh-Dole Act provided that those who develop inventions using federal funding have the right to patent and license those inventions.

The government, however, retains what are known as "march-in" rights. Specifically, when a patent is developed with federal funding, the government agency that provided the funding retains the right to require that the patent holder grant an exclusive or non-exclusive license to a reasonable applicant on reasonable terms. If the patent holder refuses, the government agency itself may "march in" and grant such a license.[269]

The government can exercise march-in rights in any of four scenarios, including to alleviate "health or safety needs" or "meet requirements for public use."[270] However, despite several requests by individuals, private entities, and Members of Congress that the government exercise march-in rights—all concerning prescription drugs developed with the assistance of government funding—march-in rights have never been exercised.[271]

Even if march-in rights were exercised, however, the Bayh-Dole Act does not furnish the government with authority to obtain relevant trade secrets,[272] such as the "know-how" required to manufacture a particular drug.[273] When patents alone are insufficient to enable the manufacture of biologics, march-in rights alone also

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ownership this way, but a memorandum issued by the Reagan administration extended this right to *all* contractors, a move that has never been codified by statute. *See* THOMAS, *infra* note 269, at 6.

[269] JOHN R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 7 (2016) ("The Bayh-Dole Act provides the government with the ability to 'march in' and grant licenses for patents that resulted from publicly funded R&D").

[270] The four scenarios specified in the Bayh-Dole Act are:

> **"(1)** action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
>
> **(2)** action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
>
> **(3)** action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
>
> **(4)** action is necessary because the agreement required by section 204 [related to a mandate for manufacturing within the United States] has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204."

35 U.S.C. § 203(a); 35 U.S.C. § 204.

[271] *See* THOMAS, *supra* note 269, at 8–10 (listing six requests as of 2016, five of which cited high drug cost). Similar calls have proliferated during the Covid-19 pandemic. *See, e.g.,* Peter J. Pitts, *Remdesivir and Federal March-in Rights*, HEALTH AFF. (Apr. 30, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210421.570435/full/.

[272] *See* 35 U.S.C. §§ 202–03 (outlining procedure and scope of patent licensing but making no mention of trade secrets).

[273] *See supra* Section III (describing how patent information alone does not enable production of therapeutically equivalent biosimilar for some biologics).

fall short as a tool for ensuring more affordable biologic production. Should march-in rights ever be exercised, their utility will likely be negated by the patentee's retention of trade secrets—a negation that exemplifies the government's failure to appreciate the role trade secrets should play in pharmaceutical policy.

2. Section 1498

Trade secrets are absent from another powerful tool available to the government: 28 U.S.C. § 1498. The section provides that whenever the federal government uses a patented invention without a license from the patent holder (or licenses that invention to a government contractor without obtaining a license from the patent holder) the patent holder's remedy is to sue the government (rather than any government contractor) in the United States Court of Federal Claims. Under the statute, the patent holder would recover "reasonable and entire compensation," which the courts have interpreted as an appropriate licensing royalty.[274] For example, courts applying § 1498 have awarded compensation such as a 10% royalty or a 7.5% royalty.[275]

Many examples of the federal government using patents without obtaining a license and leaving the patent holder to seek recourse under § 1498 respond to crisis events (e.g., world wars).[276] Nevertheless, the circumstances that might lead to an invocation of § 1498 do not require such urgent circumstances. In the 1950s, the federal government purchased supplies of the antibiotic tetracycline hydrochloride from an Italian company rather than the patent holder Pfizer because the Italian company's price was 72% less expensive.[277] More recently during the Anthrax scare of 2001, the federal government used the threat of § 1498 to convince the Bayer pharmaceutical company to reduce by 50% the price

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[274] *See generally* Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National* Crises, 23 YALE J.L. & TECH. 1 (2020).

[275] *See Tektronix, Inc. v. United States*, 552 F.2d 343 (Ct. Cl.), *opinion modified on denial of reh'g,* 557 F.2d 265 (Ct. Cl. 1977) (10% royalty awarded); Decca Ltd. v. United States, 640 F.2d 1156 (Ct. Cl. 1980) (7.5% royalty awarded). For a discussion of § 1498 in the context of arguing that patents do not constitute private property for the purposes of the Constitution's 5th Amendment Takings Clause, see Robin Feldman, *Patents as Property for the Takings* (forthcoming N.Y.U. J. IP & ENT. L.), *available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4050135*.

[276] *See* Morten and Duan, *supra* note 274, at n.9, 13 (describing section 1498 as the "nuclear option" and arguing that Covid-19 pandemic is a crisis event).

[277] Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 303–05 (2016) (describing the transaction as an exercise of § 1498 given that without benefit of § 1498, the government's purchase would have been an improper infringement of Pfizer's patents).

of its antibiotic that could be used to treat anthrax exposure.[278] The government has also applied the statute to use patented hazardous waste clean-up methods and fraudulent check-detection software.[279] Comparing Bayh-Dole Act to § 1498, although both statutes underscore the government's power to act outside the constraint of patents, § 1498 applies to all patents, while Bayh-Dole applies only to those patents developed with government funding.[280] As with Bayh-Dole, however, § 1498 makes no mention of trade secrets. Thus, if the federal government were to license a contractor to make a modern biologic medicine, under the shelter of § 1498's limitations on a potential patent infringement suit, the contractor would be unable to make the medication for lack of the relevant trade secrets.

3. The TRIPS Waiver

The failure to take account of trade secrets extends beyond U.S. borders. The powers accorded to the U.S. government in § 1498 parallel the compulsory licensing clause of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), which went into effect in 1995.[281] TRIPS facilitates trade among member states by standardizing a set of international rules governing intellectual property rights.[282] One such rule authorizes a government, under certain conditions, to issue compulsory licenses permitting the licensee to use patent-protected rights without the patent owner's permission.[283] But one of the conditions requires that the compulsory licensee use the license to supply mainly the domestic market.[284] In 2003, World Trade Organization members agreed to waive that TRIPS requirement for pharmaceutical products, thereby freeing the compulsory licensee to use the license to supply non-domestic markets with pharmaceuticals.[285] Pharmaceutical

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[278] *See id.* at n. 136 *and accompanying text*; Aaron S. Kesselheim & Jerry Avorn, Aaron S. Kesselheim & Jerry Avorn, *Biomedical Patents and the Public's Health Is There a Role for Eminent Domain*?, 295 J. AM. MED. ASS'N 434, 435 (2006); Keith Bradsher & Edmund L. Andrews, *A Nation Challenged: Cipro; U.S. Says Bayer Will Cut Cost of Its Anthrax Drug*, N.Y. TIMES, Oct. 24, 2001, https://www.nytimes.com/2001/10/24/business/a-nation-challenged-cipro-us-says-bayer-will-cut-cost-of-its-anthrax-drug.html.

[279] *See* Brennan, *supra* note 277, at 302.

[280] *See* Michael Liu et al., *March-In Rights And Compulsory Licensing—Safety Nets For Access To A COVID-19 Vaccine*, HEALTH AFF. (May 6, 2020), https://www.healthaffairs.org/do/10.1377/forefront.20200501.798711/full/; THOMAS, *supra* note 269, at 8 (outlining other differences between two statutes, such as that march-in rights can be initiated by private parties in addition to government and that payment under § 1498 is obtained through litigation damages against government, in contrast to licensed royalty contemplated by march-in rights).

[281] *See* Liu et al, *supra* note 280 ("[Section 1498] is reflected in a section of a World Trade Organization document, the Trade-Related Aspects of Intellectual Property Rights (TRIPS)").

[282] *See* SHAYERAH I. AKHTAR ET AL., CONG. RSCH. SERV., IF11858, POTENTIAL WTO TRIPS WAIVER AND COVID-19 1–3 (2021).

[283] *See id.*

[284] *See id*.

[285] The 2003 TRIPS waiver process is long and cumbersome, however, and certainly not a useful process for ensuring vaccines during a pandemic. The waiver has been used before only by

firms have staunchly opposed this move, which they allege will erode incentives to conduct future research and development.[286]

The power of § 1498 and the Covid-19 TRIPS waiver is limited by the failure of both measures to take account of trade secrets.[287] Like march-in rights, § 1498 and TRIPS can compel government access only to patents—not to all information needed to manufacture a drug or vaccine.[288] So, for example, the importance of trade secrets to vaccine production renders ineffective any Covid-19 vaccine TRIPS waiver that fails to give the compulsory licensee access to trade secrets.[289] The omission of trade secrets from § 1498 and TRIPS waivers limits the efficacy of these tools when, as with biologics, manufacturing know-how and other trade secrets constitute barriers to production.[290]

4. Operation Warp Speed

In the spring of 2020, the United States launched a program titled Operation Warp Speed, which was designed to speed up the development of multiple vaccines for protecting against the accelerating COVID-19 pandemic. Despite its success in rapidly developing an effective Covid-19 vaccine, Operation Warp

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Canadian company that exported HIV/AIDS therapy to Rwanda, and the process of obtaining the waiver took 2 years. Nicholas G. Vincent, *Trip-ing Up: The Failure of TRIPS Article 31bis*, 24 GONZ. J. INT'L 1, 19 (2020) (discussing issues with the only use of the 2003 TRIPS waiver through a program for Rwanda to import HIV/AIDS medication from Canada). As a result, a similar TRIPS waiver has been adopted for Covid-19 vaccines; that waiver would better enable the U.S. government to export a Covid-19 vaccine produced in the U.S. to lower-income countries that lack vaccine stockpiles or adequate manufacturing capabilities. *See id.*; *Ministerial Decision on the TRIPS Agreement,* World Trade Organization, WT/L/1141 (2022) (The COVID TRIPS waiver represents an improvement on the previous TRIPS waiver in two ways. Firstly, the COVID waiver allows that members "need not require the proposed user of the subject matter of a patent to make efforts to obtain an authorization from the right holder," as was previously required in section §31(b) of the 2003 TRIPS waiver. Secondly, the COVID waiver states that the "determination for adequate remuneration" required under §31(h) may consider the "humanitarian and not-for-profit purpose of specific vaccine distribution programs." *See id.*; Rachel Thrasher, *One Step Forward, Two Steps Back? Ensuring a TRIPS Waiver Drives Health Equity*, BOSTON U. GLOB. DEV. POL. CTR. (Mar. 30, 2022), https://www.bu.edu/gdp/2022/03/30/one-step-forward-two-steps-back-ensuring-a-trips-waiver-drives-health-equity/.

[286] *See, e.g.*, *PhRMA Statement on WTO TRIPS Intellectual Property Waiver*, PHRMA (May 5, 2021), https://phrma.org/Coronavirus/PhRMA-Statement-on-WTO-TRIPS-Intellectual-Property-Waiver (pharmaceutical lobbying group condemning TRIPS waiver); Brook Baker, *Debunking Pharma's Talking Points on the TRIPS Waiver*, Health Glob. Access Project (May 13, 2021), https://healthgap.org/debunking-pharmas-talking-points-on-the-trips-waiver/ (listing objections by pharmaceutical industry to proposed TRIPS waiver).

[287] *See* 35 U.S.C. § 203(a); 28 U.S.C. § 1498; Thrasher, *supra* note 285 (noting that proposed TRIPS waiver as of March 2022 did not include access to trade secret protected manufacturing information).

[288] Morten & Duan, *supra* note 274, at 78–79, 84 (recognizing that § 1498 cannot "overcome" trade secrets or regulatory exclusivities); Thrasher, *supra* note 285 (noting obstacles to vaccine production other than patent protections).

[289] Thrasher, *supra* note 285.

[290] *See* Jane Feinmann, *Covid-19: Global Vaccine Production is a Mess and Shortages are Down to More than Just Hoarding*, 375 BMJ n2375 1, 3 (2021) (noting main barriers to Covid-19 vaccine manufacturing are manufacturing know-how and other production issues).

Speed[291] falls short in relation to trade secret rights. As part of the project, the U.S. government signed contracts with vaccine manufacturers, including Moderna and Pfizer.[292] The Moderna contract preserves the government's authority to invoke march-in rights for patents. However, it allows the companies to retain any trade secrets covering the vaccines.[293] The distinction between the treatment of patents and trade secrets underscores the government' failure to appreciate, or sufficiently bargain for, access to trade secret information.

The Covid-19 vaccine contracts, moreover, fail to protect the government's interests with respect to much more than just manufacturing know-how: The contract signed by Pfizer also expressly reserves to Pfizer the ownership of any data generated during vaccine production, precluding government access to clinical trial methodology and raw data, for example.[294] Despite the government's extensive role in making Covid-19 vaccines a reality,[295] the government contracts

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[291] Operation Warp Speed was a program by the federal government to support the accelerated development of several candidates for a COVID-19 vaccine. *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*, U.S. Government Accountability Office (Feb. 11, 2021), https://www.gao.gov/products/gao-21-319.

[292] Pfizer did not enroll in Operation Warp Speed but received a contract to supply doses of its Covid-19 vaccine to the government, guaranteeing a market for production of its vaccine. *See* SIMI V. SIDDALINGAIAH, CONG. RSCH. SERV., IN11560, OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIAL 1–2 (2021).

[293] *See* DEPT. OF THE ARMY, U.S. ARMY CONTRACTING COMMAND, STATEMENT OF WORK FOR COVID-19 PANDEMIC—LARGE SCALE VACCINE MANUFACTURING DEMONSTRATION 17 and 23 (2020) ("If invented solely by Pfizer, *Pfizer will be able to elect, in its discretion, whether to hold Subject Inventions as trade secrets*, and holding a Subject Invention as a trade secret will not forfeit title to the Government." (emphasis added)); ("If Pfizer shall need to disclose trade secret information to the Government, Pfizer and the Government will first determine in good faith whether the Government desires to receive any such trade secret information and if the Government so desires to receive such trade secret information, all such information shall be held by the Government in confidence in perpetuity.") [hereinafter PFIZER CONTRACT; U.S. DEPT. HEALTH & HUM. SERV., ASPR-BARDA, CONT. NO. 75A50120C00034 15 (2020) ("The parties agree that the data generated prior to entering into or outside the agreement will, when delivered to the [U.S. Government], be considered to be limited rights data. The government will obtain unlimited rights to data funded under this contract"). Limited rights data includes information protected by trade secrets. *See* U.S. FED. ACQUISITION REGUL. 52.227-14 (2022); *see generally* Sydney Lupkin, *Pfizer's Coronavirus Vaccine Supply Contract Excludes Many Taxpayer Protections*, NAT'L PUB. RADIO (Nov. 24, 2020), https://www.npr.org/sections/health-shots/2020/11/24/938591815/pfizers-coronavirus-vaccine-supply-contract-excludes-many-taxpayer-protections; Sydney Lupkin, *A Federal Coronavirus Vaccine Contract Released At Last, But Redactions Obscure Terms*, NAT'L. PUB. RADIO (Oct. 24, 2020), https://www.npr.org/sections/health-shots/2020/10/24/927474041/a-federal-coronavirus-vaccine-contract-released-at-last-but-redactions-obscure-t; *but see* RIZVI, *supra* note 190, at 16 (asserting that Moderna contract allows government to retain rights to certain manufacturing know-how because techniques like scaling-up were not developed until contract was signed).

[294] PFIZER CONTRACT, *supra* note 293, at 17–18 ("Pfizer also shall own any and all data generated by Pfizer within the scope of this Statement of Work ('Subject Data'). For the avoidance of doubt, the parties do not anticipate Pfizer generating any Subject Data using Government funding.").

[295] *See* SIDDALINGAIAH, *supra* note 292, at 2 (table showing government funding disbursed by Warp Speed); *see also Moderna Feud with NIH over COVID Vaccine*, 39 NAT. BIOTECH. 1481,

allow critical intellectual property rights to flow completely to the companies, rather than maintaining any aspect of those rights for the government itself.

VII. PATHWAYS FORWARD

There are moments in history when one can stand back and see how various pieces of the jurisprudential puzzle are fitting together—or failing to fit together. Now is one of those moments. With the development of modern, complex biologic medicines, trade secrets are now expanding into the patent domain in a manner that frustrates the basic openness of the patent system and the surrounding regulatory regimes such as the Biosimilars Act.

Unlike some jurisprudential conundrums, multiple pathways exist for establishing an appropriate boundary between trade secrets and patents. The solutions necessitate a basic recognition that the promise of the patent system cannot be fulfilled without providing full and adequate disclosure. In other words, when the Patent Act provides that a patent applicant must satisfy sufficient disclosure that one skilled in the art can make and use the invention, the patent applicant actually must do so, disclosing the full range of information necessary to make that drug, including much information that is now held back as trade secrets.

In the same vein, the relevant information should be fully disclosed by the FDA when the drug is approved. The company applying for approval already must provide that information—from detailed specifications of the process, to full clinical trial data, to safety protocols. The full range of that information should be released in a timely manner. Thus, to the extent the patent holder develops new techniques and learns new information as the invention moves from the initial idea, through the mass production process, to clinical trials, and to the pharmacy counter, that information will be publicly available so that a biosimilar manufacturer can make the medication at the appropriate time established by the Biosimilars Act. Society cannot encourage the entry of follow-on medications while simultaneously allowing companies to hide the necessary information.

Inventors might counter that at the time of the patent application, they do not yet have sufficient information to determine how to completely make, stabilize, and distribute a complex biologic product.[296] Such information will only emerge later in the process. To the extent the information emerges later, however, the drug approval system already requires disclosure to the FDA, and the Biosimilars Act anticipates that biosimilar companies will be able to access and rely on that information.

In the same vein, pharmaceutical companies frequently argue that if their ability to extend and string together various forms of protection is diminished,

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1481 (2021) (describing role of NIH scientists in developing genetic blueprint for Moderna's mRNA vaccine).

[296] For a discussion of whether the patent system is better served by earlier or later patenting, including a review of the academic debate, see ROBIN FELDMAN, RETHINKING PATENT LAW (2012).

incentives will be reduced for pharmaceutical innovation, reducing the number of drugs that will be produced. Congress, however, has already considered that issue in striking a balance between incentivizing new innovation and blocking downstream innovation. The question is whether the bargain will be enforced or whether companies will be able to take advantage of strategic interplay between various systems of protection to shift that bargain.

It is understandable that companies never want to offer up their crown jewels. They may be reluctant to reveal production information for fear that others outside the U.S. might exploit the information, in contravention of international intellectual property laws, or sell counterfeit products back into the U.S. market, in contravention of U.S. patent laws. Enforcement of the patent regime is a separate question, however, from whether companies should be required to follow that regime. Nothing in the Patent Act provides that failure of the U.S. to enforce its own patent regimes at home or encourage the enforcement of international regimes abroad excuses a patent applicant's disclosure obligation.

Finally, drug companies may be hoping to exploit information gained in the process of inventing and perfecting their product for the purpose of creating the next generation of products. Openness, however, is the basic trade-off of patents and the surrounding regulatory regimes. If you want the power of the mighty patent, you must disclose.

The reforms described above could be implemented either through legislative or regulatory reforms. From a legislative perspective, Congress could clarify what is necessary to satisfy the disclosure obligation of the Patent Similarly, Congress could specify that the FDA must release the necessary information with approval of the drug. As described above, the Biologics Act provides 12 years of data protection for a biologic, in exchange for the ability of biosimilar drugs to rely on that data, in part, for their own approval processes. At the moment, much of the information that the FDA releases is redacted. Congress could specify that in order to launch, all of the data must be released to fulfill the promise of rapid entry of biosimilar and interchangeables.

Congressional action is always preferable for agencies, which must worry about the threat that pharmaceutical companies will sue for any actions they take. Nevertheless, congressional action is not necessary, and agency action is possible based on existing congressional authority. Specifically, the Patent Office could more carefully apply the language of the Patent Act to biologic drugs, ensuring that disclosing sufficient information that someone skilled in the art can make and use the invention takes place. In the same vein, courts also could apply the plain language of the Patent Act with greater fidelity, holding that disclosing an approximation or range does not satisfy the requirement that one skilled in the art must be able to make and use the invention. Finally, scholars have argued that the FDA has the regulatory authority, despite assertions of supposed trade secret

protection, to disclose much more information than it currently provides.[297] In short, although Congressional action provides comfort and cover for regulatory agencies, much can be done without Congress to provide a pathway for realizing the promise of biosimilar medicine.

VIII. CONCLUSION

As assertion of trade secrets expands across the landscape and into biologic medicine, such assertions are appearing in numerous facets of biologic medicine, from development, to production, through FDA approval. Despite the recent federalization of trade secrets, the relevant federal law specifies that federalization is not intended to preempt any other areas of law, which would include the Patent Act and the related regulatory system for approval of biosimilars, the Biosimilars Act. Nevertheless, as the assertion of trade secret rights is currently unfolding, trade secrets are clashing with impeding the operation of the Patent Act and the Biosimilars Act, thereby impairing biosimilar entry and the consequent promise of affordable biologic medication. Thus, the modern interaction and application of various regimes is disrupting the bargains and balances struck between original inventors and follow-on companies in the patent system.

With the benefit of experience since the passage of the Biosimilars Act in the United States, legislators and regulators are now in a position to observe the manner in which the interactions between these systems are undermining the relevant goals. Without appropriate boundaries between trade secret and patent laws, companies will be able to take advantage of both regimes, without contributing the requisite quid pro quo to society.

Following the dictates of the Patent Act, patent applicants should not be able to obtain the grant of a patent and satisfy the requirement of providing sufficient disclosure so that one skilled in the art can make and use the invention, without actually providing the information to do so. Nor should companies be able to take advantage of the additional data protections provided in the Biosimilars Act, while still keeping critical clinical trial and safety protocol information secret. Absent reforms in both of these realms, biologic companies will be able to have their cake and eat it, too—to the detriment of societal interests.

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[297] *See generally* Christopher Morten, *Publicizing Corporate Secrets* (forthcoming U. PENN. L. REV.); *see also* Feldman & Graves, *Naked Price, supra* note 2 (arguing that price and price-related terms do not constitute trade secrets and can be disclosed by regulatory agencies).