DANCE OF THE BIOLOGICS

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ABSTRACT

From COVID-19 vaccines to cancer treatments, biologic medicines are gaining importance in the U.S. health care system. Their high price tags, however, make these medications difficult for many Americans to afford. The Biosimilars Act, enacted in 2010, aimed to reduce costs and increase access to biologic medications by encouraging follow-on competition. The legislative effort followed in the footsteps of its predecessor, the Hatch-Waxman Act of 1984.

Although the Hatch-Waxman system succeeded in creating a landscape of more affordable and widely used generic drugs, the Biosimilars Act has failed to live up to its promise. Biologic drugs in the United States remain largely unaffordable, and no popular follow-on biologic market, akin to its non-biologic counterpart, has arisen.

Investigating the reasons behind these disappointing results requires an analysis of the inner workings of the Biosimilars Act, but such an analysis is difficult to find. In fact, the system set forth by the Biosimilars Act is so complex that scholarship has largely avoided explaining it. To fill this gap in the literature and examine why the results of the Act have been so underwhelming, this Article explains the following: how the Biosimilars Act works in theory, how the parties are gaming the system, and why neither the theory nor the practice functions effectively. Through strategic tactics, biologic and biosimilar companies alike are ignoring and sidestepping the system.

The causes can be traced to the structure of the Act, itself. Specifically, by giving too much control to the parties involved, the Act enables them to work against society's interests and the legislature's goals. Although these misaligned incentives led to disappointing outcomes, the Article suggests that realigning the system does not require a major overhaul, but rather feasible tweaks. The changes recommended could expand the biologic market, create greater competition with cheaper alternatives, and spur affordable pricing for lifesaving biologic drugs.

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I. INTRODUCTION

In a flurry of last-minute, behind-the-scenes negotiations in 2010, Congress established a historic pathway for the rapid entry of biosimilar medications.[1] The legislation was charmingly known as the BPCIA[2] (which this Article will refer to as the "Biosimilars Act"). The Act was intended to usher in an era of follow-on biologic drugs that would drive prices down for consumers.[3]

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1. In 2007, Senate Health, Education, Labor and Pensions (HELP) Committee members—Senators Edward M. Kennedy, Hillary Clinton, Orrin Hatch, and Mike Enzi—drafted a biosimilars bill, S. 1695, whose language largely parallels that of the later enacted Biosimilars Act. *See* Krista Hessler Carver, Jeffrey Elikan & Erika Lietzan, *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 746 (2010). The following year, the Senate HELP committee reported S. 1695, but "[n]o committee report accompanied the reported bill, which was considered unusual." Many commentators, including the trade press, noted the curious timing of this action and speculated correctly that this bill might become a part of a larger healthcare package in the following Congress. *See id.* at 776–77; *see also* JOHN R. THOMAS, CONG. RSCH. SERV., R42890, THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES IN PHARMACEUTICAL INNOVATION 8 (2013) (noting that the Biologics Price Competition and Innovation Act of 2009 was enacted as part of the larger Affordable Care Act); Erika F. Lietzan, *Biosimilar Law and Regulation: An Essential Guide*, at 13–14 (Food & Drug L. Inst., FDLI Monograph Ser. Vol. 2, No. 5, 2011), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2220857 (reporting that the White House was pushing for major changes in the biosimilar provisions of the Affordable Care Act even as the bill cleared both chambers of Congress and headed to conference); Tony Hagen, *AAM Makes a Plea to Save the BPCIA,* CTR. FOR BIOSIMILARS (May 27, 2020), https://www.centerforbiosimilars.com/view/aam-makes-a-plea-to-save-the-bpcia (noting a commentator's view that the Biosimilars Act was attached to the Affordable Care Act at the last moment); Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. (2009).

2. The Biologics Price Competition and Innovation Act of 2009 was originally proposed as stand-alone legislation. *See* Biologics Price Competition and Innovation Act of 2007, S. 1695, 110th Cong. (2007). However, after revision, the legislation ended up being enacted, without being formally re-introduced, as Subtitle A of Title VII of the Affordable Care Act of 2010. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111–148, tit. VII, subtit. A, §§ 7001–03, 124 Stat. 119, 804–21 (2010) (Biologics Price Competition and Innovation Act of 2009 codified as amended at, *inter alia*, 42 U.S.C. § 262(k), (l), and 35 U.S.C. § 271(e)). For a complete discussion of the many bills and hearings regarding biosimilars that led up to S. 1695 and its development into the enacted legislation, see Carver, Elikan & Lietzan, *supra* note 1, at 716–806.

3. *See, e.g.*, Kasey E. Koballa, Note, *The Biologics Price Competition and Innovation Act: Is A Generic Market for Biologics Attainable*?, 9 WM. & MARY BUS. L. REV. 479, 483 (2018) ("In an effort to reduce the costs of biologics and provide pharmaceutical manufacturers with initiatives to strive continuously for innovation in biological therapies, President Barack

Biologic medicine plays an increasingly important role in this nation's health care system. The field of biologic medicine includes drugs such as Humira (the blockbuster treatment for rheumatoid arthritis), cancer therapeutics, a treatment for Crohn's disease, and the most effective COVID-19 vaccines. In general, the pharmaceutical industry has pivoted sharply towards biologics, particularly cancer therapeutics.[4] For example, oncology drugs constituted the largest number of all the new drugs launched in 2017.[5] Moreover, biologic medicines account for an increasing portion of spending on prescription medicine,[6] constituting 89% of Medicare Part B spending growth from 2008 to 2021.[7]

Thus, encouraging follow-on competition for biologics in a manner that will increase access and reduce prices remains a critical goal in the United States. Rather than heralding the Biosimilars Act's passage as historic, however, industry and commentators reacted with skepticism—some

Obama signed into law the [Biosimilars Act] . . . ."); Letter from Rep. Anna Eshoo et al. to President Barack Obama (Oct. 14, 2011), https://op.bna.com/hl.nsf/r?Open=bdmr-8msjms (noting that the Biosimilars Act was intended to lower the cost of drugs in the United States); Brendan McArdle, *Rumble in the BPCIA: Biologics vs. Biosimilars*, 17 HOUS. J. HEALTH L. & POL'Y 381, 386–88 (2017) (explaining that Congress intended for the Biosimilars Act to reduce prices and increase competition).

4. *See* Denise Roland, *Cancer-Drug Giant Roche Loses Edge as Rivals Grow*, WALL ST. J. (Apr. 28, 2019), https://www.wsj.com/articles/cancer-drug-giant-roche-loses-edge-as-rivals-grow-11556449201; Jared Hopkins, *Pfizer Pivots to Cancer Drugs for Growth*, WALL ST. J. (Jan. 27, 2019), https://www.wsj.com/articles/pfizer-pivots-to-cancer-drugs-for-growth-11548601200; Press Release, Sanofi, Sanofi Delivers 2018 Business EPS Growth of 5.1% at CER (Feb. 7, 2019), http://www.news.sanofi.us/2019-02-07-Sanofi-delivers-2018-business-EPS-growth-of-5-1-at-CER; Press Release, Merck, Merck to Acquire Peloton Therapeutics, Bolstering Oncology Pipeline (May 21, 2019), https://investors.merck.com/news/press-release-details/2019/Merck-to-Acquire-Peloton-Therapeutics-Bolstering-Oncology-Pipeline/default.aspx; Press Release, Novartis, Novartis Successfully Completes Acquisition of Endocyte (Dec. 21, 2018), https://www.novartis.com/news/media-releases/novartis-successfully-completes-acquisition-endocyte; *see also* Robin Feldman, *The Cancer Curse: Regulatory Failure by Success*, 21 COLUM. SCI. & TECH. L. REV. 82, 88–92 (2019) (describing the shift to cancer in terms of spending, research and development, and new drugs approved).

5. IQVIA INST., MEDICINE USE AND SPENDING IN THE U.S.: A REVIEW OF 2017 AND OUTLOOK TO 2022 33–34 (2018) (finding that cancer-related drugs made up the largest share of all new active substances launched in 2017).

6. Andrew Mulcahy, Christine Buttorff, Kenneth Finegold, Zeid El-Kilani, Jon F. Oliver, Stephen Murphy & Amber Jessup, *Projected US Savings from Biosimilars, 2021-2025*, 28 AM. J. MANAGED CARE 329, 329 (2022).

7. Nguyen X. Nguyen, T. Anders Olsen, Steven H. Sheingold & Nancy De Lew, U.S. DEP'T OF HEALTH AND HUM. SERVS., MEDICARE PART B DRUGS: TRENDS IN SPENDING AND UTILIZATION, 2008-2021, 1–2 (2023), https://aspe.hhs.gov/sites/default/files/documents/fb7f647e32d57ce4672320b61a0a1443/aspe-medicare-part-b-drug-pricing.pdf.

doubting that biosimilars would ever emerge as a major force in U.S. pharmaceuticals.[8]

Ten years out, the predictions of total failure have proven untrue. Nevertheless, the Biosimilars Act has failed to live up to its promise. Price reductions have been underwhelming at best, and the United States still lags well behind Europe in the introduction of follow-on biosimilars and in price reductions when those biosimilars enter.[9]

The experience of the first decade of the Biosimilars Act helps explain why the results have been so disappointing. Put simply, the incentives of the system are misaligned. The Act gives too much discretion and control to the involved parties, allowing them to navigate against society's interests and the goals of the legislation itself. The result is a highly constrained market, limited competition, and high prices.

Perhaps one indicator of the problems is the dearth of literature explaining the workings of the Biosimilars Act. The pathway is so complicated that few academics have even dared to tread its byways, let alone offer a detailed explanation of how it works and why it fails. Indeed, in 2015, the Federal Circuit, citing Winston Churchill, compared the Biosimilars Act to "a riddle wrapped in a mystery inside an enigma."[10] Stepping into the terrifying void, this Article explains how the system works in the abstract, how the parties are ignoring or reshaping the system, and why the system does not operate effectively either in the abstract or on the ground. Most important, this Article suggests that nudging the system into alignment does not require a major overhaul, but rather hovers tantalizingly within reach. The general choreography of the patent dance could remain, but in addition, the biosimilars regime could: (1) require that the brand biologic disclose (through the United States Food and Drug Administration (the FDA)) all patents related to a particular drug; and (2) standardize certain steps in the patent dance process.

8. *See, e.g.*, Yaniv Heled, *Follow-on Biologics Are Set Up to Fail*, 2018 U. ILL. L. REV. ONLINE 113, 114-15 (2018) (expressing skepticism about the likelihood of biosimilars becoming competitive in the United States, especially since the Biosimilars Act set up "an Industry-favorable, obstructed pathway for the approval of follow-on biologics"); Jason Kanter & Robin Feldman, *Understanding and Incentivizing Biosimilars*, 64 HASTINGS L.J. 57, 60–70 (2012) (asserting that the Biosimilars Act failed to provide sufficient incentives for biosimilar development); W. Nicholson Price II, *Regulating Secrecy*, 91 WASH. L. REV. 1769, 1798 (2016) (asserting that many brand biologics may never see any biosimilar competition, and even when biosimilars enter the market, the corresponding brand biologic may still remain expensive).

9. *See infra* Section II.D.

10. Sandoz Inc. v. Amgen Inc., 794 F.3d 1347, 1351 n.1 (Fed. Cir. 2015), *vacated in part*, *rev'd in part*, 582 U.S. 1 (2017), *remanded to* 877 F.3d 1315 (Fed. Cir. 2017).

With such changes, the Biosimilars Act, and the patent dance at its center, could create a more effective pathway to competition.

II. BACKGROUND

The most effective governmental systems generally provide incentives that encourage parties to act in alignment with the interests of society, instead of relying on pure altruism. Although the history of this line of logic is well-trodden,[11] it is worth dedicating a few words as a reminder of this path.

Adam Smith, widely deemed the father of modern economics, considered rational self-interest to be the main motivation of individual action and a far more reliable motivation than benevolence or public mindedness.[12] John Maynard Keynes, one of the foremost economists of the twentieth century, explained that government has a key role in directing this private self-interest towards public benefit.[13] For example, Keynes reasoned that it is appropriate for the government, at times, to artificially stimulate consumption or encourage investment, moving private interests into alignment with the public interest through tools such as taxation or interest rates.[14]

Later economic critiques, principally those by Robert Lucas, argued that such policies must be considered in terms of their impact on incentives at the

11. *See infra* notes 12–17 and accompanying text.

12. *See* ADAM SMITH, AN INQUIRY INTO THE NATURE AND CAUSES OF THE WEALTH OF NATIONS (Edwin Cannan ed., The Univ. of Chicago Press 1977) (1799) (Smith's seminal work, presenting the notion of rational self-interest as key to the success of an economy, and arguing that societal interests can be best furthered through the individual exercise of rational self-interest in a free and just economy); BERNARD MANDEVILLE, THE FABLE OF THE BEES: OR, PRIVATE VICES, PUBLICK BENEFITS 23 (Irwin Primer ed., Capricorn Books 1962) (1724) (arguing that what appear to be private vices are necessary to produce public benefits, and that in successful societies, "those very Vices, of every particular Person, by skillful Management, were made subservient to the Grandeur and worldly Happiness of the whole"); *see also* KENNETH J. ARROW & FRANK H. HAHN, GENERAL COMPETITIVE ANALYSIS vi (1971) (explaining that the success of *Wealth of Nations* in Smith's time and beyond led to "a long and fairly imposing line of economists from Adam Smith to the present" arguing for a conception of "economy motivated by self-interest").

13. *See* JOHN MAYNARD KEYNES, GENERAL THEORY OF EMPLOYMENT INTEREST AND MONEY 378 (1936) (referring to the State's "guiding influence on the propensity to consume," including "all manner of compromises and of devices by which public authority will co-operate with private initiative").

14. *Id.* at 377–78. *But see generally* Henry Farrell & John Quiggin, *Consensus, Dissensus, and Economic Ideas: Economic Crisis and the Rise and Fall of Keynesianism*, 61 INT'L STUDS. Q. 269 (2017) (recounting the debate among economists and policymakers about the need for Keynesian stimuli in addressing the 2008 Financial Crisis as well as noting briefly that whether and how Keynesian theory should be applied to economic volatility remains the subject of debate).

individual level, not by using macroeconomic models constructed under previous policies.[15] Though Lucas' emphasis differed from Keynes', Lucas maintained the principle that the government should seek to align private incentives with the interests of society.[16] Subsequent scholars have affirmed that the government, relying on the rational self-interest of market participants, should seek to regulate behavior through economic incentives and disincentives, in addition to legal restrictions.[17]

The goal of the Biosimilars Act is to increase competition and reduce prices, after an initial period of protection for biologic drugs. Following the logic that runs through the works of Smith, Keynes, Lucas, and their successors, the government's actions, as embodied in the Biosimilars Act, should seek to align industry's private incentives with the societal interests reflected in the goals of the Act.[18] If the Act instead leaves room for industry participants to operate against society's goals, incentives are improperly aligned, and the Act runs contrary to the underpinnings of Smith's work and its progeny. The following Section will provide the background for this discussion, describing the Hatch-Waxman system for rapid entry of generic drugs, the passage of the Biosimilars Act, the information desert resulting from the Biosimilars Act, and the disappointing performance of biosimilars in the United States.

A. HATCH-WAXMAN ACT

Enacted in 1984, the Hatch-Waxman Act was a piece of intricate, bipartisan legislation that created an easier approval pathway for generic

15. *See generally* Robert E. Lucas, Jr., *Econometric Policy Evaluation: A Critique*, 1 CARNEGIE-ROCHESTER CONF. SERIES ON PUB. POL'Y 19 (1976) (arguing that large-scale econometric models based on historical data may lead to misleading long-term forecasts as they fail to take into consideration how policy changes may affect the rational choices of individual actors).

16. *See generally id.*; Robert E. Lucas, Jr. & Thomas J. Sargent, *After Keynesian Macroeconomics*, in AFTER THE PHILLIPS CURVE: PERSISTENCE OF HIGH INFLATION AND HIGH UNEMPLOYMENT, at 49 (Fed. Rsrv. Bank Bos., Conf. Ser. No. 19, 1978) (proposing an alternative to Keynesian macro-econometric models but acknowledging that the goal of this model—analogous to the goals of Keynesian macro-econometric models—is to provide policymakers with scientific tools to align private incentives with societal interests).

17. *See, e.g.*, Norman J. Thomson, *Fiscal Incentives for Private Heritage Conservation*, 57 AUSTL. Q. 255 (1985) (describing how the Australian government could provide economic incentives to private citizens to put effort towards conservation of heritage assets, in which the public has an interest); Stephen K. Aikins, *Political Economy of Government Intervention in the Free Market System*, 31 ADMIN. THEORY & PRAXIS 403 (2009) (emphasizing the need for safeguards and controlled government intervention in the market, while acknowledging the importance of such intervention).

18. *See supra* notes 12–17 and accompanying text.

drugs.[19] Hatch-Waxman allows generic manufacturers to submit an "Abbreviated New Drug Application" (ANDA) instead of a "New Drug Application" (NDA) for approval. To qualify, the generic must be bioequivalent to an existing drug[20] with the same active ingredient(s), delivery methods, dosage, strength, labeling information, and indications.[21] Bioequivalence broadly means that there is no significant difference between the generic and the brand in the rate and extent to which the active ingredient(s) are dispersed in the target area.[22] If the generic manufacturer can prove bioequivalence, it can use safety and efficacy data from the brand drug's trials, greatly reducing the time and expense required for market entry.[23] Although generic products can enter the market only after the original drug patent expires, Hatch-Waxman allows generic manufacturers to begin development and start the FDA approval process before the brand patent's expiration. Thus, the generic can be ready to launch soon after the patent expires.[24]

In addition, Hatch-Waxman gave generics a way to resolve intellectual property claims without risking damages and the uncertainties of a jury trial.[25] Prior to Hatch-Waxman, companies wishing to challenge a patent had to enter

19. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

20. 21 U.S.C. § 355(j)(2)(A)(iv).

21. 21 U.S.C. § 355(j)(2)(A)(i)–(iii), (v); *see* ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 26–27 (2017) (explaining the Hatch-Waxman Act's approval criteria for generic drugs and providing definitions for each criterion). The FDA, however, may grant a waiver allowing deviation from the listed criteria. 21 U.S.C. § 355(j)(2)(C) ("If a person wants to submit an [ANDA] which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application.").

22. *Orange Book Preface: Preface to the Forty Fourth Edition*, U.S. FOOD & DRUG ADMIN. (Jan. 25, 2024), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface ("Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.").

23. FELDMAN & FRONDORF, *supra* note 21, at 28.

24. *Id.*

25. *See* Brian D. Coggio & Sandra A. Bresnick, *The Right to a Jury Trial in Actions Under the Hatch-Waxman Act*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 765, 770-71 (1997); 35 U.S.C. § 271(e)(2), (4).

the market and face infringement litigation.[26] Entering the market meant that the company would become liable for the damages its product caused the brand by virtue of product sales. In contrast, Hatch-Waxman created a system of "artificial infringement" in which the mere action of filing for approval triggers the potential for a specialized infringement action—albeit without damages or a jury trial.[27] The prior pathway remains in place as an alternative. In what is known as "launching at risk," generics could obtain FDA approval, launch the product, forgo Hatch-Waxman's "artificial infringement" option, and invite litigation claims of actual infringement, with all the accompanying risks of damages and a jury trial.[28]

Hatch-Waxman also provides an incentive for generics to challenge improperly granted patents. The first generic to file for approval and successfully challenge a patent as either invalid or not infringed receives a six-month period in which no other generics can enter the market.[29] During the

26. Matthew Makowski, Comment, *Toward a Centralized Hatch-Waxman Venue,* 89 U. CHI. L. REV. 1837, 1838 (2022) (noting that Hatch-Waxman established a statutory scheme allowing the brand and generic to engage in patent infringement suits *before* the generic starts marketing).

27. Makowski, *supra* note 26, at 1845 ("[H]atch-Waxman creates an unusual cause of action for patent infringement that derives solely from a filing with a federal regulatory agency . . . . [T]he Supreme Court has called the Hatch-Waxman patent infringement scheme 'a highly artificial act of infringement that consists of submitting an ANDA.'").

28. For a fuller discussion of launching at risk, see *infra* note 166. Launching at risk has been relatively rare for generics. *See* Xiang Yu & Anjan Chatterji, *Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systemic Evaluation of Asymmetric Risks in Litigation*, 10 NW. J. TECH. & INTELL. PROP. 19, 34 (2011).

29. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (describing the 180-day exclusivity period policy for generic drug applicants); *see also id.* § 355(j)(5)(D) (describing the circumstances in which a generic drug applicant forfeits its 180-day exclusivity period). Multiple scholars have discussed the impact of the 180-day, or six-month, exclusivity policy for generics. *See* Gregory H. Jones, Michael A. Carrier, Richard T. Silver & Hagop Kantarjian, *Strategies That Delay or Prevent Timely Availability of Affordable Generic Drugs in the United States*, 127 BLOOD F. 1398, 1399 (2016) (finding that the 180-day exclusivity results in a "short-term reduction in price"); C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 949 (2011) (noting that the 180-day exclusivity policy "is encouraging lots of *challenges* to [weak] patents"); Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 508 (2016) (asserting that the six-month "exclusivity period can easily be worth hundreds of millions of dollars to a generic, representing a substantial majority of the potential profits to be gained from generic entry"). Two situations can lead to shared exclusivity for six months: (1) if multiple generics each file an ANDA with a Paragraph IV certification (i.e., a certification that the brand's patent is invalid or non-infringed under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), (5)(B)(iv)(I)) concerning the same patent(s) on the same first day, or (2) if multiple generics each file an ANDA with a Paragraph IV certification for different dosage forms or strengths of the same brand drug. *See* David E. Korn, Erika Lietzan & Shaw W. Scott, *A New History*

six-month period, only the first-filing generic and the brand drug company are allowed on the market.[30]

Although Hatch-Waxman provided an easier and cheaper pathway for generic drugs to enter the market, these advantages did not extend to one category of drug products: biologics. Biologic drugs are produced using organic material and are far more chemically complex than non-biologic drugs.[31] Although non-biologic drugs often are referred to as "small molecule drugs," this Article will refer to the two categories of drugs as biologics and non-biologics, for ease of reading.

Biologic medicines are significantly more complex than their non-biologic counterparts. Although the active ingredients of non-biologic drugs typically consist of a few dozen atoms and can be replicated easily, biologic medicines are produced by using living cells. Among other things, they contain proteins, whole cells, and nucleic acids, each consisting of thousands of atoms. As a result, small variations in the manufacturing process or the host cells can drastically affect the purity, safety, and efficacy of the biologic, and it is highly

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and Discussion of 180-Day Exclusivity, 64 FOOD & DRUG L.J. 335, 342–43 (2009); *see also* Robin Feldman, *The Price Tag of "Pay-for-Delay,"* 23 COLUM. SCI. & TECH. L. REV. 1, 8 n.26 (2021).

30. 21 U.S.C. § 355(j)(5)(B)(iv)(I) ("[I]f the [abbreviated new drug] application contains a certification described in paragraph (2)(A)(vii)(IV) [i.e., a Paragraph IV certification, *see supra* note 29] and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant."). As the law is currently interpreted, the brand company, which has permission to market the drug, can choose to create its own generic version or authorize another company to market a generic version at any time, including during this six-month period. These are known as authorized generics or captive generics, and they can cut into the incentive for a generic company to enter the market. *See* Robin Feldman, *Captive Generics: The Wolf in Sheep's Clothing*, 59 HARV. J. ON LEGIS. 383, 390 (2022) (pinpointing the rise of captive generics with the explanation that "brand companies have addressed the problem of true generics by following the old adage, 'if you can't beat 'em, join 'em'"); *see also generally* Jay Hancock & Sydney Lupkin, *Drugmakers Master Rolling Out Their Own Generics to Stifle Competition*, KAISER HEALTH NEWS (Aug. 5, 2019), https://khn.org/news/ drugmakers-now-masters-at-rolling-out-their-own-generics-to-stifle-competition/ (stating that PDL's authorized generic version of Tekturna was timed to secure the company's benefit of being first to market). The intricate calculus of authorized generics has inspired complex settlement agreements between brands and generic challengers, which may not be in the public interest. *See* Feldman & Frondorf, *supra* note 29, at 523 (analogizing settlements between brands and generics that have no-authorized-generics clauses as similar to a schoolyard bully who takes lunch money in exchange for a promise not to hit kids and defends the action by saying, "[B]ut didn't you want me to stop hitting [the kids]?").

31. Favour Danladi Makurvet, *Biologics vs. Small Molecules: Drug Costs and Patient Access*, 9 MED. DRUG DISCOVERY 1, 1 (2021).

unlikely that two independent manufacturing processes can result in identical biologics.

Due to the complexity of biologic drugs and their sensitivity to minor changes during the manufacturing process, demonstrating bioequivalence is nearly impossible for biologic products.[32] Without bioequivalence, no generics could be made for biologic products under the Hatch-Waxman Act. Thus, a further pathway was needed to allow for abbreviated applications of later versions of biologics, known as biosimilars.

B. PASSAGE OF THE BIOSIMILARS ACT

In 2010, Congress sought to extend the benefits of Hatch-Waxman to the biologic realm, passing the Biosimilars Act as part of the Affordable Care Act.[33] The Biosimilars Act created an abbreviated pathway for the approval of biosimilars, but notably without the bioequivalence requirement present in Hatch-Waxman.[34] Instead, a biosimilar applicant must prove that its product is highly similar to the brand-name reference drug without meaningful clinical differences.[35] Moreover, the Biosimilars Act created a sub-category of biosimilar products: interchangeable biosimilars.[36] The standard for interchangeability generally is higher than for biosimilars. In addition to demonstrating no meaningful clinical differences from the original product, an interchangeable biosimilar must demonstrate that when patients alternate back and forth between the brand and the biosimilar, the biosimilar does not

32. *See, e.g.*, Robin Feldman, *Purple Is the New Orange*, 2024 U. ILL. L. REV. (forthcoming) (manuscript at 22–24) (on file with author); Martina Weise, *From Bioequivalence to Biosimilars: How Much Do Regulators Dare?*, 140 ZEITSCHRIFT FÜR EVIDENZ, FORTBILDUNG UND QUALITÄT IM GESUNDHEITSWESEN [ZEFQ] 58, 58 (2019) (Ger.).

33. *Implementation of the Biologics Price Competition and Innovation Act of 2009*, U.S. FOOD & DRUG ADMIN. (Feb. 12, 2016), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/implementation-biologics-price-competition-and-innovation-act-2009 [hereinafter *BPCIA Implementation*].

34. *See* 42 U.S.C. § 262(k) (outlining the abbreviated pathway for biosimilar approval and omitting "bioequivalence" as a required criterion for showing biosimilarity); *see also* U.S. FOOD & DRUG ADMIN., BIOSIMILARS INFO SHEET (n.d.), https://www.fda.gov/media/154912/download (explaining that while non-biologic generics must show bioequivalence to the brand-name reference drug in order to gain approval, biosimilars need only show that they are highly similar to the reference brand biologic).

35. Anne Park Kim & Ross Jason Bindler, *The Future of Biosimilar Insulins*, 29 DIABETES SPECTRUM 161, 163 (2016); *see also* U.S. FOOD & DRUG ADMIN., *supra* note 34.

36. 42 U.S.C. § 262(k)(4) (enabling the FDA to designate a biosimilar as *interchangeable* if it meets additional safety and efficacy requirements).

produce decreased efficacy or increased risk.[37] Known as "switching studies," these studies are costly and time-consuming.[38] As with generic drugs, an interchangeable biosimilar can be substituted for the original product by a pharmacist, state law permitting, without consulting the physician who wrote the prescription.[39] The standard for interchangeability is so high that only seven biosimilars have been designated as interchangeable so far.[40]

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37. *BPCIA Implementation*, *supra* note 33; *see also* U.S. FOOD AND DRUG ADMIN., INTERCHANGEABLE BIOLOGICAL PRODUCTS (2017), https://www.fda.gov/media/151094/download#.

38. Benjamin P. Falit, Surya C. Singh & Troyen A. Brennan, *Biosimilar Competition in the United States: Statutory Incentives, Payers, and Pharmacy Benefit Managers*, 34 HEALTH AFFS. 294, 296 (2015) (noting significant expense of conducting large-scale switching study: "[Switching studies] can cost more than $50,000 per patient").

39. 42 U.S.C. § 262(i)(3) ("[An interchangeable] biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product."). Most states have adopted laws allowing automatic substitution of biosimilars that are interchangeable "without prescriber intervention." *See* Heled, *supra* note 8, at 126 ("[T]hirty-seven states and Puerto Rico have passed legislation addressing biologics substitution, with most of them imposing special pre-requisites for biologics substitution.").

40. The seven biosimilars that have been designated as interchangeable so far are: Rezvoglar (insulin glargine-aglr) and Semglee (insulin glargine-yfgn), both interchangeable with Lantus (insulin glargine); Cyltezo (adalimumab-adbm) and Abrilada (adalimumab-afzb), both interchangeable with Humira (adalimumab); Cimerli (ranibizumab-eqrn) and Byooviz (ranibizumab-nuna), both interchangeable with Lucentis (ranibizumab); and Wezlana (ustekinumab-auub), interchangeable with Stelara (ustekinumab). *See* Skylar Jeremias, *Rezvoglar Becomes Second Interchangeable Insulin Biosimilar*, CTR. FOR BIOSIMILARS (Nov. 23, 2022), https://www.centerforbiosimilars.com/view/rezvoglar-becomes-second-interchangeable-insulin-biosimilar#; *FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes*, U.S. FOOD & DRUG ADMIN. (July 28, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes; *FDA Approves Cyltezo, the First Interchangeable Biosimilar to Humira*, U.S. FOOD & DRUG ADMIN. (Oct. 18, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-cyltezo-first-interchangeable-biosimilar-humira; *FDA Approves Coherus' Cimerli as Interchangeable Biosimilar to Ranibizumab*, CTR. FOR BIOSIMILARS (Aug. 3, 2022), https://www.centerforbiosimilars.com/view/fda-approves-coherus-cimerli-as-interchangeable-biosimilar-to-ranibizumab; *Abrilada Approved as Second Interchangeable Humira Biosimilar*, CTR. FOR BIOSIMILARS (Oct. 5, 2023), https://www.centerforbiosimilars.com/view/abrilada-approved-as-second-interchangeable-humira-biosimilar; *Eye on Pharma: New GI Data and Byooviz Interchangeability Propel Biosimilars into the Future*, CTR. FOR BIOSIMILARS (Oct. 25, 2023), https://www.centerforbiosimilars.com/view/eye-on-pharma-new-gi-data-and-byooviz-interchangeability-propel-biosimilars-into-the-future; *FDA Approves First Stelara Biosimilar, Wezlana*, CTR. FOR BIOSIMILARS (Nov. 1, 2023), https://www.centerforbiosimilars.com/view/fda-approves-first-stelara-biosimilar-wezlana; *see also FDA Roundup: September 15, 2023*, U.S. FOOD & DRUG ADMIN. (Sept. 15, 2023), https://www.fda.gov/news-events/press-announcements/fda-roundup-september-15-2023; Robert M. Califf, Commissioner, U.S. Food & Drug Admin., Remarks to the 2023 Food and Drug Law Institute (FDLI) Annual

Furthermore, although generic drugs are assigned the same nonproprietary name as their brand name counterpart, the FDA requires that all biosimilars' nonproprietary names must include a four-letter suffix that is "devoid of meaning."[41] The FDA believes that this naming convention will, among other things, facilitate monitoring of biologic and biosimilar drug use, along with detection of any safety issues.[42] Various stakeholders have noted, however, that the suffix might indicate to patients and physicians that the biosimilar differs in clinically meaningful ways from the brand biologic.[43] Indeed, one study found that when the nonproprietary name of a biosimilar included the four-letter suffix, participants were more skeptical about its similarity to the brand biologic than without the suffix.[44] In addition, the FDA's goal of improved monitoring and detection, through the use of the four-letter suffix, likely remains unachieved: One study found that out of more than 2,500 biosimilar-related adverse drug reports (ADRs), only 11 of the

Conference (May 17, 2023), https://www.fda.gov/news-events/speeches-fda-officials/remarks-commissioner-robert-califf-2023-food-and-drug-law-institute-fdli-annual-conference-05172023; Angela Maas, *Biosimilars Are Picking Up Market Share, but Some Uncertainties Still Exist*, PHARM. STRATEGIES GRP. (Sept. 8, 2022), https://www.psgconsults.com/blog/biosimilars-are-picking-up-market-share-but-some-uncertainties-still-exist.

41. U.S. FOOD & DRUG ADMIN., NONPROPRIETARY NAMING OF BIOLOGICAL PRODUCTS: GUIDANCE FOR INDUSTRY 1, 8, 10 (2017), https://www.fda.gov/media/93218/download.

42. U.S. FOOD & DRUG ADMIN., NONPROPRIETARY NAMING OF BIOLOGICAL PRODUCTS: UPDATE (2019), https://www.fda.gov/media/121316/download.

43. Fed. Trade Comm'n, FTC Comment to FDA 2019 Biologics Naming Guidance (May 6, 2019), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-fda-department-health-human-services-its-updated-guidance-industry-nonproprietary/ftc_comment_to_fda_2019_biologics_naming_guidance_5-6-19.pdf.

44. This study asked the participant to answer questions after viewing a print advertisement for a fictitious biologic drug. The study found that, absent any information about interchangeability, the presence of the four-letter suffix lowers the likelihood that participants will use that biosimilar. When the advertisement mentioned whether the biosimilar was interchangeable, the four-letter suffix did not significantly reduce the likelihood that the participants will use the biosimilar. But it still reduced the perceived similarity of the biosimilar to its reference brand biologic. Mariana P. Socal, Jace B. Garrett, William B. Tayler, Ge Bai & Gerard F. Anderson, *Naming Convention, Interchangeability, and Patient Interest in Biosimilars*, 33 DIABETES SPECTRUM 273, 274-77 (2020). *But see* Allison R. Kolbe, Aaron Kearsley, Lubna Merchant, Eva Temkin, Archita Patel, Jing Xu & Amber Jessup, *Physician Understanding and Willingness to Prescribe Biosimilars: Findings from a US National Survey*, 35 BIODRUGS 363, 369 (2021) (noting that "[t]he presence or absence of the suffix on the reference product's nonproprietary name did not have a significant effect on prescriber understanding or choice in the prescribing scenario," but cautioning that study depended on self-reported data from healthcare professionals).

reports used the suffix, while the rest of the reports were filed using the brand name only.[45]

Although the model of interchangeable biosimilars mirrors that of generic drugs, the Biosimilars Act differs from Hatch-Waxman in several critical respects. First, biosimilars that fail to meet the high standard for interchangeability cannot be substituted for the brand drugs at pharmacies, but must be specifically prescribed by providers in order to be used.[46] This limit on substitution reduces the price-alleviating potential of biosimilars relative to generics, which most state pharmacists can substitute for the brand drugs without contacting the prescribing physician for confirmation.[47]

Second, the Biosimilars Act provides a longer period of exclusivity to brands, creating a twelve-year exclusivity period for new biologics.[48] This exclusivity period is far longer than the five-year exclusivity period offered to new chemical entities under Hatch-Waxman.[49]

In explaining the longer period of protection, biologic companies reason that research and development for biologics is longer and more expensive than for non-biologic drugs.[50] Nevertheless, some scholars have argued that the

45. *See* Stanton R. Mehr, *If Four-Letter Suffixes Aren't Used in Biosimilar Tracking, What Use Are They?*, BIOSIMILAR DEV. (Nov. 6, 2018), https://www.biosimilardevelopment.com/doc/if-four-letter-suffixes-aren-t-used-in-biosimilar-tracking-what-use-are-they-0001.

46. *See* 42 U.S.C. § 262(i)(3) (stating that a biosimilar must be interchangeable in order to be substituted for the reference product without provider intervention).

47. U.S. FOOD & DRUG ADMIN., FYs 2013 – 2017 REGULATORY SCIENCE REPORT: ANALYSIS OF GENERIC DRUG UTILIZATION AND SUBSTITUTION (n.d.), https://www.fda.gov/drugs/generic-drugs/fys-2013-2017-regulatory-science-report-analysis-generic-drug-utilization-and-substitution (updated Feb. 16, 2018) (analyzing pharmacies' substitution of generic drugs for brand drugs without provider intervention, including an analysis of the possible barriers to substitution in certain populations).

48. Elizabeth Richardson, *Biosimilars*, HEALTH AFFS.: HEALTH POL'Y BRIEF 3 (Oct. 10, 2013), https://www.healthaffairs.org/do/10.1377/hpb20131010.6409/full/healthpolicybrief_100-1554749622899.pdf.

49. 21 U.S.C. § 355(c)(3)(E)(ii) (providing that within five years of the approval of a new drug, no generic substitution for it may be approved, unless the generic application contains a certification of patent invalidity or noninfringement (i.e., a Paragraph IV certification, *see supra* note 29), in which case the generic application may be approved after four years).

50. *See, e.g.*, Ryan Timmis, *The Biologics Price Competition and Innovation Act: Potential Problems in the Biologic-Drug Regulatory Scheme*, 13 NW. J. TECH. & INTELL. PROP. 215, 217 (2015) ("[B]iologic drugs are inherently more difficult and costly to manufacture than traditional pharmaceuticals . . . ."); Ude Lu, Note, *Biologics Price Competition and Innovation Act: Striking A Delicate Balance Between Innovation and Accessibility*, 15 MINN. J.L. SCI. & TECH. 613, 625 (2014) ("The cost to bring a biologic drug to the market is higher than that for a small-molecule drug."); BIO, THE TRANS-PACIFIC PARTNERSHIP AND INNOVATION IN THE BIOECONOMY: THE NEED FOR 12 YEARS OF DATA PROTECTION FOR BIOLOGICS 2 (n.d.), https://

research and development time for biologics is not sufficiently greater to warrant the longer exclusivity.[51] Research and development costs are higher for biologics than for non-biologic drugs, but the delta may not be of the magnitude that would explain the difference between five and twelve additional years of exclusivity.[52]

Finally, the Biosimilars Act specifies a far more complex patent litigation and rights-clearing process for biosimilars than Hatch-Waxman does for generics. Under Hatch-Waxman, a generic applicant applying for approval can submit what is known as a Paragraph IV certification,[53] attesting to circumstances that would permit immediate entry. Applicable circumstances include that the brand's listed patents are invalid or not infringed.[54] The generic

www.bio.org/sites/default/files/TPP%20White%20Paper%20_2_.pdf ("[It takes], on average, more than a decade and in excess of $1.2 billion to bring a biological product to market.").

51. *See* Reed F. Beall, Thomas J. Hwang & Aaron S. Kesselheim, *Pre-Market Development Times for Biologic Versus Small-Molecule Drugs*, 37 NATURE BIOTECH. 708, 708–09 (2019) (observing that the median pre-market development time was 12.4 years for both biologics and non-biologic drugs and casting doubt on the rationale that biologics need longer exclusivity due to their longer development time); Joel Lexchin, *Affordable Biologics for All*, 3 JAMA NETWORK OPEN 1, 1 (2020) (asserting that "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"); *see also* Beall, Hwang & Kesselheim, *supra*, at 709 (finding that "although biologics are often thought to be more time-consuming to develop than small-molecule drugs, development times for biologics are similar to, or possibly somewhat shorter than, for small-molecule drugs," calling into question why biologics get a much longer exclusivity period than their non-biologic counterparts).

52. Oliver J. Wouters, Martin McKee & Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA 844, 12-13 tbl.3 (Supp. 2020), https://jamanetwork.com/journals/jama/fullarticle/2762311#supplemental-tab (observing that the median R&D cost, before adjusting for the cost of failures, is $391 million for biologics and $309 million for non-biologics); *see also* Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial & Decision Econ. 469, 476–77 (2007) (observing that the average R&D cost, after adjusting for the capitalization cost and the cost of failures, is 1.24 billion for biopharmaceuticals—therapeutic recombinant proteins and monoclonal antibodies—and 1.31 billion for traditional small molecule drugs). Estimates vary widely for the R&D costs of a new drug, ranging from a few hundred million to a few billion. Michael Schlander, Karla Hernandez-Villafuerte, Chih-Yuan Cheng, Jorge Mestre-Ferrandiz & Michael Baumann, *How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment*, 39 PHARMACOECONOMICS 1243, 1246 (2021) ("Estimates of the total average capitalized (pre-launch) R&D costs needed to bring a new compound to the market varied widely, from $161 million to $4.5 billion . . . .").

53. *See supra* notes 29–30.

54. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (stating that the generic applicant must submit "a certification, in the opinion of the applicant and to the best of his knowledge, . . . that [each] patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug . . .").

must notify the brand upon filing a Paragraph IV certification, and the brand then has 45 days to sue for patent infringement if it wishes to challenge the generic's attestation.[55]

In deciding whether to file a Paragraph IV certification, the generic company need only consider the specific and limited set of rights asserted by the brand company. When a brand company applies for approval of a non-biologic drug, the brand must list all of the patents and non-patent exclusivities[56] that it might assert in protection of the drug, updating that list with any new rights acquired.[57] The FDA publishes the list in what is known as the Orange Book.[58] When the generic certifies that its version does not infringe any relevant rights or that those rights are invalid, the generic need only certify to rights listed in the Orange Book.[59]

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55. *Id.* § 355(j)(5)(B)(iii) ("[B]efore the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent . . . ."). Brand companies may hold back their patents by not listing them in the Orange Book and then decide to sue outside the timeline mandated by the Hatch-Waxman Act. Celgene Corporation, for example, filed a complaint asserting three non-Orange Book patents against Sun Pharma, more than a year after Sun Pharma submitted its ANDA and sent a notice of its Paragraph IV certification to Celgene. *See* Complaint for Patent Infringement, Celgene Corp. v. Sun Pharma Glob. FZE, No. 19-10099 (SDW) (LDW) (D.N.J. Apr. 6, 2020).

56. In addition to patent rights, an FDA-approved non-biologic drug may be entitled to exclusive marketing or data rights for a predetermined period of time if certain statutory requirements are met. These include the orphan drug exclusivity and the new clinical investigation exclusivity, among others. These market exclusivities are colloquially called *non-patent exclusivities, regulatory exclusivities,* or simply *exclusivities*. Renu Lal, *Patents and Exclusivity*, FDA/CDER SBIA CHRONICLES (U.S. Food & Drug Admin., Silver Spring, MD), May 19, 2015*; see also* Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53, 103 (2016) (providing a chart of approximately a dozen non-patent exclusivities available for biologic and non-biologic drugs); Richard B. Racine, *The Interplay Between U.S. Pharmaceutical Patents and FDA Law*, FINNEGAN: MANAGING INTELL. PROP. (Dec. 2010), http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=ad4b058b-0150-4ec7-90f4-57e6641272a6 (describing the New Chemical Entity exclusivity and calling it a "non-patent exclusivity").

57. 21 U.S.C. § 355(b)(1)(A)(viii) (explaining FDA's mandate that new drug applicants must file with their application "the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug").

58. *Id.* § 355(c)(2) (requiring that new drug applicants must submit required patent information for listing in the Orange Book, and that the FDA must regularly update the Orange Book).

59. S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. U. L. REV. 1673, 1681 (2022); *see also supra* note 55 (noting authorities holding that brand's failure to list patent in NDA does not bar brand from suing generic for infringement of omitted patent); *infra* note 177 (same).

By contrast, the Biosimilars Act lays out an intricate patent litigation process known colloquially as the "patent dance."[60] The patent dance proceeds in two phases, with layers of notification and negotiation, both of which phases will be described in Part III, below.[61] In deciding whether to join the dance and enter the market, however, biosimilar companies face a troubling lack of information. The Section below describes that information desert.

C. THE INFORMATION DESERT

The biosimilar system suffers from a lack of information throughout the process, one that seriously impedes competitive entry. Consider the dearth of information facing a company contemplating whether to start down the road of producing a particular biosimilar. As a starting point, the company would want to know the answers to four simple questions: What is the drug? How do you make it? What patents apply? When do those patents expire? Each of these should be a relatively simple question to answer. Under the current system, however, they are not.

1. What Is the Drug?

The process of defining a particular drug is complicated for biologics. With a non-biologic drug like aspirin, one can identify the active ingredient of the

60. "Patent dance" refers to the intricately choregraphed exchange of patent-related information and the associated infringement litigation between the brand biologic and the biosimilar entrant. The dance commences when the FDA notifies the biosimilar entrant that its application has been accepted for review and the biosimilar, in turn, sends a copy of the application along with the manufacturing process information to the brand biologic. The brand and biosimilar then generate initial lists of patents that are arguably infringed by the biosimilar. After a complex process of exchanging lists, the two parties negotiate a single list of patents to be litigated in the first phase of litigation. If no such agreement can be reached, the parties exchange separate lists of patents to be litigated in the first phase. The brand then sues the biosimilar for infringement of the patents on the negotiated or separate lists. The second phase of the patent dance begins when the biosimilar notifies the brand, 180 days in advance, that the biosimilar will commence commercial marketing. At this point, the brand may start the second phase of litigation by initiating a suit against the biosimilar for infringement of any patent that was included in the initial lists but that was not included in the negotiated or separate lists. In this phase, the brand may move for a preliminary injunction blocking the biosimilar's commercial launch. *See* 42 U.S.C. § 262(l). For a detailed description of the patent dance, see *infra* Sections III.A.1, III.A.2. For flow charts breaking down the intricate steps of the patent dance, see *infra* Section VI.B.

61. *See* Alejandro Menchaca, *The Inner Workings of the BPCIA Patent Dance*, CTR. FOR BIOSIMILARS (July 24, 2021), https://www.centerforbiosimilars.com/view/the-inner-workings-of-the-bpcia-patent-dance; *see also infra* note 166 (noting that under both the Hatch-Waxman and Biosimilars Acts, a claim of actual infringement and damages entitles either party to a jury trial, while a claim of artificial infringement entitles neither party to a jury trial); *infra* Section III.A (describing the dance in detail).

drug by drawing its chemical structure.[62] Without too much difficulty, a generic company then can develop a sequence of chemical reactions that will lead to the chemical molecule.[63] Biologic drugs, however, are far too complex to draw—or even to understand their physical and chemical properties fully.[64]

Biologics are created through processes using living cells. While non-biologics may contain a few dozen atoms, biologics contain thousands or even millions of atoms that are folded into intricately complex, multi-layered shapes that cannot be captured in a two-dimensional drawing.[65] Scientists are not yet capable of completely identifying the structure, function, and composition of these biologically derived molecules.[66] Moreover, given that the processes involve living cells, every detail of the process matters. Small changes in everything from the cell line to the temperature and environment in which it is cultured, to the purification methods, can produce significant differences in the final molecule.[67] As a result, a biologic drug is identified, by proxy, through the process of making it. As is often said in the biologics field, "the process is

62. Pharmaceutical lingo refers to the active ingredient of a drug as the API, which stands for "the active pharmaceutical ingredient." *See generally* Vinod Kumar, Vasudha Bansal, Aravind Madhavan, Manoj Kumar, Raveendran Sindhu, Mukesh Kumar Awasthi, Parameswaran Binod & Saurabh Saran, *Active Pharmaceutical Ingredient (API) Chemicals: A Critical Review of Current Biotechnological Approaches*, 13 BIOENGINEERED 4309 (2022).

63. *See* Makurvet, *supra* note 31, at 1–4 (describing in detail the contrast between the creation of a generic and a biosimilar); *see also* Feldman, *supra* note 32 (explaining that with non-biologic drugs, "multiple chemical reactions involving different processes or different chemicals may yield the same molecule, and two companies using different pathways can be confident, nevertheless, that their products will be chemically indistinguishable").

64. Understanding the physical and chemical properties of a drug is referred to as "characterizing" the drug. *See Protein Characterization, Identification & Purification*, JORDI LABS, https://jordilabs.com/blog/protein-characterization-identification-purification/ (last visited Jan. 4, 2023).

65. *See* Makurvet, *supra* note 31, at 2; *see also* U.S. FOOD & DRUG ADMIN., BIOLOGICAL PRODUCT DEFINITIONS 1 (n.d.), https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf.

66. *See* Steven A. Berkowitz, John R. Engen, Jeffrey R. Mazzeo & Graham B. Jones, *Analytical Tools for Characterizing Biopharmaceuticals and the Implications for Biosimilars*, 11 NATURE 527, 527 (2012) (noting that for many "larger and more complex" biologics, "the extent to which existing analytical technologies can be used to support the likelihood of clinical comparability between a follow-on version and the original product is much more limited than for small-molecule drugs, and it is not possible to demonstrate that the two products are absolutely identical").

67. *See* Makurvet, *supra* note 31, at 1–2; W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologic Competition and Innovation*, 101 IOWA L. REV. 1023, 1033–34 (2016); Arti K. Rai & W. Nicholson Price II, *An Administrative Fix for Manufacturing Process Patent Thickets*, 39 NATURE BIOTECH. 20, 22 (2021).

the product."[68] This leads to the second, more important question: How do you make it?

2. How Do You Make It?

In theory, the question of how a particular drug is made should not be a problem with a biologic. First, the molecule itself would have been patented at the outset. A valid patent is required to include sufficient information that one skilled in the art can make, use, and sell the invention.[69] The requirement for adequate disclosure is society's due—the quid pro quo for receiving a patent.[70] In exchange for granting the powerful patent right, an inventor must teach future scientists who are skilled in the field of biologics enough information so that after the patent expires, others are able to make and use it.[71]

Unfortunately, the truth for biologic patents is far from the ideal. Inventors of biologics are able to satisfy the disclosure obligation by providing no more than approximations or ranges for a variety of elements, such as temperature, molecular composition, concentration, and reaction agent.[72] Other patents cite a wide variety of possible manufacturing processes through which the drug might be produced—listing, for example, bacterial, mammalian, yeast, and

68. H.R. REP. NO. 106-556, at 41 (2000); *see also* RAJ K. PURI, U.S. FOOD & DRUG ADMIN., CTR. FOR BIOLOGICS EVALUATION & RSCH., FDA'S PERSPECTIVES ON QUALITY AND NON-CLINICAL EVALUATION OF CELL/TISSUE-BASED PRODUCTS 6 (AUG. 26, 2010), https://www.pmda.go.jp/files/000153661.pdf; Yaniv Heled, *The Case for Disclosure of Biologics Manufacturing Information*, 47 J. MED. & ETHICS 54, 56 & n.40 (2019); *NCI Initiative Aims to Boost CAR T-Cell Therapy Clinical Trials*, NAT'L CANCER INST. (Apr. 23, 2020), https://www.cancer.gov/news-events/cancer-currents-blog/2020/car-t-cell-nci-manufacturing-clinical-trials.

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

70. 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. *See, e.g.*, Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484–85 (1974).

71. *See* 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.03 (2003) (explaining that since 1790, patent laws have mandated that an inventor provide sufficient information to teach a person in the same field to make and use the invention, even after the patent expires). *See generally* Robin Feldman, *The Inventor's Contribution*, 2005 UCLA J.L. & TECH 6.

72. *See* Jayson Singh Sohi, *Changes to the Best Mode Requirement: Weakening Enforcement Undermines the Purpose of Patent Law and Exacerbates an Ethical Patent Trilemma*, 17 INTELL. PROP. L. BULL. 157, 158 (2013); *see also* Robin Feldman, *Trade Secrets in Biologic Medicine: The Boundary with Patents*, 24 COLUM. SCI. & TECH. L. REV. 1, 27 n.139 (2022) (providing the example of Patent US 8,663,945 B2).

insect cells as types of host cells—without sorting any further among these.[73] Consider the biologic drug Enbrel, which treats rheumatoid arthritis. Enbrel's patent includes hundreds of techniques and materials that might be used to express the active protein, but scholars have pointed out that only a small subset of these would yield a compound biosimilar to Enbrel.[74]

Patents with these proverbial kitchen-sink claims may include more narrow claims as well,[75] but there is no guarantee the narrow examples are the ones that work. The narrow claims may be red herrings that serve to divert attention away from the process the company actually intends to use. In short, given the exquisite precision necessary to create a biologic drug, patents in the biologic space can easily fall short of fully teaching the invention so that it can be put into practice.

Patent timing plays a role as well. The patent on the initial molecule may issue many years before the related drug receives marketing authorization from the FDA, shortening the patent monopoly period to eleven to fourteen years.[76] By the time the drug reaches the market, the company will have developed and refined the method of making the drug in numerous ways and may continue to do so throughout the life of the drug. The original patent will contain none of that information.

If critical information is omitted from a biologic patent, the company can either keep that information private, keep it in the form of a trade secret, or file additional patent applications across time. Indeed, some biologic companies hold large numbers of patents related to a single drug,[77] far more than the average patents listed for non-biologic drugs in the Orange Book. For example, the biologic company that owns the rheumatoid arthritis drug

73. *See, e.g.*, Price & Rai, *supra* note 67, at 1050–51 (describing Enbrel manufacturing patents).

74. *See id.* at 1051 (describing Enbrel composition patent).

75. *See, e.g.*, U.S. Patent No. 8,343,737 B2 col. 95 ls. 7–13 (filed May 13, 2011) (with claim 2 listing "bacterial cells, yeast cells, insect cells and mammalian cells" as potential types of cells used in the cell culture but with additional claims narrowing the group).

76. *See* Robin Feldman, *Patent Term Extensions and the Last Man Standing*, 42 YALE L. & POL'Y REV. 1, 29 (2023) (finding that the monopoly period after FDA approval induced by the primary patents were, on average, 13.5 years for all drugs included in the study and 11.3 years for drugs that received patent term extensions on their primary patents); *see also* C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 330 (2012) (finding that the average nominal patent protection term for drugs, including primary and secondary patents, is 15.9 years).

77. *See, e.g.*, Ryan Knox & Gregory Curfman, *The Humira Patent Thicket, the Noerr-Pennington Doctrine and Antitrust's Patent Problem*, 40 NATURE BIOTECH. 1761, 1761 (2022) (noting that AbbVie was granted 132 patents protecting Humira).

Humira holds more than 100 patents on the drug.[78] Each of a biologic's patents, however, may suffer from the inadequacy described above, in which the information offered fails to clarify precisely how to make the drug.

Given the FDA approval process, the brand biologic does give the FDA its precise information, which must be updated if the company changes its process. The FDA, however, respects the company's assertion that such information is confidential and does not make the information publicly available.[79]

Other information on making and using the product also remains bottled up at the FDA—information that Congress intended to make public. Both the Biosimilars Act and its muse, the Hatch-Waxman Act, anticipated enhancing market efficiencies by allowing producers of follow-on drugs, such as generics and biosimilars, to use the prior safety and effectiveness data developed by the brand.[80] Recreating the data would pose a significant financial burden to the generic and biosimilar manufacturers, without the promise of patent rights at the end to recoup those costs. The process of recreating that data also would raise ethical concerns, given that some patients would receive placebos despite the existence of safe and effective medications.[81]

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78. *Id.*; *see also* Mayor of Balt. v. AbbVie Inc., 42 F.4th 709, 711 (7th Cir. 2022) ("AbbVie, [Humira's] owner, obtained 132 additional patents related to [Humira] . . . .").

79. *See* 21 C.F.R. § 20.61(d) (2023) (allowing the brand biologic to designate part or all of the information submitted to the FDA as exempt from public disclosure); 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 Vaccines*, 109 CALIF. L. REV. 493, 523–24 (2021) (explaining that FDA policy bars the FDA from disclosing any confidential commercial information and noting that the FDA allows pharmaceutical companies to designate clinical trial data as confidential commercial information with limited oversight and verification); *see also* 21 C.F.R. § 314.430(g)(1) (2023) (stating that the FDA does not disclose information about manufacturing methods or processes).

80. *See Review and Approval*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/biosimilars/review-and-approval (last visited Sept. 19, 2023) ("The goal of a biosimilar development program is to demonstrate biosimilarity between the proposed biosimilar and its reference product, not to independently establish the safety and effectiveness of the proposed biosimilar.").

81. 129 CONG. REC. 19,844–45 (1983) (statement of Rep. Waxman) ("The generic manufacturer need not conduct human clinical trials. Such retesting is unnecessary and wasteful because FDA has already determined that the drug is safe and effective. In fact, such retesting may be unethical because it requires that some sick patients take placebos and be denied treatment known to be effective."); FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION ii (2009) ("Duplication of safety and efficacy information is costly, an inefficient use of scarce resources, and, as the FDA has explained, raises ethical concerns associated with unnecessary human testing.").

The detailed information within the clinical trial data, however, is less important for generic companies than for biosimilar companies, which will need to do their own supplemental trials. Access to complete information on the prior clinical trials creates the pathway for the additional trials. Unfortunately, FDA processes frustrate that goal. The FDA defers to company assertions that clinical trial protocols and other information are protectible information that may not be circulated outside the agency.[82] Some courts have ruled that clinical trial information does not always qualify for trade secret protections,[83] but the FDA still fails to disclose it, on the theory that clinical trial information constitutes "confidential commercial information,"[84] which cannot be released under FDA regulations. The FDA also exempts clinical trial data from the Freedom of Information Act (FOIA), preventing anyone in the agency from revealing such information.[85]

In short, neither the patent system nor the FDA processes operate as legislators intended, providing too little of the information that biosimilar companies need to make follow-on versions of biologic drugs. As a result, biosimilar companies must spend seven to ten years of painstaking and expensive research to get to the point of bringing a drug to market.[86]

3. What Are the Patent Rights?

In the non-biologic space, the FDA's public list of drugs includes all patents associated with each drug.[87] However, in the biologic space, no public

82. *See* Feldman, *supra* note 72, at 32–33 ("[D]rug companies have long claimed clinical trial protocols and data (i.e., safety and efficacy data) as trade secrets, restricting their dissemination beyond the FDA.").

83. *Id.* at 42 n.238 (first citing Morten & Kapczynski, *supra* note 79, at 534; then citing Pub. Citizen Health Rsch. Grp. v. FDA, 964 F. Supp. 413, 416 (D.D.C. 1997); and then citing Pub. Citizen Health Rsch. Grp. v. FDA, 704 F.2d 1280, 1286 (D.C. Cir. 1983)).

84. *See* Morten & Kapczynski, *supra* note 79, at 522–24; *see also* 21 C.F.R. § 20.61(b)–(c) (2023) (defining confidential commercial information and barring the FDA from publicly disclosing any such information).

85. Feldman, *supra* note 72, at 42–43.

86. *See, e.g.*, Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469, 471 (2013) ("It takes 7 to 8 years to develop a biosimilar . . . ."); *Comparison of the Cost of Development of Biologicals and Biosimilars*, GENERICS AND BIOSIMILARS INITIATIVE (Nov. 03, 2022), https://www.gabionline.net/reports/comparison-of-the-cost-of-development-of-biologicals-and-biosimilars (claiming that it take 8 to 10 years of research to bring a biosimilar to market); Miriam Fontanillo, Boris Kors & Alex Monnard, *Three Imperatives for R&D in Biosimilars*, MCKINSEY & CO. (Aug. 19, 2022), https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars# ("[A] typical biosimilar [takes] six to nine years to go from analytical characterization to approval.").

87. *See supra* notes 56–58 and accompanying text.

list of all patents associated with each brand biologic drug exists. To assess the number or types of patents covering a biologic, a prospective biosimilar company would have to search the entire corpus of more than 3 million active patents in the United States.[88] Further, these patents do not necessarily include the name of the drug, the name of its active ingredient, or even the structure of the associated molecule. For example, they might simply describe lab methods related to molecule production in a way that would be difficult to associate with the drug. Thus, searching is a long, arduous, and often unfruitful process.[89]

As an alternative, biosimilar companies could search through the detailed court records from previous litigation. However, that process also has limitations. Not only would the process be tedious, but success would be contingent upon the existence of previous litigation, as well as the existence of sufficient litigation to cover all patents the company might assert or have acquired later on.[90]

If the case does not result in a judicial opinion related to a particular patent, the information may not exist in obtainable form. For example, if the parties settle, no obtainable litigation record may have formed. Also, the parties can influence the information that emerges through initial litigation choices. Although parties are barred from withholding patent information when discovery rules require production,[91] a party's choice of which patents to

88. In 2020, there were approximately 3,340,000 active patents in the United States. *See, e.g.*, Veera Korhonen, *Number of Patents in Force in the United States from 2004 to 2020*, STATISTA (June 2, 2023), https://www.statista.com/statistics/256738/number-of-patents-in-force-in-the-us/; Bruce Berman, *Too Many Patent Suits? The Data Suggests There Are Too Few*, IPWATCHDOG (Apr. 6, 2023), https://ipwatchdog.com/2023/04/06/many-patent-suits-data-suggests/id=159050. By May 2021, the United States Patent and Trademark Office (USPTO) issued more than 11 million utility patents. *Milestones in U.S. Patenting*, U.S. PAT. & TRADE OFF., https://www.uspto.gov/patents/milestones (last visited Feb. 23, 2024).

89. For example, in a sworn statement, an Amgen executive noted that Amgen owned more than 400 patents that might be relevant to the recombinant manufacturing and purification process used in their drug Neupogen® (filgrastim). He added that many of these 400 patents along with others from Amgen's collection of more than 1400 patents could be asserted against Zarxio®, a biosimilar to Neupogen® marketed by Sandoz. Declaration of Stuart Watt in Support of Amgen's Motion for a Preliminary Injunction at 3–5, Amgen Inc. v. Sandoz Inc., No. 3:14-CV-04741-RS (N.D. Cal. Feb. 5, 2015).

90. Charlotte Geaghan-Breiner, Note, *The Patent Trap: The Struggle for Competition and Affordability in the Field of Biologic Drugs*, 54 COLUM. J.L. & SOC. PROBS. 589, 595, 601–06, 610–11 (2021).

91. FED. R. CIV. P. 26(b)(1) ("[P]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case.").

litigate can nonetheless restrict the information that could be accessed by additional entrants who hope to learn from the prior litigation. Moreover, when court filings and document discovery contain information related to manufacturing processes and clinical trial protocols and data, companies often redact those details as confidential business information.[92] Companies try to redact the information unilaterally where possible (e.g., in document discovery), or by application to the court (e.g., in a motion to seal and to file a redacted a version) as even judicial opinions and orders may be redacted.[93] For all these reasons, litigation records are not a robust source of information.

As the discussion above makes clear, a prospective biosimilar company contemplating whether to enter the market has no idea what patent or other rights might be asserted. Nor can the company determine whether those patents or other rights are valid or might be validly applied to the version it will develop.

4. When Do Those Rights Expire?

This, perhaps, is the easiest of the four questions to answer, because there is no answer. If one does not know what patent rights exist, one cannot know when they will expire. Moreover, when the brand company can withhold critical information as a trade secret and then dribble out patent applications along the way, obtaining a clear picture of the potential rights that will be asserted becomes impossible.

In short, a prospective biosimilar company will be completely unable to answer any of the four basic questions of what the drug is, how it is made, what patent rights apply, and when those rights expire. Instead, a company trying to develop a biosimilar must stumble blindly through the information desert.

92. *See, e.g.*, Phase Four Indus., Inc. v. Marathon Coach, Inc., No. 04-4801 JW, 2006 WL 1465313, at *12 (N.D. Cal. May 24, 2006) ("Certain pages in the production have been redacted . . . on the basis of trade secret, proprietary and confidential business information.").

93. *See id.*; Defendants' Reply in Support of Motion to Dismiss Pursuant to Rule 12(B)(1) and 12(B) Redacted Version of Document Sought to be Sealed, Celltrion, Inc. v. Genentech, Inc., No. 4:18-cv-00274-JSW (N.D. Cal. Apr. 2, 2018) (emphasis added) (filing redacted version of document sought to be sealed); Mitze v. Saul, 968 F.3d 689, 692 (7th Cir. 2020) ("Even in cases involving substantial countervailing privacy interests such as . . . trade secrets, . . . courts have opted for redacting instead of sealing the order or opinion." (citing Hicklin Eng'g, L.C. v. Bartell, 439 F.3d 346, 348–49 (7th Cir. 2006), *abrogated on other grounds by* RTP LLC v. ORIX Real Est. Cap., 827 F.3d 689, 691–92 (7th Cir. 2016))).

D. FEW BIOSIMILARS, FEWER BARGAINS

The impact of the Biosimilars Act has been underwhelming, both in its facilitation of biosimilar development and in the actual price reductions resulting from biosimilar entry. As of 2020, a decade after the passage of the Biosimilars Act, only eighteen biosimilars, corresponding to seven biologics, had entered the U.S. market.[94] That is more of a trickle than a waterfall. Moreover, the United States lags behind Europe in biosimilar development, with half as many approvals and market entrants.[95] In a nation known for its pharmaceutical innovation, this gap is surprising and raises questions about the effectiveness of the Biosimilars Act in facilitating biosimilar entry.

Price reductions for biosimilars in the United States also have been disappointing from the perspective of percentage discounts. U.S. biosimilars have been marketed at an average of a 30% discount from brand biologics[96]—a much smaller percentage than the 80%–85% discount typically offered by generic versions of non-biologic drugs.[97] Some observers argue that these savings are more significant than generic discounts, given that biologics are priced an average of twenty-two times more than non-biologic drugs.[98] In other words, 30% of a vastly higher price represents more dollars saved than 85% of a far lower price. One could argue, however, that the amount of money saved is an incomplete metric, from the standpoint of affordability. A 30% discount on an exorbitant price will leave biosimilars nearly as unaffordable as brand biologics, whereas an 85% discount on generics sharply alters the financial implications of the treatment.

Although there are many contributing factors,[99] the impact of the Biosimilars Act has been particularly small in comparison to Hatch-Waxman,

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94. *See* Victor Van de Wiele, Aaron S. Kesselheim & Ameet Sarpatwari, *Barriers to US Biosimilar Market Growth: Lessons from Biosimilar Patent Litigation*, 40 HEALTH AFFS. 1198, 1199 (2021).

95. *See id.*

96. IQVIA INST., BIOSIMILARS IN THE UNITED STATES, 2020-2024: COMPETITION, SAVINGS, AND SUSTAINABILITY 2 (2020) ("Price declines for biosimilars range significantly but appear to reflect prior assumptions of roughly 30% discounts, though higher discounts have occurred and are possible in the future.").

97. *Generic Drugs: Questions & Answers*, U.S. FOOD & DRUG ADMIN. (Mar. 16, 2021), https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers ("[Generic medicines] are typically sold at substantial discounts, an estimated 80 to 85% less, compared with the price of the brand-name medicine.").

98. *Id.* (noting that generics sell at a discount of 80–85% on average compared to name-brand drugs); Makurvet, *supra* note 31, at 4.

99. *See* Feldman, *supra* note 32 (arguing that the success of the Biosimilars Act has been limited by the dearth of patent disclosure in the biologics regime as well as the lack of

which substantially improved access to less-expensive drugs.[100] For example, prior to passage of the Hatch-Waxman Act in 1984, generic drugs accounted for only 19% of prescriptions dispensed in the United States, yet a dozen years later, generic drugs accounted for 43%,[101] and currently, they account for more than 87% of all non-biologic drugs dispensed in the United States.[102] In contrast, the Biosimilars Act falls short of that trajectory. A dozen years after passage of the Act, biosimilars accounted for less than 30% of biologic prescriptions sold in the United States.[103]

Moreover, with the greater precision needed to develop a biosimilar, along with the additional costs and uncertainties imposed by the system, biosimilar manufacturing is largely the sport of kings. In 2020, fourteen out of the twenty-two biosimilars on the U.S. market were developed and launched by seven large pharmaceutical companies, such as Sandoz and Pfizer.[104] Many biosimilars are made by biologic companies themselves, who enter the biosimilar market to challenge a biologic drug made by a different biologic company.[105]

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regulatory exclusivity for the first-filing biosimilar); Van de Wiele, Kesselheim & Sarpatwari, *supra* note 94, at 1199-1202 (arguing that non-compliance with the litigation process established by the Biosimilars Act and the large number of patents asserted by brand biologics are two main issues limiting the success of the Biosimilars Act).

100. *See* Aaron Kesselheim & Jonathan Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 295 (2015) (noting that the Hatch-Waxman Act has been greatly impactful and that generics constituted eighty-four percent of all prescriptions dispensed in the United States in 2012).

101. CONG. BUDGET OFF., HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY, at ix (1998) ("In 1996, 43 percent of the prescription drugs sold in the United States [were] generic" but only "[t]welve years earlier, the figure was just 19 percent.").

102. Scott Biggs & Doug Long, *Insights Into the 2023 U.S. Pharmaceutical Market*, IQVIA (July 25, 2023), https://www.iqvia.com/locations/united-states/blogs/2023/07/insights-into-the-2023-us-pharmaceutical-market ("In 2022, 87.2% of small molecule drug prescriptions were dispensed as unbranded generics.").

103. ASS'N FOR ACCESSIBLE MED., THE U.S. GENERIC & BIOSIMILAR MEDICINES SAVINGS REPORT 25 (2022), https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf.

104. IQVIA INST., *supra* note 96, at 2, 6 (noting that as of publication, there were 22 biosimilars launched in the U.S. market and stating, "Of biosimilar products marketed in the United States, 14 were developed and launched by seven large pharma companies: Sandoz developed and launched three, while Pfizer developed three and also acquired and launched two more after their Hospira acquisition in 2015").

105. For example, in the rheumatoid arthritis space, Amgen's biologic drug Enbrel competes with AbbVie's biologic drug Humira. As for rheumatoid arthritis biosimilars, Amgen is launching a biosimilar to challenge AbbVie's biologic Humira, while Novartis is launching a biosimilar to challenge Amgen's Enbrel. *See* John Miller, *Big Pharma vs Big Pharma in Court*

Overall, these results are disappointing, particularly in comparison to the success of Hatch-Waxman. Without significant price reductions and widespread entry, the Biosimilars Act cannot deliver on its promise of increasing access and affordability in the United States, along with the many benefits that competition generates. To understand the factors leading to the underwhelming performance of the Biosimilars Act, one must examine the patent dance, which is the intricate, patent-litigation process at the center of the Act—and the moment of truth for would-be biosimilars.[106]

III. THE BIOLOGICS DANCE

A. DISPUTING INFRINGEMENT CLAIMS UNDER THE BIOSIMILARS ACT

The difficulties described above all factor into the strategic behaviors and choices that both brand and biosimilar companies make as they move through the process of approval and rights clearance in the Biosimilars Act. Nevertheless, at the heart of these difficulties lies the dispute resolution process, which is the core of the Biosimilars Act. Far more complex than the simple notice-and-lawsuit method in Hatch-Waxman, the biosimilar process consists of two phases, each involving several negotiations between the involved parties. As the following description of the process will demonstrate, its length and intricacy are driven, in part, by a lack of built-in patent disclosure in the biologic regulatory regime. Specifically, in Hatch-Waxman, both parties know prior to the filing of an application for generic manufacture, and even prior to the generic's decision whether to enter the market in the first place, which patents the brand can assert to protect its drug. In contrast, the litigation process outlined in the Biosimilars Act revolves around determining *which* biologic patents would even be at issue should a biosimilar come to market.

Many have used the phrase "patent dance" to refer to the exchanges between the parties that occur as part of the Biosimilars Act, with some referring only to the first phase as the dance and others describing the entire process as the dance.[107] Given that the entire exercise prompted by the

Battles Over Biosimilar Drugs, REUTERS (Oct. 2, 2016), https://www.reuters.com/article/us-pharmaceuticals-biosimilars/big-pharma-vs-big-pharma-in-court-battles-over-biosimilar-drugs-idUSKCN12208Q. Amgen, AbbVie, and Novartis are all large pharmaceutical companies that make biologic drugs.

106. *See supra* note 60 and accompanying text. For a detailed description of the patent dance, see *supra* Sections III.A.1–2.

107. *Compare* Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 17 (2018) (referring only to the first phase as the patent dance), *with* Michael A. Sanzo, *The Promise and Problem of Biologics*, 34 SANTA CLARA HIGH TECH. L.J. 78,

Biosimilars Act resembles an extended and intricately choreographed ballet, this Article uses "patent dance" to refer to every tiptoe of the process.

1. Phase One of the Patent Dance

a) The Dance Commences

The first phase of litigation begins when the FDA notifies the biosimilar company that the company's biosimilar application has been accepted for review.[108] Within twenty days, the biosimilar company must give the brand company a copy of that application, along with information describing the manufacturing process used to create the biosimilar.[109] With biologic medicines, the product generally is defined by describing the process of creating the drug,[110] and that process forms the basis for the key patent rights.

The design of these steps in the patent dance may have reflected the contemporary climate when Congress drafted the legislation. From the mid-2000s to the mid-2010s, concerns emerged regarding entities dubbed "patent trolls" or non-practicing entities.[111] Patent trolls produce no products. Their business model involves aggregating large patent portfolios and asserting those patents against companies in various markets, largely in the technology sector.[112] At the time, one could assert a patent against a company by simply

97–99 (2017) (using "patent dance" to refer to the entire process of litigation and patent dispute resolution outlined in the Biosimilars Act).

108. 42 U.S.C. § 262(l)(2).

109. *Id.* (stating that the biosimilar "shall provide to the [brand] a copy of the application submitted . . . and such other information that describes the process or processes used to manufacture the biological product").

110. *See supra* text accompanying notes 64–68 (describing the complexity of biologic molecules and the notion that "the process is the product").

111. *See* Adam Smith, Note, *Patent Trolls—An Overview of Proposed Legislation and a Solution that Benefits Small Businesses and Entrepreneurs*, 9 OHIO ST. ENTREPRENEURIAL BUS. L.J. 201 (2014). Other terms for patent trolls include non-practicing entities (NPEs)—reflecting the fact that, in patent lingo, they do not "practice" the patent but only assert it—and mass aggregators. *See* Michael Mazzeo, Jonathan H. Ashtor & Samantha Zyontz, *Do NPEs Matter? Non-Practicing Entities and Patent Litigation Outcomes*, 9 J. COMPETITION L. & ECON. 879, 880 (2013) (using "patent trolls" and "NPEs" interchangeably); Tom Ewing & Robin Feldman, *The Giants Among Us*, 1 STAN. TECH. L. REV. 1, 1, 15 (2012) (explaining that mass aggregators do not conduct research or manufacture products, but rather pursue other goals of interest to their founders and investors).

112. Ewing & Feldman, *supra* note 111, at 1–2. Debates around curbing patent trolls proliferated in the discussion leading up to the 2011 patent reform legislation known as the America Invents Act, with the life sciences industry opposing these reforms. *See* Robin Feldman & W. Nicholson Price II, *Patent Trolling: Why Bio & Pharmaceuticals Are at Risk*, 17 STAN. TECH. L. REV. 773, 776 (2014).

filing a patent infringement lawsuit and listing a patent.[113] This judicial process for patent litigation stood in contrast to the filing requirements for other types of litigation, in which those bringing suit were required to specify a sufficient basis for their claim or risk dismissal on an early motion.[114] As a result, scholars and commentators complained that patent trolls could extract settlements regardless of the merit of their claims simply because the expenses associated with pursuing the litigation exceeded the settlement amount demanded.[115]

Various pieces of legislation were introduced to address the problem.[116] In the runup to that legislation, the pharmaceutical industry opposed the

113. *See* FED. R. CIV. P. Form 18; Jun Zheng, *A New Era for Patent Infringement Pleading: Twombly, Iqbal, and the Demise of Form 18*, 24 TEX. INTELL. PROP. L.J. 15, 19–20 (2016) ("Form 18 requires the following information: (1) an allegation of jurisdiction; (2) a statement that the plaintiff owns the patent; (3) a statement that defendant has been infringing the patent 'by making, selling, and using [the device] embodying the patent'; (4) a statement that the plaintiff has given the defendant notice of its infringement; and (5) a demand for an injunction and damages."). In September 2014, a Judicial Conference committee unanimously approved a proposal to abrogate Form 18. This proposal was adopted by the Supreme Court in April 2015 and absent a Congressional objection, Form 18 was abrogated as of December 2015. *See* JUD. CONF. COMM. ON RULES OF PRAC. & PROC., REPORT OF THE JUDICIAL CONFERENCE COMMITTEE ON RULES OF PRACTICE AND PROCEDURE 13 (2014), http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Reports/ST09-2014.pdf; Zheng, *supra*, at 30–31.

114. Keith N. Hylton, *When Should a Case Be Dismissed? The Economics of Pleading and Summary Judgment Standards*, 16 SUP. CT. ECON. REV. 39, 41 n.9 (2008) (noting that for most litigation, "defendants challenge cases at the pleading stage by filing a motion to dismiss for failure to state a claim").

115. Eric Rogers & Young Jeon, *Inhibiting Patent Trolling: A New Approach for Applying Rule 11*, 12 NW. J. TECH. & INTELL. PROP. 291, 295 (2014); Robin Feldman, *Intellectual Property Wrongs*, 18 STAN. J.L. BUS. & FIN. 250, 283 (2013).

116. *See generally* Leahy-Smith America Invents Act, Pub. L. No. 112–29, § 34, 125 Stat. 284, 340 (2011) (allowing for greater access to the USPTO to deter patent trolls); Saving High-Tech Innovators from Egregious Legal Disputes Act, H.R. 845, 113th Cong. § 2 (2013) (enabling fee shifting to encourage challenging patent trolls); Patent Abuse Reduction Act, S. 1013, 133th Cong. § 2 (2013) (requiring use of claims charts during pleadings to discourage patent trolls); Patent Litigation and Innovation Act, H.R. 2639, 113th Cong. § 2 (2013) (likewise, requiring use of claims charts during pleadings to discourage patent trolls); End Anonymous Patent Act, H.R. 2024, 113th Cong. (2013) (mandating that issued patents disclose the patent owner(s) and parties in interest). Hearings and legislation tend to emerge as part of a long process that begins with at least a few years of public and private discussions. *See, e.g.*, *Patent Trolls: Fact or Fiction?: Hearing Before the Subcomm. on Cts., the Internet, & Intell. Prop. of the H. Comm. on the Judiciary*, 109th Cong. (2006); *Abusive Patent Litigation: The Impact on American Innovation and Jobs, and Potential Solutions: Hearing Before the Subcomm. on Cts., Intell. Prop., & the Internet of the H. Comm. on the Judiciary*, 113th Cong. (2013); *International Trade Commission and Patent Disputes: Hearing Before the Subcomm. on Intell. Prop., Competition, & the Internet of the H. Comm. on the Judiciary*, 112th Cong. (2012).

proposed reform,[117] likely because the reform restricted the extended discovery that was available, and the industry assertedly needed extensive discovery regarding a new entrant's processes to determine what patents to assert.[118] Although congressional legislation largely failed, the patent trolling problem has eased thanks to a procedure called *inter partes* review.[119] Streamlining the mechanism to challenge questionable patents, this procedure is conducted not by a federal court but instead by the Patent Trial and Appeal Board.[120] The pharmaceutical industry's concerns over obtaining information about an entrant's operations prior to filing suit are reflected in the first step of the Biosimilars Act patent dance, in which the biosimilar company must describe its manufacturing process.

b) The Back-and-Forth Tango

As described above, the patent dance begins when the biosimilar company gives the brand both a copy of its application for FDA approval and information describing the biosimilar's manufacturing process. Following that, the brand has sixty days to submit a list of patents that it believes can be reasonably asserted against the biosimilar. We refer to this list as the "Initial Brand List."[121]

In typical patent law fashion, the different stages of the patent dance are identified with a confusing mix of numbers, which are based on the sections of the law that outline this process.[122] To make the patent dance more accessible, this Article uses a simple language scheme for describing each step. The following table shows the correlation between the simple language and the numerical legal system. In addition, this Article includes an appendix with flowcharts breaking down the intricate steps of the patent dance.

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117. H.R. REP. NO. 113-279, at 93–94 (2013) (noting that several stakeholder groups, including the Biotechnology Industry Association (BIO) and the Pharmaceutical Research and Manufacturers Association (PhRMA), issued letters expressing opposition to the "Innovation Act").

118. *See id.* at 109–11 (noting that several pharmaceutical industry groups expressed concerns regarding the proposed provisions of the Innovation Act limiting discovery).

119. Carolyn Treasure & Aaron Kesselheim, *How Patent Troll Legislation Can Increase Timely Access to Generic Drugs*, 176 JAMA INTERNAL MED. 729, 729 (2016) (describing how *inter partes* review is "directed at patent trolls" but also "ha[s] an impact on brand and/or generic drug patent litigation").

120. *Id.*

121. 42 U.S.C. § 262(l)(3)(A)(i) ("[T]he [brand] shall provide to the [biosimilar] applicant . . . a list of patents for which the [brand] believes a claim of patent infringement could reasonably be asserted.").

122. *See id.* § 262(l)(3)(A)(i)–(5)(B)(i), (l)(7).

Table 1: Patent Dance Nomenclature

Numerical Legal Name	Simple Language Used in This Article
3A List[123]	Initial Brand List
3B List[124]	Biosimilar List
7AB List[125]	Supplemental Brand List
4AB List[126]	Negotiated List
5A Notice[127]	Number Notice
5B Lists[128]	Failed-Negotiation Lists
Subparagraph B Statement[129]	Biosimilar Detailed Statement
Paragraph 3(C) Statement[130]	Brand Detailed Statement

In response to receiving the Initial Brand List—that is, the patents the brand believes can be asserted against the biosimilar, the biosimilar company has sixty days to do two things. First, the biosimilar company may give the brand a list of patents that the *biosimilar* company believes the brand could assert as infringing (and that the biosimilar presumably believes are invalid or will not be infringed).[131] In other words, the biosimilar is saying to the brand, "we think you could throw these patents at us, as well, and we want them resolved as part of this process." The current Article refers to this list as the "Biosimilar List." Second, the biosimilar company must give the brand either: (1) a "detailed statement" (the "Biosimilar Detailed Statement") explaining why each patent listed in the Initial Brand List or the Biosimilar List is invalid or will not be infringed by the biosimilar; or (2) a statement declaring that the biosimilar will not enter the market until the listed patents have expired.[132]

123. *See id.* § 262(l)(3)(A).
124. *See id.* § 262(l)(3)(B).
125. *See id.* § 262(l)(7)(A)–(B).
126. *See id.* § 262(l)(4)(A)–(B).
127. *See id.* § 262(l)(5)(A).
128. *See id.* § 262(l)(5)(B).
129. *See id.* § 262(l)(3)(B)(ii)(I).
130. *See id.* § 262(l)(3)(C).
131. *Id.* § 262(l)(3)(B)(i) (stating that the biosimilar "may provide to the [brand] a list of patents to which the [biosimilar] applicant believes a claim of patent infringement could reasonably be asserted by the [brand]").
132. *Id.* § 262(l)(3)(B)(ii)(I), (II) (stating that the biosimilar "shall provide to the [brand], with respect to each patent listed [in the Initial Brand List] or [the Biosimilar List,] . . . a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the [biosimilar] applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product . . . or . . . a statement that the [biosimilar] applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires").

When the brand receives the Biosimilar Detailed Statement and the Biosimilar List, the brand has sixty days to provide its own "detailed statement" (the "Brand Detailed Statement") explaining why each patent addressed in the Biosimilar Detailed Statement either is *valid* or *will* be infringed.[133]

The Act also specifies dance steps to include if the brand receives more patents along the way. If the brand receives a new patent after providing the biosimilar company with an Initial Brand List, and the brand believes the new patent could serve as the basis for an infringement claim, the brand has thirty days after the patent issues to augment its Initial Brand List[134] with a

133. *Id.* § 262(l)(3)(C) ("[The brand] shall provide to the [biosimilar] applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the [brand] that such patent will be infringed by the commercial marketing of the biological product . . . and a response to the statement concerning validity and enforceability.").

134. A brand could choose to omit patents from its Initial Brand List and Supplemental Brand List, in hopes of holding such patents in reserve and then springing them on the biosimilar after the biosimilar receives FDA marketing approval and begins marketing. Three factors deter a brand from engaging in that strategic behavior. First, the brand would lose an opportunity for a preliminary injunction. The Biosimilars Act authorizes the brand to move for a preliminary injunction during the second phase of the patent dance, after the biosimilar's notice of commercial marketing. *See infra* Section III.A.2. However, if the underlying patent was not on the Initial Brand List or Supplemental Brand List, the Act does not give the brand that authorization. *See id.*; *infra* notes 156, 158, 171, and accompanying text (citing 42 U.S.C. § 262(l)(8)). Second, the Biosimilars Act's "list it or lose it" provision expressly bars the brand from suing under 35 U.S.C. § 271 for infringement—through the Biosimilars Act pathway or through an ordinary infringement suit—of any patents omitted from the Initial Brand List and Supplemental Brand List that should have been included. *See* 35 U.S.C. § 271(e)(6)(C) ("The owner of a patent that should have been included in the [Initial Brand L]ist described in section 351(l)(3)(A) of the Public Health Service Act, including [in the Supplemental Brand List] as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section [35 U.S.C. § 271] for infringement of the patent with respect to the biological product."). The provision is clear, although it has broad implications. Despite that clarity, there is some dispute concerning whether the provision reaches that broadly. *See* KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46679, DRUG PRICES: THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES 37–38 & nn.334–35 (2024); *cf.* Amgen Inc. v. Hospira, Inc., 866 F.3d 1355, 1361 (Fed. Cir. 2017); Amgen Inc. v. Apotex Inc., 827 F.3d 1052, 1058 (Fed. Cir. 2016), *cert. denied*, 580 U.S. 1030 (2016); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7002(c)(1), 124 Stat. 119, 816 (2010). Finally, in the negotiation phase, which is discussed next, the Biosimilars Act limits the Negotiated List (the first list in the negotiation phase) to patents included in the Initial Brand and Biosimilar Lists. *See* 42 U.S.C. § 262(l)(4)(A). (One would expect Congress to also limit subsequent lists in the negotiation phase, which are called Failed-Negotiation Lists, to patents included in the Initial Brand and Biosimilar Lists. Oddly, the Act fails to do so, which may have been a drafting error by Congress. Regardless, the hole left by that failure is plugged by the "list it or lose it" provision.)

Supplemental Brand List.[135] The biosimilar company then has thirty days to provide another statement to the brand about the validity and infringement potential of the patents on the Supplemental Brand List.[136]

c) Coming to a Compromise (or Not)

To recap, at this point, the brand has provided its Initial Brand List of infringed patents (augmented with a Supplemental Brand List of any new patents received).[137] The biosimilar company has responded with its (optional) Biosimilar List of patents it believes the *brand* both holds and might assert,[138] and with its (mandatory) Biosimilar Detailed Statement regarding each patent on the Initial Brand List or any Biosimilar List.[139] In turn, the brand has responded with a (mandatory) Brand Detailed Statement regarding each patent on the Biosimilar Detailed Statement.[140]

Now comes a negotiation phase. After the biosimilar company receives the Brand Detailed Statement, the parties have fifteen days to decide which patents from the Initial Brand and Biosimilar Lists belong on a "final and complete list," which we refer to as the "Negotiated List." Each of these patents will be included in an action for patent infringement.[141] If the parties cannot agree on which patents should constitute the Negotiated List, each party draws up a second set of lists, which we refer to collectively as the "Failed-Negotiation Lists."[142]

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135. 42 U.S.C. § 262(l)(7)(A)–(B) (stating that if a patent "is issued to, or exclusively licensed by, the [brand] after the date that the [brand] provided the list to the [biosimilar] applicant under paragraph (3)(A); and . . . the [brand] reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the [brand] . . . , the [brand] shall provide the [biosimilar] applicant a supplement to the list provided by the [brand]"). Note that the patents on the Supplemental Brand List are expressly included by the Biosimilars Act among the patents that may be litigated in the *second* phase of the patent dance. *See id.* § 262(l)(7). For further discussion of the Supplemental Brand List, see *infra* note 179 and accompanying text.

136. *Id.* § 262(l)(7) ("[T]he [biosimilar] applicant shall provide a statement to the [brand] in accordance with paragraph (3)(B).").

137. *See supra* notes 121, 134–135, and accompanying text.

138. *See supra* note 131 and accompanying text.

139. *See supra* note 132 and accompanying text.

140. *See supra* note 133 and accompanying text.

141. 42 U.S.C. § 262(l)(4)(A) ("[T]he [brand] and the [biosimilar] applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the [biosimilar] applicant or [brand] shall be the subject of an action for patent infringement under paragraph (6).").

142. *Id.* § 262(l)(4)(B), (5)(B)(i) (stating that if within 15 days, there is a "[f]ailure to reach agreement," then "the [biosimilar] applicant and the [brand] shall simultaneously exchange . . .

In the Failed-Negotiation List process, the biosimilar company, as a general matter, gets to determine the *number* of patents it believes should be subject to an infringement action.[143] This restriction, in theory, allows the biosimilar company to control the patent litigation's scope, preventing the brand from flooding the biosimilar with claims of infringement.

The process begins when the biosimilar notifies the brand of the number of patents that will be on the biosimilar's Failed-Negotiation List. This notice is referred to here as the "Number Notice."[144] Within five days of the Number Notice, the biosimilar and the brand simultaneously exchange their Failed-Negotiation Lists, which list the patents they each believe should be included in an infringement action.[145] The number of patents on the brand's list cannot exceed the number of patents on the biosimilar's list.[146] At this point, the

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the list[s] of patents that" the brand and the biosimilar applicant each believe "should be the subject of an action for patent infringement").

143. *Id.* § 262(l)(5)(A) ("The [biosimilar] applicant shall notify the [brand] of the number of patents that [the biosimilar] applicant will provide to the [brand].").

144. *Id.* § 262(l)(5)(A).

145. *Id.* § 262(l)(5)(B)(i) ("[The biosimilar and brand] shall simultaneously exchange—the list[s] of patents that" each believe "should be the subject of an action for patent infringement.").

146. *Id.* § 262(l)(5)(B)(ii)(I) ("[T]he number of patents listed by the [brand] under clause (i)(II) may not exceed the number of patents listed by the [biosimilar] applicant under clause (i)(I).").

Section 262(l)(5)(A) and (B) clearly contemplate that the biosimilar's Number Notice (*see supra* text accompanying notes 144–145) should state the same number as the number of patents actually included in the biosimilar's Failed-Negotiation List. But it is unclear what happens if the biosimilar, after giving its Number Notice, provides a Failed-Negotiation List showing *fewer* patents, thereby duping the brand into giving a Failed-Negotiation List longer than the biosimilar's. In a litigation raising an analogous issue, the biosimilar did not negotiate the Negotiated List in good faith under section 262(l)(4) or comply with section 262(l)(5). The district court ruled that, consequently, the brand would not be limited to a reasonable royalty for damages, since that limitation of damages was intended as a benefit for the biosimilar's compliance with sections 262(l)(4) *and (5)*. *See* Janssen Biotech, Inc. v. Celltrion Healthcare Co., 239 F. Supp. 3d 328, 331–32 (D. Mass. 2017); *see also* GOODWIN PROCTER LLP, GUIDE TO BIOSIMILARS LITIGATION AND REGULATION IN THE U.S. § 4:19 & n.8 (2022) [hereinafter GOODWIN PROCTER GUIDE TO BIOSIMILARS LITIGATION].

In addition, the biosimilar's failure to comply with, among other provisions, Sections 262(l)(5)(A) and (B) entitles the brand to bring a declaratory judgment action for a declaration that any patent on the Initial Brand or Supplemental Brand List is valid, enforceable, or infringed. *See* 42 U.S.C. § 262(l)(9)(B); GOODWIN PROCTER GUIDE TO BIOSIMILARS LITIGATION § 4:19 & n.9. Without that right of action, the brand will have no real recompense for the biosimilar's noncompliance. However, none of the foregoing addresses the express statutory requirement that the number of patents on the brand's Failed-Negotiation List not exceed the number of patents on the biosimilar's Failed-Negotiation List. *See* 42 U.S.C. § 262(l)(5)(B)(ii)(I). Certainly, making the brand trim its list would be unfair to the brand,

negotiation process has finished, and the parties have narrowed down the universe of potentially litigable patents to a relatively short list of key patents that will be the focus of the ensuing litigation.

If, for whatever reason, the biosimilar does not include *any* patents on its list, the brand may include one patent on its list.[147] In either case, the brand has thirty days to bring an infringement action covering all the patents on the Negotiated List or (absent a Negotiated List) the Failed-Negotiation Lists.[148] As noted,[149] the number of patents on the brand's Failed-Negotiation List cannot exceed the number of patents on the biosimilar's list. This prevents the brand from flooding the litigation by listing hundreds of patents—regardless of whether the patents are valid or validly applied to the product—that the biosimilar will have to battle. Once again, the biosimilar controls the number of patents.

No later than thirty days after the brand's complaint is served, the biosimilar must provide a copy of the complaint to the FDA, which publishes notice of the complaint in the Federal Register.[150] So far, the Federal Register notices do not appear to have included the patents involved in the complaint.[151]

2. Phase Two of the Patent Dance

a) Phase Two Begins

Under the Biosimilars Act's sister act, Hatch-Waxman, the brand receives an automatic 30-month stay after filing litigation, during which the FDA is

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because the excess of patents on the brand's list was procured by the biosimilar's own wrongdoing. Perhaps the solution is to deem the biosimilar's list to include as many patents on the brand's list as are needed to make the two lists equal in number.

147. 42 U.S.C. § 262(l)(5)(B)(ii)(II) (noting the exception that "if a [biosimilar] does not list any patent under clause (i)(I), the [brand] may list 1 patent under clause (i)(II)").

148. *Id.* § 262(l)(6)(A)–(B) (providing that whether or not there is agreement on the patent list, "the [brand] shall bring an action for patent infringement with respect to each such patent").

149. *See id.*

150. *Id.* § 262(l)(6)(C)(i)–(ii) (stating that the biosimilar "shall provide the Secretary with notice and a copy of such complaint" for patent infringement within 30 days of when the complaint is served and that the "Secretary shall publish in the Federal Register notice of a complaint").

151. In the Federal Register notices that the authors could locate, none contains patent information. *See* 88 Fed. Reg. 14171 (Mar. 7, 2023); 87 Fed. Reg. 7844 (Feb. 10, 2022); 83 Fed. Reg. 46174 (Sept. 12, 2018); 82 Fed. Reg. 57279 (Dec. 4, 2017); 82 Fed. Reg. 55105 (Nov. 20, 2017); 82 Fed. Reg. 36150 (Aug. 3, 2017); 81 Fed. Reg. 64180 (Sept. 19, 2016); 81 Fed. Reg. 18858 (Apr. 1, 2016); 80 Fed. Reg. 51277 (Aug. 24, 2015).

barred from approving the generic's application for marketing.[152] The 30-month stay is included to give the courts time to resolve the patent disputes.

The Biosimilars Act does not contain an automatic stay in which the FDA is barred from granting the biosimilar's request for a license. However, the Act does contain a different timing device for market entry that similarly gives the courts time to resolve litigation issues.[153]

Specifically, the biosimilar must tell the brand the planned date of its first commercial marketing at least 180 days in advance. This notice marks the start of the second phase of litigation.[154]

The second phase of litigation gives the brand a chance to assert any remaining patents on any of the opening lists but not eventually litigated in the first phase.[155] To that end, after the biosimilar gives notice of commercial marketing, the brand may file suit and move for a preliminary injunction on any patents that were included in the Initial Brand List, Biosimilar List, and Supplemental Brand List but did not make it onto the Negotiated or Failed-Negotiation Lists.[156] The district court hearing a brand's preliminary injunction motion may limit the number of patents to be considered.[157]

A preliminary injunction would halt manufacture or sale of the biosimilar until the patent disputes are resolved in the second-phase lawsuit.[158] Note,

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152. *See infra* note 170.

153. For a different timing device in the Biosimilars Act, see *infra* notes 301–303 and accompanying text (describing the 12-year and 4-year exclusivities granted to the brand biologic).

154. 42 U.S.C. § 262(l)(8)(A) (noting that the biosimilar "shall provide notice to the [brand] not later than 180 days before the date of the first commercial marketing of the biological product").

155. *See* Carrier & Minniti, *supra* note 107, at 18.

156. 42 U.S.C. § 262(l)(8)(B)(i)–(ii) (providing that the brand "may seek a preliminary injunction"). The statutory text says only that in phase two the brand may seek a preliminary injunction, and does not say expressly that the brand also initiates a new lawsuit in which the preliminary injunction may be sought. *See id.* But the practice is clearly that if the brand in phase two seeks a preliminary injunction, it initiates a new lawsuit in which to file its preliminary injunction motion. *See, e.g.*, Second Amended Complaint ¶¶ 1, 11–15, 49–52, d, AbbVie Inc. v. Alvotech hf., 582 F. Supp. 3d 584 (N.D. Ill. Jan. 26, 2022) (lawsuit initiating second-phase litigation and seeking preliminary injunction).

157. *See, e.g.*, *In re* Katz Interactive Call Processing Pat. Litig., 639 F.3d 1303, 1310–13 (Fed. Cir. 2011) (holding that district courts hearing patent infringement claims may mandate the patent holder to select only representative claims against each defendant).

158. 42 U.S.C. § 262(l)(8)(B)(i)–(ii) (stating that the brand "may seek a preliminary injunction prohibiting the [biosimilar] applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is . . . included in the list provided by the [brand] under paragraph (3)(A) or in the list provided by the [biosimilar]

however, that although the patent dance provisions of the Biosimilars Act authorize a preliminary injunction only in the second phase, other provisions of the Biosimilars Act might authorize injunctive relief in both phase one and phase two.[159]

If the court denies the brand's motion for a preliminary injunction in phase two, the biosimilar can enter the market, assuming the 180 days have expired.[160] With or without a preliminary injunction, the patent litigation will proceed to the merits. The only difference would be whether the biosimilar may enter the market while the litigation proceeds.[161]

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applicant under paragraph (3)(B); and . . . not included, as applicable, on . . . the list of patents described in paragraph (4); or . . . the lists of patents described in paragraph (5)(B)").

159. The patent dance provisions of the Biosimilars Act specify the potential for a preliminary injunction only in relation to phase two of the litigation. *See* 42 U.S.C. § 262(l)(6), (8) (specifying availability of a preliminary injunction during phase two of the litigation but remaining silent on the availability of a preliminary injunction in phase one). However, although much of the Biosimilars Act was codified in the part of federal law related to licensing biologic products (Title 42 of the U.S. Code), some of the Act's language required amendments to the Patent Act (Title 35 of the U.S. Code). Some courts and scholars suggest that the Biosimilars Act's amendments to the Patent Act make injunctive relief available in *both* phases, despite the absence in the patent dance sections of any language providing for injunctive relief in phase one. *See* AbbVie Inc. v. Alvotech hf., 582 F. Supp. 3d 584, 591–92 (N.D. Ill. 2022) (holding that because the Biosimilars Act authorizes the brand to bring an artificial infringement claim under 35 U.S.C. § 271(e)(2) in both phases, the Act also authorizes the brand to obtain injunctive relief under 35 U.S.C. § 271(e)(4) in both phases); Carl J. Minniti III, Sandoz v. Amgen*: Why Current Interpretation of the Biologic Price Competition and Innovation Act of 2009 Is Flawed and Jeopardizes Future Competition*, 97 J. PAT. & TRADEMARK OFF. SOC'Y 172, 177, 179 (2015) (discussing the Biosimilars Act's amendments to the Patent Act); *supra* note 2 (citing Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. VII, subtit. A, §§ 7001–03, 124 Stat. 119, 804-21 (2010) which reflects the Biosimilars Act's amendments to the Patent Act); *cf.* GOODWIN PROCTER GUIDE TO BIOSIMILARS LITIGATION, *supra* note 146, § 4:58 (observing, even without reference to the Biosimilars Act's amendments to the Patent Act, that if a biosimilar provides notice of commercial marketing while phase-one litigation is still pending, a court could then enter a preliminary injunction on any patent being litigated in phase one to prevent entry into the market).

160. The exclusivities granted to brands under the Biosimilars Act also must have expired. *See infra* text accompanying notes 301–303 (describing those 12-year and 4-year exclusivities).

161. If there is no preliminary injunction, and the biosimilar launches while the merits are pending, the brand will be able to request damages. *See infra* note 166; *infra* text accompanying notes 166–169 (discussing the option to launch at risk).

b) The Biosimilar Gets Strategic Options

The biosimilar company does have some strategic options in addition to the ones listed above.[162] In particular, by creating two phases, the statute allows the parties to select key patents for litigation in the first phase and leave other patents for litigation in the second phase.[163] The intent may be to encourage the parties to focus on the key issues in the dispute, rather than wasting time going down every possible rabbit hole. More practically, the bifurcated phasing provides the biosimilar with strategic options, given that the biosimilar can choose when to initiate the second phase by deciding when to provide its notice of commercial marketing.[164]

Specifically, the Biosimilars Act does not require the first phase to finish before the second phase can be started.[165] Consider the circumstance in which, after the biosimilar has provided its notice of commercial marketing, there is no preliminary injunction halting the biosimilar's entry into the market. In

162. *See supra* text accompanying notes 131–132, 138–139, 143–146, 160.

163. *See* AbbVie, 582 F. Supp. 3d at 593 ("The BPCIA creates a procedure by which the parties can litigate the most contested and consequential patents immediately, *see* [42 U.S.C.] § 262(l)(6), giving both parties what is likely a definitive answer, with lower costs and on an expedited schedule.").

164. *See* Sandoz Inc. v. Amgen Inc., 582 U.S. 1, 10 (2017) ("Because the [biosimilar] applicant (subject to certain constraints) chooses when to begin commercial marketing and when to give notice, it wields substantial control over the timing of the second phase of litigation.").

165. *See* Thomas J. Sullivan, *The Patent Dance*, EUR. BIOPHARM. REV. 72, 74 (2018) ("A . . . mechanism to shorten a suit under the BPCIA would be to collapse the two phases of litigation into a single action in a scenario where the biosimilar applicant provides its 180-day notice of commercial marketing contemporaneously with its notification to the [brand drug-maker] of its [biosimilar application]."). By collapsing the two phases, the parties are effectively writing their own rules. Also, the fact that the second phase can be started before the first phase is complete is a boon to those biosimilars that prioritize getting to market over obtaining the brand's patent disclosure in the patent dance. The second biosimilar typically falls into this category. Unlike the second biosimilar, the first biosimilar has a relatively strong incentive to go through the patent dance: During its own patent dance, the first biosimilar will gain meaningful patent disclosure from the brand (as the brand makes *no* patent disclosure prior to the first biosimilar's patent dance), whereas the second biosimilar's patent dance is less likely to procure meaningful patent disclosure beyond what emerged from the first biosimilar's patent dance. Thus, the second biosimilar has a relatively strong incentive to start phase two immediately so that it can get to market as soon as possible (even if the first phase is so truncated as to generate little or no patent disclosure by the brand). The second biosimilar's conduct in these circumstances presents a variant of the free rider problem discussed below. *See infra* Section III.B.1. Note that while in theory the second biosimilar obtains meaningful disclosure from its patent dance with the brand, in practice the second biosimilar's need for disclosure is often satisfied, at least in significant part, from the disclosure generated by the first biosimilar's patent dance with the brand.

other words, imagine if the biosimilar provides notice of commercial marketing, launching the second phase, and the first phase of the dance has not even reached the point at which the brand *could* file a first-phase suit (let alone move for preliminary injunction). In addition, either 1) the brand's second-phase preliminary injunction motion is denied; 2) the brand doesn't move for a preliminary injunction in the second phase; or 3) the brand never even commences a second-phase suit. In those circumstances, nothing is blocking the biosimilar's entry, and thus the biosimilar has the strategic option of launching at risk.[166] To launch at risk, the biosimilar could simply obtain FDA approval, launch the product after the 180-day waiting period,[167] and invite a claim of actual infringement and damages.

166. *Cf. supra* text accompanying note 28 (describing launching at risk under the Hatch-Waxman Act); *see infra* note 197. Launching at risk under the Biosimilars Act is similar to launching at risk under the Hatch-Waxman Act. The added "risks" flow from the damages the brand will suffer when the generic or biosimilar actually enters the market. Once the generic or biosimilar enters the market and incurs damages liability, the brand can bring a claim for actual infringement and damages. When the brand claims actual infringement and damages, the parties have a right to jury trial. *See* Steven A. Nash & Rebecca Workman, *A New Pathway for Follow-on Biologics*, 20 FED. CIR. BAR J. 193, 216 n.160 (2010) ("Where no biosimilar launch has occurred, the [brand biologic] will be limited to equitable relief [such as an injunction]. Thus, similar to ANDA cases, there will be no right to a jury trial."); GOODWIN PROCTER GUIDE TO BIOSIMILARS LITIGATION, *supra* note 146, § 4:56 (concluding that right to jury trial arises when the brand claims actual infringement and damages, but not when the brand claims only artificial infringement: "As in the Hatch-Waxman context, the alleged infringement in a [Biosimilars Act] case may be prospective only where the biosimilar applicant has not yet commercially marketed any product. In this situation, the patentee typically only seeks injunctive relief because no money damages are at issue, and therefore the patentee's claim is not expected to trigger a right to a jury trial. . . . [But if] a biosimilar applicant were to obtain FDA approval for its product and launch its product prior to patent resolution, the [brand biologic] may allege infringement under § 271(a) and seek damages, triggering a right to a jury trial on infringement and validity of the patents at issue."). As a practical matter, jury trials will probably be more common in Biosimilars Act litigation than in Hatch-Waxman litigation, because biosimilars are more likely than generics to launch at risk, and thus to face a claim of actual infringement and damages. *See infra* note 196 (regarding greater likelihood that biosimilars will launch at risk); Ha Kung Wong & April Breyer Menon, *The State of Biosimilars in 2023*, JD SUPRA (Mar. 17, 2023), https://www.jdsupra.com/legalnews/the-state-of-biosimilars-in-2023-6368882/ (concluding that launching at risk is not uncommon under Biosimilars Act and noting that, of 40 approved biosimilars, 27 have been launched, and 11 of those launched—i.e., 40.7%—were launched at risk).

167. The biosimilar applicant wishing to market its drug commercially must give notice to the brand 180 days in advance. 42 U.S.C. § 262(l)(8)(A). During that period, the brand may move for a preliminary injunction against any commercial marketing of that drug. *Id.* § 262(l)(8)(B). If a preliminary injunction is granted, the commercial marketing of the drug is barred until the court's resolution of the validity, enforcement, and infringement of any patent that is "included in the [Initial Brand List] or the [Biosimilar List] and . . . not included, as

In the litigation that follows a biosimilar's launch at risk, the brand will allege an actual infringement, given that the biosimilar's commercial marketing constitutes actual infringement. In contrast, filing an application for *approval* of a biosimilar constitutes only artificial infringement, allowing the parties to resolve the patent issues before the biosimilar incurs liability for damages from actual infringement.[168] A biosimilar that launches at risk faces the added risk of damages and a potential jury trial. By declining to launch at risk and thus by engaging only in artificial infringement, the biosimilar can assure that a judge, rather than a jury, serves as the trier of fact.[169]

Waiting for the completion of all first-phase litigation, and then commercially marketing while second-phase litigation is ongoing, is not the only launch-at-risk option for a biosimilar. Nothing in the statute obligates the FDA to wait for completion of the dance (or any of its steps) before approving the application.[170] If the biosimilar provides notice of commercial marketing before the Negotiated List is finished or the Failed-Negotiation Lists are exchanged, then the parties likely would automatically enter the second phase. That second phase proceeds as an infringement litigation involving the patents on all existing lists—the Initial Brand List, Biosimilar List, and Supplemental Brand List.[171] If no launch has yet occurred (e.g., because a preliminary injunction against commercial marketing of the biosimilar was granted), the

applicable, on . . . the [Negotiated List] or . . . the [Failed-Negotiation Lists]." *Id.*; *see id.* § 262(l)(7) (making the Supplemental Brand List subject to 42 U.S.C. § 262(l)(8)); *supra* text accompanying notes 155–158. Note that if the court has not decided the preliminary injunction motion by day 180, the biosimilar is then free to begin commercial marketing of its drug and can continue unless and until the court grants the preliminary injunction motion.

As noted above, it is possible to collapse phases one and two if the biosimilar provides its notice of commercial marketing at the start of, or during, phase one. *See supra* note 159; *supra* notes 165–166 and accompanying text; *see also infra* text accompanying notes 171, 218. But collapsing phases one and two can lead to a dizzying number of interpretive problems depending on precisely when in phase one the notice of commercial marketing is provided. A full analysis of these issues and conflicts, however, is beyond the scope of this Article.

168. *See supra* note 166.

169. *See supra* note 166.

170. In contrast, the Hatch-Waxman Act includes a 30-month stay of approval once a patent infringement action is initiated within 45 days of when the generic manufacturer notifies the brand manufacturer that a Paragraph IV certification has been filed. *See* 21 U.S.C. § 355(c)(3)(C), (j)(5)(B)(iii).

171. 42 U.S.C. § 262(l)(8) (permitting brand to move for preliminary injunction against biosimilar's marketing of drug pending court's resolution of infringement claims with respect to any patent on Initial Brand or Biosimilar List that is not on Negotiated or Failed-Negotiation Lists); *id.* § 262(l)(7) (stating that any patent on Supplemental Brand List "shall be subject to [§ 262(l)](8)").

brand's claim is for artificial infringement; if the launch has occurred, the brand can bring a claim for actual infringement and damages.[172]

c) The Brand Also Gets Strategic Options

The Biosimilars Act also leaves room for strategic behavior by the brand. In particular, under the Biosimilars Act regime, if the brand's Initial Brand List does not list a relevant patent, the brand will face at least two consequences. First, the brand will face limitations on its ability to sue the biosimilar company in phase one and phase two. In phase one, the Negotiated List is limited to patents on the Initial Brand and the Biosimilar Lists.[173] A patent omitted from the Initial Brand List cannot be on the Negotiated List, unless, of course, the biosimilar put the patent on its Biosimilar List. Thus, the brand will not be able to sue in phase one for infringement of that patent.[174] Nor, in phase two, can the brand sue or obtain a preliminary injunction for infringement of any patent not litigated in phase one, unless the patent to be sued on was listed in the Initial Brand List (or the Biosimilar List).[175]

Second, the Biosimilars Act's "list it or lose it" provision creates an even more severe penalty.[176] This provision prevents the brand from bringing an ordinary suit under 35 U.S.C. § 271 for infringement of any patents that should have been, but were not, included in its Initial Brand List and Supplemental Brand List.[177]

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172. *See supra* text accompanying notes 27–28, 167–169.

173. *See* 42 U.S.C. § 262(l)(4)(A).

174. *See id.* § 262(l)(6); *cf. supra* note 134 (noting possible drafting error in statutory provision concerning Failed-Negotiation Lists).

175. *See* 42 U.S.C. § 262(l)(8)(B)(i); *supra* note 171; *see also supra* note 156 and accompanying text.

176. *See supra* note 134; *see also infra* text accompanying and following notes 177–178; KEVIN J. HICKEY, CONG. RSCH. SERV., IF11214, DRUG PRICING AND THE LAW: PHARMACEUTICAL PATENT DISPUTES 2 (2019).

177. *See supra* note 176. In contrast, under the Hatch-Waxman regime, if a brand's NDA fails to list a relevant patent, then the generic need not provide a Paragraph IV certification as to that patent. *See supra* note 59 and accompanying text. And absent that certification, the brand can sue the generic for infringement (if the brand can allege actual infringement unprotected by the safe harbor of 35 U.S.C. § 271(e)(1)) but cannot obtain a thirty-month stay in which the FDA cannot approve the generic. *See* HICKEY, *supra* note 176, at 2 (concluding that NDA's failure to list relevant patent bars brand from obtaining 30-month stay); Celgene Corp. v. Sun Pharma Glob. FZE, No. 19-10099 (SDW) (LDW), 2020 WL 1921700, at *2–3 (D.N.J. Apr. 6, 2020) (holding that NDA's failure to list relevant patent does not bar brand from suing generic for infringement of that patent (citing cases)); *see also infra* this footnote. To be clear, if the brand's NDA fails to list a relevant patent, although there may be implications related to the 30-month stay, the brand faces no fine, penalty, or restriction of its right to sue the generic for infringing that patent (though, again, the brand would have to allege actual

Despite this deterrent, the brand might still choose not to list certain patents in its Initial Brand List or Supplemental Brand List. The brand might be under the impression that it may still assert the patent in litigation against other biosimilars, and the company may have a strong incentive to hold back certain patents. Specifically, when a company alleges infringement of a patent in any type of litigation, the allegation puts that patent at risk. In response, the alleged infringer will immediately claim that the patent is invalid or does not apply to the drug at issue.

No company wants to risk its crown jewels unless absolutely necessary. Thus, the brand might ignore the "list it or lose it" provision and hold back its most important patent or patents, on the expectation that asserting other patents will be enough either to stop the biosimilar or to obtain a settlement that keeps the biosimilar off the market for a period of time.[178] If that strategy is successful, the brand's most important patents remain unchallenged and thus remain a possible deterrent to future biosimilar entry. Ultimately, however, the "list or lose it" provision may well be held to bar the brand from asserting those patents in future litigation against others trying to enter.

Even if the strategy fails—with the result that the biosimilar succeeds in knocking out the less important patents and enters the market—holding patents in reserve may still have value to the brand. Historically, average prices have dropped most sharply when several generics enter the market to challenge a brand. Although the brand has lost some market share with the entry of one biosimilar, holding some patents in reserve might help deter multiple entry, even if ultimately the "list it or lose it" provision will bar the brand from enforcing those patents.

Another strategic choice for the brand involves the Supplemental Brand List. The Biosimilars Act expressly includes the Supplemental Brand List within the patents that could be included in the second phase.[179] As described

infringement unprotected by the safe harbor of 35 U.S.C. § 271(e)(1)). *See* JOHN R. THOMAS, CONG. RSCH. SERV., R42354, PATENT INFRINGEMENT AND EXPERIMENTAL USE UNDER THE HATCH-WAXMAN ACT: CURRENT ISSUES 8 (2013); *Celgene*, 2020 WL 1921700, at *2–3. This stands in contrast to the Biosimilars Act as described in the text accompanying this note.

178. *See infra* Section III.B.3 (describing pay-for-delay settlements).

179. 42 U.S.C. § 262(l)(7). To be clear, both text and logic demonstrate that the Supplemental Brand List is part of the first phase (and not just the second). The textual evidence is twofold. First, the statutory provision creating the Supplemental Brand List is in paragraph 7 of § 262(l). The statutory provision creating the second phase is in paragraph 8 of § 262(l). Thus, the placement of the provision creating the Supplemental Brand List in paragraph 7 rather than paragraph 8 is evidence that the Supplemental Brand List is part of the first phase. Second, the statute calls the Supplemental Brand List a "supplement to the [Initial Brand L]ist," 42 U.S.C. § 262(l)(7)(B). Because the Initial Brand List is indisputably part

above,[180] if the brand, after providing the biosimilar with its initial list of relevant patents, receives a new patent that it believes could serve as a basis for an infringement claim, the brand has thirty days to send a Supplemental Brand List.[181] Sending the Supplemental Brand List in the second phase provides the *brand* with strategic choices comparable to those offered to the biosimilar through the bifurcated phasing. Specifically, if the brand can influence the timing of a patent approval by the U.S. Patent and Trademark Office (USPTO), the brand can time the sending of the Supplemental Brand List to reach the biosimilar at an inopportune moment for the biosimilar (e.g., close to the biosimilar's launch date).

Biosimilars would do well, however, to recall that the statute, while expressly making the Supplemental Brand List part of the second phase, also makes that list part of the first phase.[182] As a practical matter, the first phase could readily include a patent on the Supplemental Brand List as long as the Supplemental Brand List is provided before the Negotiated List is finished (or before the Failed-Negotiation Lists are exchanged).

Suppose, however, that a Supplemental Brand List is provided *after* completion of the Negotiated List (or *after* exchange of the Failed-Negotiation Lists) *but before* the second phase of the dance is triggered by the biosimilar

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of the first phase, a supplement to that list should be regarded as part of the first phase, too. True, paragraph 7 also expressly makes the Supplemental Brand List part of the second phase, but that fact does not weaken the conclusion that the Supplemental Brand List is part of the first phase *as well*. As a logical matter, any suggestion that the Supplemental Brand List may be part of the second phrase *exclusively*, *e.g.*, *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1057 (Fed. Cir. 2016), should be rejected. An interpretation of paragraph 7 that makes the Supplemental Brand List part of the second phase *exclusively* would make no sense (aside from ignoring the clear textual evidence cited earlier in this note). Suppose that the brand provides its Initial Brand List to the biosimilar, and the next day obtains a new patent and immediately provides its Supplemental Brand List to the biosimilar—all well before the parties even attempt to negotiate the Negotiated List. Under those circumstances, an interpretation making the Supplemental Brand List exclusively part of the second phase would bar both the brand and the biosimilar from including the new patent in the negotiation of the Negotiated List, even though both parties were aware of the new patent before the negotiation, and both wished to include the new patent in the negotiation. That bar would be senseless. Worse yet, such an interpretation would prevent the brand from litigating the new patent—even though the brand informed the biosimilar of the new patent one day after providing the Initial Brand List—unless and until the biosimilar decides to commence the second phase with a notice of commercial marketing. Precluding the brand from having any *opportunity* to litigate the new patent unless the biosimilar so permits would be pointless and inequitable.

180. *See supra* text accompanying notes 134–135.

181. *See supra* text accompanying notes 134–135.

182. *See supra* note 179 (discussing textual and logical reasons why the Supplemental Brand List is part of the first phase as well as the second).

filing a notice of commercial marketing. In that circumstance, could the first phase include a patent on that Supplemental Brand List as a practical matter? The statutory language is unclear. The alternatives appear to be that (1) the parties agree to amend the Negotiated List to add the new patent, (2) the brand (assuming no Negotiated List was created) can amend its Failed-Negotiation List to add the new patent as long as the addition does not cause undue prejudice to the biosimilar, or (3) the parties begin a new first phase—supplementary to but independent of the existing first phase—addressing the new patent by itself.

In short, the patent dance is an intricate and astoundingly complex series of phases, steps within those phases, and strategic choices for both parties. Some of the steps, choices, and ramifications remain unclear almost fifteen years after President Obama signed the legislation. Moreover, the brand enters the dance in the dark, without knowing in advance what processes the biosimilar is using to make its drug. The biosimilar also enters in the dark, without a clear list of the patents that the brand may assert in protection of the drug. Just understanding the basic processes set forth in the statutory language burns through an enormous amount of ink. Therefore, the Biosimilars Act truly deserves the Federal Circuit's description as "a riddle wrapped in a mystery inside an enigma."[183] Given these frailties, it is not surprising that the Act has fallen short of expectations as a means of enhancing competition in the biologic drug markets and reducing drug prices for consumers.

B. GAMING THE PROCESS

As noted earlier, biologic patent dispute resolution owes its length and complexity to the fact that, prior to its initiation, the biosimilar has little concrete idea of the patents with which its gestating product must contend. Crucially, however, biologic patent litigation also places the responsibility to share relevant information squarely on the shoulders of drug-makers, conferring on them the authority to decide which patents to include on which lists.

Recall that information in the biologic realm—particularly patents and trade secrets relating to manufacturing processes—is extremely valuable to drug-makers given that biologic drug development is difficult, expensive, and incompletely understood. It should come as no surprise, then, that brand companies have the incentive to cooperate less than fully with a regulatory scheme whose objective is to hand that information over to a potential

183. *See supra* text accompanying note 10.

competitor. The following Sections describe how these incentives are playing out on the ground.

1. *Patent Disclosure, the Purple Book Continuity Act, and the Free Rider Problem*

As described in Section II.C, *The Information Desert*, the biosimilar system suffers from a severe lack of information. Unlike the system for generic drugs, the FDA does not publish a comprehensive list of the patents a brand company could reasonably assert in protection of each biologic drug. That lack of information combines with other information gaps related to biologic drugs—including gaps in biologics patents themselves and in the clinical trial data published by the FDA. As a result, a biosimilar company exploring whether to enter a particular market will be completely unable to answer any of the four basic questions: (1) what is the drug; (2) how is it made; (3) what patent rights apply; and (4) when do those rights expire.

Congress attempted to remedy the lack of patent transparency in the biologics space by amending the Biosimilars Act with the Purple Book Continuity Act, also known as the 2020 Transparency Act.[184] The Transparency Act mandates that the Secretary of Health and Human Services publish a listing of licensed biologic drugs and update it monthly. (In fact, the FDA of its own accord began publishing such a list on September 9, 2014,[185] but the Transparency Act formalized that FDA initiative.) Analogous to the Orange Book of non-biologic drugs, the publication, officially titled "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," is better known as the Purple Book.

More significantly, the 2020 Transparency Act mandated that the Purple Book include a list of patents appearing in any Initial Brand List and Supplemental Brand List provided during a patent dance, as well as the expiration dates of those patents.[186] (Note, however, that the 2020

184. The 2020 Transparency Act was enacted as section 325 (entitled "Biological Product Patent Transparency") of the Consolidated Appropriations Act, 2021. *See* Pub. L. No. 116-260, div. BB, tit. III, subtit. C, § 325, 134 Stat. 1182, 2936–38 (2020) (amending Public Health Service Act, 42 U.S.C. § 262(k), by adding new subsection (k)(9), which requires publication of Purple Book).

185. Kurt Karst, *The "Purple Book" Makes Its Debut*, FDA L. BLOG (Sept. 9, 2014), https://www.thefdalawblog.com/2014/09/the-purple-book-makes-its-debut.

186. *See* 42 U.S.C. § 262(k)(9)(A)(iii) ("Not later than 30 days after a list of patents under subsection (l)(3)(A), or a supplement to such list under subsection (l)(7), has been provided by the [brand] to the [biosimilar] applicant respecting a biological product included on the list published under this subparagraph, the [brand] shall provide such list of patents (or

Transparency Act does not call for the publication of any Biosimilar, Negotiated, or Failed-Negotiation Lists.) The new information must be included in the Purple Book within thirty days after the brand gives each relevant list to the biosimilar.

Although this requirement is a step in the right direction, it still grounds disclosure in the patent dance, allowing drug companies to control the information disclosed. Moreover, the requirement may have inadvertently created an additional disincentive for biosimilars by creating a potential "free rider" problem. Under the new regime, patent information does not enter the Purple Book until a biosimilar company has filed an application and the patent dance begins. The first biosimilar company to file an application, therefore, has a distinct disadvantage: It must develop and seek approval for its drug product with zero knowledge of the brand's patent holdings. Later biosimilar applicants preparing for market entry may obtain an advantage by reviewing patents revealed during the first filer's patent dance. Thus, subsequent filers benefit from the risk-taking of the first filer, essentially acting as free riders.

The disadvantage of first-filing biosimilars stands in stark contrast to the treatment of first-filing generics under the Hatch-Waxman Act. With Hatch-Waxman, the first-filing generic to successfully challenge a brand's patent receives the reward of 180 days of market exclusivity. On the other hand, the first-filing biosimilar receives nothing for its troubles but the prospect of hastening the entry of its competitors.[187]

The asymmetrical burden borne by the first-filing biosimilar not only discourages companies from developing biosimilars for markets, but also creates an incentive for first-filing biosimilars to engage in strategic behaviors that will avoid triggering the requirement for patent disclosure. Thus, it creates an alignment of interests between the brand and the biosimilar: Neither one wants to see patent disclosure, a fact that encourages collusion in pursuit of that goal.[188]

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supplement thereto) and their corresponding expiry dates to the Secretary, and the Secretary shall, in revisions made under clause (ii), include such information for such biological product. Within 30 days of providing any subsequent or supplemental list of patents to any subsequent [biosimilar] applicant under subsection (l)(3)(A) or (l)(7), the [brand] shall update the information provided to the Secretary under this clause with any additional patents from such subsequent or supplemental list and their corresponding expiry dates.").

187. With a first-filing interchangeable, however, the interchangeable receives a period of at least one year in which the FDA is barred from granting interchangeability status to a subsequent filer. *See infra* note 213 and accompanying and following text (describing the relevant provision and the varying time periods that may apply).

188. For a discussion of strategic behaviors to reach that goal, *see infra* Sections III.B.2–3.

Society's interests, of course, are the opposite. Low disclosure inhibits biosimilar development, and thus contributes to the cycle of high biologic prices and low biosimilar availability. Neither of those outcomes advances societal goals.

If society's incentive is to encourage information flow to induce competitive entry, the process fails to align incentives properly. Rather, we have established an enormously elaborate system in which no one's interests are aligned with those of the greater society. It is no wonder that the process has failed to induce significant competition. The following Sections describe strategic behaviors the parties utilize in the service of their interests.

2. Evading the Patent Dance

The possibilities for evasive and obfuscating tactics deployed by both brand biologics and biosimilar companies can take a range of forms. At the most basic level, the biosimilar can simply avoid the patent dance by refusing to provide its application and manufacturing information to the brand. This refusal would trigger only a narrow set of potential consequences. As the Supreme Court ruled in 2017 in *Sandoz v. Amgen*, a brand biologic cannot seek an injunction under federal law against a biosimilar for flouting the Biosimilars Act,[189] although injunctive relief may be possible under state law.[190]

The brand does have two options if the biosimilar company simply refuses to follow the patent dance. First, the language of the Biosimilars Act allows the brand to file a declaratory judgment action asking for a finding of infringement, validity, or enforceability of its patents.[191] Second, if the

189. When Sandoz filed for approval to bring into the market a biosimilar to filgrastim, marketed by Amgen under the brand name Neupogen®, Sandoz refused to provide Amgen with a copy of its biosimilar application, despite the requirement of 42 U.S.C. § 262(l)(2)(A). Amgen sought injunctive relief to force compliance, and the case went to the Supreme Court. In a unanimous opinion, the court held that when a biosimilar applicant fails to provide its application and manufacturing information to the brand, the only federal remedy available to the brand is to bring a declaratory judgment action for artificial infringement defined under 35 U.S.C. § 271(e)(2)(C)(ii). Sandoz Inc. v. Amgen Inc., 582 U.S. 1, 12–16 (2017).

190. *See* Sandoz, 582 U.S. at 6, 17–19 (holding that when a biosimilar fails to "provide its application and manufacturing information to the manufacturer of the biologic . . . an injunction is not available under federal law" and remanding on the question of whether an injunction is available under state law).

191. *Id.* at 11, 14–17; 42 U.S.C. § 262(l)(9)(C) ("If a [biosimilar] applicant fails to provide the application and information required under paragraph (2)(A), the [brand], but not the [biosimilar] applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."); *see also infra* note 216 (describing the declaratory judgment option in greater detail).

biosimilar company has received approval and launched the product, the brand can file a good old patent infringement action, moving forward with the conventional patent litigation route that remains waiting in the wings.[192]

The *Sandoz* decision essentially renders participation in the patent dance optional for the biosimilar. More precisely, the Supreme Court held that a brand cannot get an injunction, under federal law, requiring a biosimilar to provide the application it submitted to the FDA or details about its manufacturing process.[193] On remand, the Federal Circuit held that the brand cannot get such an injunction under state law either due to preemption.[194] Nevertheless, the decision makes clear that a biosimilar's failure to provide its application and manufacturing information comes at a cost. When a biosimilar fails to provide its application and manufacturing information, it gives the brand "the control that the [biosimilar] applicant would otherwise have exercised over the scope and timing of the patent litigation." Instead, the brand will be able to file a declaratory judgment action under the Biosimilars Act on *any* number of patents it chooses to list.[195]

In addition, if the biosimilar company not only withholds its application and manufacturing details from the brand, but also proceeds with an "at risk" launch, it exposes itself not just to an actual infringement claim, but specifically to damages liability. In contrast, if the biosimilar company chooses not to launch at risk, the infringement litigation proceeds without the company incurring damages liability.[196] In short, if the biosimilar company launches at

192. Recall that the Hatch-Waxman and Biosimilars Acts provide pathways for a claim of artificial infringement, so that follow-on drug companies can resolve patent disputes without entering the market and risking a large damage award. *See supra* text accompanying note 27. However, the pathway of entering the market and taking the risk of a damage award remains. If the biosimilar refuses to follow the steps of the Biosimilar Act patent dance and chooses to launch at risk, the brand can sue for actual infringement in an ordinary patent lawsuit.

193. *See supra* note 190.

194. Amgen Inc. v. Sandoz Inc., 877 F.3d 1315, 1330 (Fed. Cir. 2017) ("Amgen's state law [claim for injunctive relief is] preempted on both field and conflict grounds.").

195. Sandoz, 582 U.S. at 3, 16.

196. The extent of damages liability is likely smaller for biosimilars than for generics, and thus biosimilars are more likely to launch at risk than are generics. Biosimilar drugs tend to sell at a smaller discount off the price of the brand drug than do generic drugs. *See supra* text accompanying notes 96–97; Zachary Silbersher, *When Do Biosimilars Launch at Risk?*, MARKMAN ADVISORS BLOG (Jan. 25, 2018), https://www.markmanadvisors.com/blog/2018/1/25/why-do-biosimilars-launch-at-risk; Kirke M. Hasson & Maria Salgado, *Biosimilars Enter the Courts: How Will Patent Infringement Settlements Be Tested for Validity Under Antitrust Laws*, A.B.A.: THE ANTITRUST SOURCE (Dec. 2016), https://www.americanbar.org/content/dam/aba/publishing/antitrust-magazine-online/dec16_hasson_12_12f.pdf. Thus, the profit made from a biosimilar drug that is launched at risk is closer in amount to the profit lost by the

risk, it exposes itself to patent litigation with the potential for a damages judgment.[197]

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brand drug as a consequence of the biosimilar's alleged infringement. As a result, the relatively high profit made by the biosimilar launched at risk gives the biosimilar maker a greater ability to pay a damages judgment. By contrast, generic drugs tend to sell at a much steeper discount off the price of the brand drug. Thus, the profit made by the generic drug launched at risk is much smaller in amount than the profit lost by the brand drug as a consequence of the generic's alleged infringement. That relatively low profit made by the generic launched at risk gives the generic relatively less ability to afford the damages liability. The bottom line is that, as commentators have observed, biosimilars are more willing and able to launch at risk than are generics, as the biosimilars are in a stronger position to pay any judgment for infringement damages. *See, e.g.*, Silbersher, *supra*; Hasson & Salgado, *supra*, at 8; *cf.* Wong & Menon, *supra* note 166 (noting that, of 27 launched biosimilars, 11 of them—i.e., 40.7%—were launched at risk, and none of those launched at risk has been ordered to pay damages, though most at-risk launches resulted in settlement). For a data-driven analysis of generic at-risk launches finding that at-risk launches in the dataset were common but that the rate of at-risk launches overall was low, see Keith M. Drake, Robert He, Thomas McGuire & Alice K. Ndikumana, *No Free Launch: At-Risk Entry by Generic Drug Firms*, 29 INT'L J. ECON. BUS. 301, 310–11 (2022).

197. A "launch at risk" occurs when the generic or biosimilar begins commercial marketing at any point during the period after the FDA's approval of the ANDA, or its biosimilar counterpart, becomes effective but before final resolution of the brand's infringement claims. Under the Hatch-Waxman regime, the brand can forestall a generic's launch at risk. If the generic files an ANDA with a Paragraph IV certification and gives notice to the brand, and within 45 days the brand sues the generic for infringement, then the FDA has 180 days to approve or disapprove the ANDA and must make any approval effective 30 months after that notice. 21 U.S.C. § 355(j)(5)(A), (B)(iii). This 30-month period is known informally as the "thirty-month stay"; it effectively bars the generic's launch for a period of time that should be sufficient for the court to rule on the brand's infringement claims. *See* CONG. RSCH. SERV., R44643, THE HATCH-WAXMAN ACT: A PRIMER 8 (2016). If the brand does not sue within 45 days, then the FDA's approval is effective immediately. 21 U.S.C. § 355(j)(5)(B)(iii). Once the FDA's approval is effective, the generic can launch; the launch is "at risk" if at the time of launch the brand's infringement claims have not yet been finally resolved.

Under the Biosimilars Act regime, a launch at risk can occur as early as phase one of the patent dance, when, for example, the parties are still negotiating which patents to put on the Negotiated List. It can also occur later, in the second phase, or even as late as after final judgment, as long as appeals are not yet exhausted.

More specifically, under the Biosimilars Act regime, much depends on whether the biosimilar provides a notice of commercial marketing. If the biosimilar provides a notice of commercial marketing and waits 180 days without the brand obtaining a preliminary injunction, then it can launch at risk. Alternatively, it can launch at risk, before the 180-day period ends, under two scenarios: (1) the brand files suit and moves for a preliminary injunction, the preliminary injunction is denied, but judgment in the underlying phase-two suit has not been entered, or (2) judgment in that suit has been entered for the biosimilar but appeals are not yet exhausted. If the biosimilar does not otherwise wait 180 days, or never provides a notice of commercial marketing, then it can launch at risk; but the brand can file a declaratory judgment action under 42 U.S.C. § 262(l)(9)(B) for a declaration of validity,

Engaging in the patent dance would require the biosimilar company to disclose valuable manufacturing information to the brand—information that the biosimilar may have spent years developing. The company may judge that such disclosure is a risk not worth taking. Although the Biosimilars Act limits the number of parties who can access the information released by the biosimilar and provides for immediate injunctive relief should those parties disclose it, the potential damage to the biosimilar could be difficult to truly remedy in case of a violation.[198] For example, Van de Wiele, Kesselheim, and Sarpatwari suggested that the brand could attempt to hinder the biosimilar company's efforts to avoid infringement by patenting the biosimilar company's manufacturing methods—ones that the biosimilar company has protected as trade secrets.[199] Even without the legal benefits of patent protection, the biologic company could find scientific value in the biosimilar company's methods and could later adopt those methods either when refining the drug at hand or when developing a future drug. A court order to stop disclosing information to unauthorized parties, or to terminate the employment of

infringement, or enforceability of any patent on the Initial Brand or Supplemental Brand List. The brand can also move for an injunction under 35 U.S.C. § 271(e)(4)(B) to enjoin infringement of any patent that is on the Initial Brand or Supplemental Brand List (or that could have been on the Initial Brand List if the biosimilar never provided its application and information to the brand). And, any time a biosimilar launches at risk, the brand can seek damages under 35 U.S.C. § 271(a) or § 271(e)(4)(C).

Note that launching at risk does not take the generic or biosimilar entirely out of the realm of the ANDA or its biosimilar counterpart. The premise of launching at risk is that the FDA has already approved the generic or biosimilar application. Only after approval can a launch at risk be even possible. Thus, launching at risk does not make the FDA withdraw its approval or require that the brand or generic conduct its own clinical trials. The main consequence of a launch at risk is that the generic or biosimilar knowingly shifts to actual infringement (with its risk of damages) from artificial infringement (with no risk of damages). But the issue raised by the brand's liability claim—does the generic or biosimilar drug infringe the brand's patent—stays the same. *See* Bristol Meyers Squibb Co. v. Mylan Pharmas. Inc., No. 17-379-LPS, 2017 WL 3980155, at *8 (D. Del. Sept. 11, 2017). That makes sense: A launch does not change the allegedly infringing drug's chemical compound or manufacturing process. The brand, however, may wish to amend to add a claim for damages and a jury trial, and possibly a claim for willful infringement. GOODWIN PROCTER GUIDE TO BIOSIMILARS LITIGATION, *supra* note 146, § 4:56 (damages and jury trial); Grace Lillian Wang, Teva v. Eisai*: What's the Real "Controversy"?*, 66 FOOD & DRUG L.J. 631, 638 n.46 (2011) (willful infringement).

198. Van de Wiele, Kesselheim & Sarpatwari, *supra* note 94, at 1200; 42 U.S.C. § 262(l)(1)(H).

199. Van de Wiele, Kesselheim & Sarpatwari, *supra* note 94.

violators, would do little to make up for the potentially long-lasting effects of such information leakage.[200]

Although brands could complain that the entire Biosimilars Act process similarly puts at risk the information that they have spent years developing, the circumstances are different. The brand has already received the benefit of excluding others from making, using, or selling the drug during the period of its patents. The disclosures required by patent law are the *quid pro quo* for receiving that valuable period of protection,[201] and any disclosures the brand must make under the Biosimilars Act regime help prevent the brand from extending its period of protection.[202]

After the *Sandoz* decision, some commentators optimistically predicted that conventional patent litigation resulting from a biosimilar manufacturer's refusal to participate in the patent dance would lead to improved transparency. Through discovery, the biosimilar company would "almost certainly" have to disclose its application and manufacturing information.[203] Similarly, the brand presumably would have to provide a list of all the patents it believes might be infringed by the biosimilar, including patent applications in process or recently purchased.[204] This perspective rested on several hopeful assumptions: that conventional patent litigation would achieve disclosure more readily than the patent dance, and that conventional litigation would not present its own opportunities for avoidance and collusion.

Life is rarely so rosy on the ground, and, indeed, the hopeful assumptions about the benefits of conventional patent litigation have proven false in practice. From the perspective of transparency, conventional patent litigation operates more poorly than the Biosimilars Act. Specifically, participation in the patent dance forces the brand biologic to disclose its patents or lose the right

200. *Id.* To the extent a biosimilar has any remedy for a brand's opportunistic use of information provided by the biosimilar, the solution appears to be a private agreement between the brand and the biosimilar, entered into before any disclosure is made by the biosimilar, in which the brand agrees not to base any patent application on (or otherwise use) the biosimilar's disclosure. *See infra* note 270.

201. *See* Feldman, *supra* note 72, at 8 (describing the classic analysis of patent disclosure as the quid pro quo for receiving a patent).

202. *See supra* note 24 and accompanying text (describing a goal of Hatch-Waxman, on which the Biosimilars Act is modeled, as preventing brands from artificially extending their period of monopoly by the amount of time a generic needs to obtain FDA approval after the brand's patent expires).

203. Jacob S. Sherkow, *The Science of Substitution: A Response to Carrier and Minniti*, 2018 U. ILL. L. REV. ONLINE 81, 87.

204. *Id.*

to assert them in litigation;[205] conventional patent litigation makes no such explicit requirement.[206] Thus, conventional patent litigation *removes* any transparency incentive. After all, in a conventional patent litigation, why show your hand when you can hold back patents to use in a future litigation against other parties[207] (and sometimes even against the same party[208])?

Since the *Sandoz* decision, biosimilar companies may have realized the drawbacks of refusing the patent dance. In the first year after *Sandoz*, most biosimilar companies involved in litigation failed to complete the patent dance; beyond that year, biosimilar companies have largely opted into the patent dance—from start to finish.[209]

What do the FDA and the brand do if the biosimilar opts not to comply with the patent dance? Standing first in the government's shoes, the FDA's approval of a biosimilar application technically does not depend on whether the biosimilar participates in the patent dance.[210] The picture is more nuanced,

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205. *See supra* note 134 (discussing consequences of brand's failure to list a relevant patent); *see also supra* notes 176–177 and accompanying and following text (same); *infra* note 240 and accompanying and following text (same). *But see* Brian D. Coggio, *Can Reference Sponsor Forfeit Right to Sue Under BPCIA?*, JD SUPRA (July 25, 2016), https://www.jdsupra.com/post/contentViewerEmbed.aspx?fid=eb404140-f7d8-44b8-aabf-3d08a5a11cc8 (arguing that "section" means "section" in 35 U.S.C. § 271(h), but it means "subsection" in "list it or lose it" provision, *see* 35 U.S.C. § 271(e)(6)(C), and thus, "list it or lose it" provision should be read narrowly); *cf.* CONG. RSCH. SERV., *supra* note 134, at 37–38 & nn.334, 335; Carrier & Minniti, *supra* note 107, at 40 n.353 (2018).

206. 35 U.S.C. § 271(e)(6); Yang Li, *Does It Still Take Two to Tango? A Modern Interpretation of the BPCIA's Patent Dance*, 9 N.Y.U J. INTELL. PROP. & ENT. L. 107, 126 (2019).

207. *But see supra* text accompanying notes 178–179 (describing ways that the brand may hold back patents even when participating fully in the Biosimilars Act patent dance).

208. Although application of res judicata in the context of patent infringement litigation is complex and highly fact-specific, there are circumstances in which res judicata will not likely bar a second action between the same parties concerning a different patent. For example, res judicata, while ordinarily barring claims that *could have been brought* in the first action, is less likely to bar the second action where the accused products in the two actions are different, where the infringing activity alleged in the second action occurred after judgment was entered in the first action, and where the first action was not fully litigated on the merits or did not involve the same issues as those litigated in the second action. *See* 6 ROBERT A. MATTHEWS, JR., ANNOTATED PATENT DIGEST § 38:14–16.50 (2023).

209. Between August 2, 2017 and March 8, 2018—the first year after the Supreme Court ruling in *Sandoz v. Amgen* on June 12, 2017—six of the eight biosimilars involved in litigation failed to complete the patent dance. Afterwards, however, only one of the eleven biosimilars involved in litigation between July 2, 2018 and April 27, 2021 failed to complete the patent dance. *See* Yun Dong, *Keep on Dancing: The Success and Failures of Patent Dance as Shown by BPCIA Litigation Cases Filed After* Sandoz v. Amgen, 83 U. PITT. L. REV. ONLINE 1, 17–19 tbl.1 (2022).

210. *See* KEVIN J. HICKEY, ERIN H. WARD & WEN W. SHEN, CONG. RSCH. SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE

however, given that other features of the Biosimilars Act, outside the patent dance, may restrict the FDA's ability to grant approval. The extent of the restriction will depend on how much time has passed between the brand drug's approval and the biosimilar applicant's request for approval, and whether other exclusivities, known as data exclusivities,[211] are in force. Recall that after the FDA approves the brand drug's license application, no biosimilar application may even be filed for four years, and the FDA is barred from approving a biosimilar application for twelve years.[212] Thus, if the biosimilar company opts out of the patent dance within that twelve-year period, the FDA cannot approve the biosimilar before the period ends (although note that the reason for lack of approval is not the biosimilar company's opt-out from the patent dance, but rather the brand's twelve-year exclusivity period). However, if the biosimilar company opts out of the patent dance *after* the brand's twelve-year exclusivity ends, then the FDA is free to approve or disapprove the biosimilar application, subject to one exception: If a first biosimilar has received a determination of interchangeability from the FDA, and the application of a second biosimilar relies on the same reference product that the first relied on, then there is a period of time in which the FDA may not make a determination that the second biosimilar is interchangeable.[213] In other words, the first interchangeable biosimilar receives an exclusivity period of at least one year (during which the FDA cannot grant approval to a second interchangeable)

116TH CONGRESS, at summary (2019) ("The patent dance does not affect FDA's ability to approve a biosimilar application."); *id.* at 30–32 (noting that while Hatch-Waxman Act bars FDA from approving generic application for 30 months after brand commences infringement litigation against generic, Biosimilars Act does not bar FDA from approving a biosimilar application while the patent dance is still ongoing); *id.* at 34 (FDA approval is not contingent on resolution of patent disputes).

211. This is commonly known as a "data exclusivity" from the perspective that it represents a benefit to the brand in exchange for giving biosimilars the ability to use the brand's clinical data. *See* Henry Grabowski, Genia Long & Richard Mortimer, *Data Exclusivity for Biologics*, 10 NATURE REV. DRUGS DISCOVERY 15 (2011).

212. *See* 42 U.S.C. § 262(k)(7)(A), (B).

213. In such a case, the FDA may not make a determination of interchangeability until the earlier of: one year after the first commercial marketing of the first interchangeable biosimilar, *see id.* § 262(k)(6)(A); 1.5 years after resolution of an infringement action brought in phase one of the patent dance against the applicant that submitted the application for that first interchangeable biosimilar, *see id.* § 262(k)(6)(B); 3.5 years after approval of the first interchangeable biosimilar if the applicant that submitted the application for that first interchangeable biosimilar has been sued for infringement in phase one of the patent dance and that suit is still ongoing within that 3.5-year period, *see id.* § 262(k)(6)(C)(i); or 1.5 years after approval of the first interchangeable biosimilar if the applicant that submitted the application for that first interchangeable biosimilar has not been sued in phase one of the patent dance, *see id.* § 262(k)(6)(C)(ii).

much as the brand receives a 12-year exclusivity period (during which the FDA cannot grant approval to any biosimilar). Note that the FDA may grant approval without the biosimilar even commencing the second phase of the patent dance, if neither the brand's exclusivity nor a first interchangeable's exclusivity is in force.[214]

Standing in the brand's shoes, once the FDA has approved the biosimilar, and the biosimilar company has opted out of the patent dance, the brand may sue the biosimilar company. The nature of the brand's claims depends on whether the biosimilar has launched at risk by the time of suit.[215] If the biosimilar has not launched at risk, the Biosimilars Act provides that the brand can bring a declaratory judgment action against the biosimilar for a declaration of infringement, validity, or enforceability.[216] If the biosimilar has launched at risk, the brand can bring conventional patent-infringement litigation against the biosimilar, including a claim for damages (e.g., lost profits).[217]

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214. *See* Sandoz Inc. v. Amgen Inc., 582 U.S. 1, 19 (2017) (holding that notice of commercial marketing can be given "before or after" FDA approval).

215. *See supra* note 197 (discussing launch at risk).

216. *See* 42 U.S.C. § 262(l)(9)(B), (C). When there is uncertainty surrounding the legal obligations or rights between two parties, a declaratory judgment resolves that uncertainty by using a binding court decision to define the legal relationship between parties and their legal rights. *See Declaratory Judgment*, CORNELL L. SCH. LEGAL INFO. INST., https://www.law.cornell.edu/wex/declaratory_judgment (last updated Sept. 2022). If the biosimilar opts out *ab initio* (i.e., without even providing its application or manufacturing information), the brand's declaratory judgment claim can allege infringement of any patent protecting the brand product. *See* 42 U.S.C. § 262(l)(9)(C). If the biosimilar opts out later in the patent dance (i.e., after providing its application and manufacturing information), the brand's declaratory judgment claim can allege infringement of any patent on the Initial Brand List or Supplemental Brand List. *Id.* § 262(l)(9)(B).

217. *See* 35 U.S.C. § 271(a) (providing for infringement liability in cases of actual infringement, namely, the making, use, offer to sell, or sale of the patentee's product); *id.* § 271(e)(4)(C) (providing that for an artificial infringement under 35 U.S.C. § 271(e)(2), courts may award damages and other monetary relief against the infringer if it engaged in the commercial manufacture, use, offer to sell, or sale of the patentee's product); AbbVie Inc. v. Alvotech hf., 582 F. Supp. 3d 584, 591–92 (N.D. Ill. 2022) (citing 35 U.S.C. § 271(e)(2), (4)); *cf.* Hasson & Salgado, *supra* note 196, at 4; *supra* note 28 and accompanying text (discussing damages liability following at-risk launch).

Note also that if a generic or biosimilar is launched at risk, then the brand is exempted from the price-negotiation provisions of the Inflation Reduction Act. *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11001, 136 Stat. 1818, 1837, 1839 (2022) (adding, among other things, section 1192(c)(1) and (e)(1) to Title XI of Social Security Act); Danielle A. Duszczyszyn, Matthew J. Luneack & Jordan M. Gringauz, *Potential Implications of Inflation Reduction Act on Pharmaceutical Patent Litigation*, BLOOMBERG L. (May 2023), https://www.bloomberglaw.com/external/document/XA2O6QAO000000/patents-professional-perspective-potential-implications-of-infla ("In Hatch-Waxman or BPCIA litigation, if there

Although the Section above describes ways in which parties can choose to evade the patent dance, other parties are choosing to reshape the dance. According to some biosimilar practitioners, if their clients prioritize getting the drug to market quickly over obtaining patent disclosure from the brand, the practitioners simply collapse the two phases of the dance by filing a notice of commercial marketing at the same time as they give the brand the application for FDA approval.[218]

One should not lose sight of the impact of these puzzling provisions of the Biosimilars Act—an impact that extends far beyond courtrooms and the C-suites of pharmaceutical companies. In particular, the persistently high biologic prices continue to limit access and strain household budgets.[219] This result flows in part from the complexity of the patent dance,[220] the paucity of disclosures regarding intellectual property rights, [221] and the ample opportunities for gaming the process.[222] These factors combine to suppress the ability of the Biosimilars Act to encourage biosimilar entry[223] and to restrain any extended monopoly pricing for brand biologics.[224] The following Sections describe additional strategic behaviors that interact with Biosimilars Act provisions and hinder the effectiveness of the legislation.

3. Pay-for-Delay

Evasion of disclosure hardly ends with evasion of the patent dance. To conclude the litigation initiated by the biologic drug-maker, both the biologic and biosimilar makers may turn to the tried-and-true scheme of pay-for-delay. A common tactic in the non-biologic realm, pay-for-delay occurs when a brand

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is an 'at-risk' launch of a generic or biosimilar product, an otherwise eligible reference product will immediately become ineligible for selection under the IRA."); CTRS. FOR MEDICARE & MEDICAID SERVS., DEPT. OF HEALTH & HUM. SERVS., MEDICARE DRUG PRICE NEGOTIATION PROGRAM: REVISED GUIDANCE, IMPLEMENTATION OF SECTIONS 1191 – 1198 OF THE SOCIAL SECURITY ACT FOR INITIAL PRICE APPLICABILITY YEAR 2026 2, 6, 72–73, 101–02, 164–66 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

218. *See supra* Section III.A.2.b (explaining that the biosimilar has the option to collapse the two phases of the patent dance by filing its notice of commercial marketing before the conclusion of the first phase and that in such circumstances the biosimilar may launch at risk absent a preliminary injunction); *see also* cases cited *supra* notes 164–165 and accompanying and following text.

219. *See infra* notes 309–310 and accompanying text; *see also supra* Section II.D.

220. *See supra* Section III.A.

221. *See supra* Section III.B.1.

222. *See supra* Section III.B.

223. *See supra* Section II.D.

224. *See infra* text accompanying notes 231–232; *see also infra* Section III.C.

drug-maker and a generic drug-maker agree to settle a patent infringement suit such that the brand transfers cash or other source of value to the generic. In exchange, the generic agrees to stay out of the market for a designated period of time. The deal is also known as a "reverse payment settlement" because the flow of value moves atypically from the plaintiff to the defendant.

This type of deal serves the interest of both parties.[225] The consumer, however, suffers harm from any delay in which lower-priced versions fail to come to market. In the non-biologic context, the tactic has been enormously damaging, costing patients at least $6.2 billion per year between 2006 and 2017.[226]

Given the relatively recent enactment of the Biosimilars Act and the low number of biosimilar challenges mounted in the United States, there would have been limited opportunities for pay-for-delay settlements in the biologic realm. In fact, many scholars have speculated that pay-for-delay schemes may occur less frequently in connection with biologic patent litigation.[227] They point out that prohibitions on automatic substitution declaw the threat of biosimilar entry and that the 2011 introduction of *inter partes* review proceedings has enabled biosimilars to challenge biologic patents in a short and relatively inexpensive filing before the Patent Office, even before filing their applications.[228] Finally, these scholars assert that despite the looming prospect of trade secret disclosure in the Biosimilars Act patent dance, biologics would find paying for delay to be less than worthwhile.[229]

Unfortunately, evidence to the contrary has begun to trickle in. One analysis of all twenty-one lawsuits related to Biosimilars Act litigation filed through August 1, 2020 found that eleven—more than 50%—ended in

225. *See, e.g.*, C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1575–76 (2006); Feldman & Frondorf, *supra* note 29, at 511 (2016); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 39–40 (2009).

226. Feldman, *supra* note 32, at 32.

227. *See, e.g.*, Carrier & Minniti, *supra* note 107, at 21; Hasson & Salgado, *supra* note 196, at 5.

228. Carrier & Minniti, *supra* note 107, at 29, 30; Jennifer E. Struiale, *Hatch-Waxman Patent Litigation and Inter Partes Review: A New Sort of Competition*, 69 ALA. L. REV. 59, 85–86 (2017).

229. *See* Carrier & Minniti, *supra* note 107, at 21 ("Because of the more modest effects of biosimilar entry, biologics' first mover advantages, and increased use of IPR proceedings, settlements involving payment and delayed entry should be less likely in the biologic setting." (citations omitted)); Hasson & Salgado, *supra* note 196, at 4–5 (arguing that the lack of automatic substitution laws for biosimilars, the lengthy regulatory exclusivity period awarded to brand biologics, and the lack of exclusivity for the first non-interchangeable biosimilar will have the likely effect of reducing biologics' incentives to pursue pay-for-delay settlements).

settlement.[230] Although cases settle for many reasons, the number of settlements at least suggests the opportunity for collusive settlements.

Other indicators suggest the possibility of pay-for-delay. Of the eleven cases that settled, five resulted in lengthy delays between FDA approval of the biosimilar and its market entry, ranging from twenty-two months to several years.[231] Four more produced shorter delays of one to eleven months.[232]

Even if the settlements do not result in delay, they can be counter-productive to the public interest while serving the interests of the parties. Recall the free rider problem, in which the first-filing biosimilar takes on the effort and risk of developing a product and challenging the biologic with no knowledge of the biologic's patents while later-filing biosimilars get the benefit of seeing patents that were publicly disclosed through the first-filer's patent dance.[233] The biologic and biosimilar could cut a deal establishing a duopoly without trading patent lists. In this way, the biosimilar gets to enter the market without facilitating further biosimilar competition through public disclosure of those lists, and the biologic gets to prevent its patents from being challenged in this litigation. The biologic also gets to better protect those patents from the curious eyes of future biosimilar challengers, who would be able to plan for the patents that will be launched against them. In short, settlements can ensure that patents deserving of reassessment remain unchallenged and that prospective biosimilars continue to operate in the dark.

4. Other Disclosure Problems in the Biosimilars Regime

Another way of gaming the process is to exploit loopholes in other statutory disclosure requirements. Although the Hatch-Waxman Act requires generic applicants to report any settlements that arise from a Paragraph IV challenge,[234] the Biosimilars Act had no reporting requirements prior to 2018. In 2018, Congress amended the Biosimilars Act in an effort to introduce commensurate requirements.[235] As part of the amendment, a biosimilar

230. Van de Wiele, Kesselheim & Sarpatwari, *supra* note 94, at 1198, 1202.

231. *Id.*

232. *Id.*

233. *See supra* text accompanying notes 186–187.

234. Limin Zheng, *How Will Trump's New FTC/DOJ Reporting Requirements Impact Biosimilars?*, BIOSIMILAR DEV. (Nov. 13, 2018), https://www.biosimilardevelopment.com/doc/how-will-trump-s-new-ftc-doj-reporting-requirements-impact-biosimilars-0001; 21 U.S.C. § 355.

235. *See* Patient Right to Know Drug Prices Act, Pub. L. No. 115-263, § 3(2)(B), 132 Stat. 3672, 3674 (Oct. 10, 2018) (codified as 21 U.S.C. § 355 note); SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, tit. IV, § 4004, 132 Stat. 3894, 3960–61 (Oct. 24, 2018) (codified as 21 U.S.C. § 355 note); AGATA DABROWSKA, VICTORIA R. GREEN & LISA

applicant must now report any settlements that occur after providing the Biosimilar Detailed Statement alleging that the patents in the Initial Brand List are invalid or not infringed.[236] As explained below, however, the new biosimilar requirements added in 2018 have had limited impact because they are entwined with the patent dance. In addition, collusive agreements between brand and biosimilar can evade these requirements, and they remain difficult to detect.

The 2018 amendment tied its disclosure requirements to a key step in the patent dance—the furnishing of the Biosimilar Detailed Statement alleging that the brand's patents are invalid or not infringed.[237] Although the Biosimilar Detailed Statement would appear to be analogous to the generic's Paragraph IV certification—both documents make assertions about whether the reference product's patents are valid or infringed—the crucial difference lies, once again, in the difference between the two regimes. Under Hatch-Waxman, if a generic applicant wants to enter the market before the patents expire, it must submit a Paragraph IV certification challenging each patent related to the brand drug that has not expired at the time of filing for approval.[238] Thus, submitting Paragraph IV certifications is part and parcel of the generic's application for FDA approval, which makes reporting of settlements difficult to avoid. This is not the case for biosimilar drug-makers; they are obligated to report a settlement only if the parties engage in the patent dance and complete at least its first few steps. If the parties settle before the biosimilar provides the Biosimilar Detailed Statement, or if the biosimilar chooses not to submit a statement, the settlement will not be reported. Thus, parties can continue to make collusive agreements with the authorities none the wiser.[239]

One could argue that the contrast between the requirement to report settlements to competition authorities under the two regimes flows from the difference in the disclosure requirements. The biosimilar company cannot submit a statement about invalidity or noninfringement of patents from the outset of filing for approval because there is no public listing of patents that the brand might assert. After all, a biosimilar company cannot allege that the brand's patents are invalid or not infringed when the biosimilar company

N. SACCO, CONG. RSCH. SERV., R45405, THE SUPPORT FOR PATIENTS AND COMMUNITIES ACT (P.L. 115-271): FOOD AND DRUG ADMINISTRATION AND CONTROLLED SUBSTANCE PROVISIONS 27 (2018).

236. *See supra* note 235.

237. *See supra* notes 235–236 and accompanying text.

238. Zheng, *supra* note 234; *Patent Certifications and Suitability Petitions*, U.S. FOOD & DRUG ADMIN. (Apr. 20, 2021), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/paragraph-iv-drug-product-applications-generic-drug-patent-challenge-notifications.

239. *See supra* notes 236–237 and accompanying text.

doesn't even know what those patents are. Thus, the biosimilar company can file its application for approval, triggering notice to the brand, and the parties can settle without ever incurring the obligation to report the settlement to competition authorities.

In theory, a brand and a generic in the Hatch-Waxman arena could manage to settle before the generic files an application—the point at which a Paragraph IV certification would be needed—and thereby avoid triggering the requirement to report the settlement. Such a scenario, however, would be less likely. The generic would have to reach out to the brand saying, "Hey, we are about to file for approval; want to settle?" Alternatively, the brand could figure out which companies are getting close to developing a competing product and reach out to them proactively, but one would expect generics to keep such competitive information under wraps.

The strategies considered thus far in this Section largely follow from the biosimilar's initiative not to participate in the patent dance. The brand, however, has games to play as well. For example, noncompliance with the Biosimilars Act is far from the sole domain of the biosimilar. Given that brand biologics are not required to identify patents at the time of filing for approval, as brand non-biologics are in the Hatch-Waxman realm, biologics have their own reasons to avoid the patent dance. As a result, they may choose not to send the Initial Brand List of patents to a prospective biosimilar maker in order to avoid having that list included later in the Purple Book. Of course, certain statutory provisions disincentivize this brand behavior—the "list it or lose it" provision and the provision limiting preliminary injunction motions to patents that were on the Initial Brand List or Supplemental Brand List (but not the Negotiated or Failed-Negotiation Lists).[240] The extent to which courts will enforce those provisions, however, remains to be seen.

5. *Using 28 U.S.C. § 1782 to Circumvent the Confidentiality Protecting the Biosimilar's Disclosures*

By statutory command, both the biosimilar application and the manufacturing information that the biosimilar developer gives the brand at the outset of the patent dance are accorded confidential treatment.[241] The recipients and the use of those materials are severely limited.[242] Although the Biosimilars Act allows the brand and its inside and outside counsel to receive the materials, the Act bars those recipients from disclosing the materials to

240. *See supra* note 134.
241. *See* 42 U.S.C. § 262(l)(1)(A)–(D).
242. *Id.*

anyone else, including other brand employees, outside scientific consultants, or other outside counsel.[243] Nor can the brand or its inside or outside counsel use the materials for any purpose other than determining whether the brand could bring a claim for infringement of the brand's patent(s) if the biosimilar manufactured or sold the drug at issue in the biosimilar application.[244]

Nevertheless, in one recent case, the brand arguably succeeded in sidestepping these confidentiality strictures. Amgen sells osteoporosis drugs, whose active ingredient is denosumab, and owns patents on denosumab. Sandoz filed an application with the FDA for approval of a denosumab biosimilar. Amgen and Sandoz engaged in the patent dance, pursuant to which Sandoz gave its biosimilar application (though not its manufacturing information)[245] to Amgen. Amgen then brought a phase-one infringement suit against Sandoz and two of its European affiliates in the District of New Jersey.[246]

Although the Court's ultimate decision is silent on Amgen's motivation,[247] Amgen apparently realized that it could use the biosimilar's application to support a preliminary injunction motion in European courts against the biosimilar's European affiliates, which were about to manufacture their own denosumab biosimilar. However, the patent dance's statutory confidentiality strictures barred the use of any document received in the patent dance. Thus, Amgen needed a way, independent of the patent dance, to obtain a statutorily unrestricted copy of the biosimilar application.

The solution Amgen found was 28 U.S.C. § 1782.[248] That provision authorizes any interested party who seeks documents for use in a foreign

243. *Id.* § 262(l)(1)(B)–(C).

244. *Id.* § 262(l)(1)(D).

245. *See* Memorandum of Law in Support of Amgen Inc.'s *Ex Parte* Application Pursuant to 28 U.S.C. § 1782 for an Order Compelling Discovery for Use in a Foreign Proceeding at 2 n.3, *In re*: Request from Vienna, Misc. No. 23-mc-258-CFC (D. Del. Sept. 26, 2023), ECF No. 2.

246. *In re*: Request from Vienna, Misc. No. 23-mc-258-CFC, 2023 WL 6278815, at *1 (D. Del. Sept. 26, 2023) (citing Amgen Inc. v. Sandoz Inc., No. 2:23-cv-020406, D.I. 1 (D.N.J. May 1, 2023).

247. *See id.*

248. *See id.* at *6. Section 1782 provides in relevant part: "The district court of the district in which a person resides or is found may order him to . . . produce a document . . . for use in a proceeding in a foreign or international tribunal . . . . The order may be made . . . upon the application of any interested person . . . . To the extent that the order does not prescribe otherwise, . . . the document or other thing [shall be] produced[] in accordance with the Federal Rules of Civil Procedure. A person may not be compelled . . . to produce a document . . . in violation of any legally applicable privilege."

proceeding to apply to the federal district court, in the district where the person possessing the documents resides, for an order compelling production. Amgen reasoned that if it obtained the biosimilar application, not through the statutory patent-dance provisions (which include the confidentiality strictures described above), but rather through Section 1782, the patent dance's confidentiality strictures would not apply. According to this reasoning, Amgen could freely use the biosimilar application in the European courts. Thus, in *In re: Request from Vienna*,[249] Amgen applied to the District Court for the District of Delaware, where Sandoz resides, for an order under Section 1782 compelling Sandoz to produce its biosimilar application.[250]

When ruling on a Section 1782 application, the judge's decision is discretionary, not mandatory.[251] As the Supreme Court has explained, the statute sets forth criteria that applicants must meet to be eligible for a favorable exercise of discretion; if the applicant meets the criteria, then the district court must consider discretionary factors when ultimately determining whether to grant or deny the application.[252] The District Court ruled that Amgen met the eligibility requirements[253] and also ruled in favor of Amgen on the discretionary factors.[254]

The court also rejected Sandoz's argument that the statutory confidentiality protecting documents provided in the patent dance barred Amgen's Section 1782 application.[255] The court held that those statutory

249. *In re*: Request from Vienna, 2023 WL 6278815. While this discussion of *In re*: *Request from Vienna* is based on court filings, the fullness of the discussion is limited by the facts that many of those filings are under seal or redacted, and that, because the case is still ongoing, new filings continue to appear on the docket even as this Article goes to press.

250. *Id.* at *1–2. More precisely, Amgen sought an order permitting it to serve Sandoz with a subpoena for several categories of documents, including the biosimilar application. *Id.*

251. Intel Corp. v. Advanced Micro Devices, Inc., 542 U.S. 241, 255 (2004).

252. *Id.* at 255–66; *In re*: Request from Vienna, 2023 WL 6278815, at *2. The eligibility criteria are: the person from whom the documents are sought "resides or is found" within the district; the documents are "for use in a proceeding before a foreign or international tribunal"; and the application is made by an "interested person." 28 U.S.C. § 1782(a). Discretionary factors identified by the Supreme Court are: "whether the person from whom discovery is sought is a participant in the foreign proceeding since such a person may possess evidence unobtainable absent § 1782(a) aid"; "the nature of the foreign tribunal, the character of the foreign proceedings, and the receptivity of the foreign court to federal judicial assistance"; "whether the request conceals an attempt to circumvent foreign proof-gathering restrictions"; and "whether the request is unduly intrusive or burdensome." *In re:* Request from Vienna, 2023 WL 6278815, at *5 (internal quotation marks omitted) (quoting *Intel*, 542 U.S. at 264–65).

253. *In re*: Request from Vienna, 2023 WL 6278815, at *2–4.

254. *Id.* at *5.

255. *Id.* at *6.

provisions, by their terms, accord confidentiality only to documents obtained during the patent dance.[256] They do not apply, the court held, to documents obtained through discovery tools independent of the patent dance.[257]

On the one hand, the decision does not significantly weaken the Biosimilars Act. Rather, the decision applies only in limited circumstances, given that Section 1782 is applicable only where a foreign proceeding is reasonably contemplated.[258] Moreover, a federal district court decision does not constitute binding precedent.[259]

On the other hand, the decision chips away at the Biosimilars Act's confidentiality protections,[260] and thus will discourage biosimilar companies from giving their biosimilar applications and manufacturing information to brands during future patent dances. The decision also upholds what is indisputably an end-run around the Biosimilars Act, and thereby encourages other efforts to circumvent the Act's provisions.[261] Indeed, it was undisputed

256. *Id.*

257. *Id.*

258. More concretely, the circumstances apply only where a biosimilar's foreign affiliate is manufacturing or marketing an analogous biosimilar that may infringe foreign patents analogous to the brand's U.S. patents.

259. *See, e.g.*, Colby v. J.C. Penney Co., 811 F.2d 1119, 1124 (7th Cir. 1988) (holding that district court decisions in federal system cannot be binding precedent: "[D]istrict judges in this circuit must not treat decisions *by other district judges,* in this and *a fortiori* in other circuits, as controlling . . . . Such decisions will normally be entitled to no more weight than their intrinsic persuasiveness merits. The reasons we gave for giving some though not controlling weight to decisions of other federal courts of appeals do not apply to decisions of other district courts, because the responsibility for maintaining the law's uniformity is a responsibility of appellate rather than trial judges and because the Supreme Court does not assume the burden of resolving conflicts between district judges whether in the same or different circuits. Federal district judges in Detroit do not make law that is binding on federal district judges in Chicago." (emphasis in original)).

260. While the decision does indeed chip away at the statutory confidentiality protections, biosimilars can still protect themselves through carefully drafted protective orders. Indeed, after Amgen served its subpoena on Sandoz, the parties entered into a stipulated protective order that restricts Amgen's use of confidential materials received from Sandoz. *See* Stipulated Protective Order ¶ 25, *In re*: Request from Vienna, Misc. No. 23-mc-258-CFC (D. Del. Nov. 14, 2023), ECF No. 39 (limiting use of confidential materials to instant action and to patent infringement proceedings brought in European courts by Amgen, and barring use of those materials for patent prosecution or other commercial use).

261. Furthermore, any attempted circumvention of *domestic* law should counsel reluctance by the court to grant § 1782 relief. *See, e.g.*, *In re* Pishevar, No. 21-mc-105, 2023 WL 2072454, at *4 (D.D.C. Feb. 17, 2023) ("Nothing in the record indicates that Mr. Pishevar is seeking discovery here via Section 1782 to circumvent the proof-gathering rules or policies of either *this Court* or the courts of England." (emphasis added)). Note that the list of discretionary factors identified in the Supreme Court's principal holding interpreting § 1782 was broader

that Amgen had received Sandoz's application during the patent dance.[262] Amgen, therefore, was restricted by statutory confidentiality from using that document in the European litigation and sought a way to circumvent the restriction.[263] Arguably, that circumvention alone warranted denial of the Section 1782 relief sought by Amgen.[264]

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than the District of Delaware's paraphrase of that holding: The Supreme Court held that, in deciding the scope of any § 1782 relief, "a district court could consider whether the § 1782(a) request conceals an attempt to circumvent foreign proof-gathering restrictions or other policies of a foreign country *or the United States*." Intel Corp. v. Advanced Micro Devices, Inc., 542 U.S. 241, 264-65 (2004) (emphasis added); *cf. In re*: Request from Vienna, 2023 WL 6278815, at *5 ("whether the request 'conceals an attempt to circumvent foreign proof-gathering restrictions'" (quoting *Intel*, 542 U.S. at 265)). Even if the Supreme Court had not so mentioned circumvention of domestic law, a district court could still consider such circumvention to be a relevant discretionary factor: The Supreme Court's list of factors was non-exhaustive, as the Court held that it was listing "factors" rather than "the factors." *Intel*, 542 U.S. at 264 ("We note below factors that bear consideration in ruling on a § 1782(a) request."). Nevertheless, the decision to grant § 1782 relief here will lessen that reluctance.

262. *In re*: Request from Vienna, 2023 WL 6278815, at *1 ("[During the patent dance,] Sandoz Inc. provided Amgen a copy of its [Biologics License Application ('BLA')], which contains certain information about the processes Sandoz Inc. uses to manufacture its denosumab biosimilar.").

263. *Id.* at *6 (ruling that while the Biosimilars Act prohibited the use of BLAs obtained as a part of the patent dance in foreign litigation, it does not bar Amgen from using BLAs obtained through other means, including a § 1782 application).

264. The last point bears expansion. Amgen *already possessed* the biosimilar application sought by the § 1782 application. Thus, insofar as the § 1782 application sought that same document, there was a question as to whether the § 1782 application presented a genuine case or controversy. True, a party that already possesses a document may use federal litigation to obtain an identical version of the same document from a witness—be it an adversary or a third party—because the witness's *act of producing* the document has evidentiary value independent of the document's content. *Cf.* United States v. Doe, 465 U.S. 605, 613, 617 (1984) (holding that the "act of producing the [subpoenaed] documents would involve testimonial self-incrimination," and accordingly that "the act of producing the documents at issue in this case is privileged and cannot be compelled without a statutory grant of use immunity"); Lorraine v. Markel Am. Ins. Co., 241 F.R.D. 534, 552–53 (D. Md. 2007) (holding that act of production constitutes "evidence sufficient to support a finding that the matter in question is what its proponent claims" (citation and internal quotation marks omitted)). However, nothing in *In re: Request from Vienna* indicates any reliance by Amgen on an act-of-production theory. It appears that the only reason Amgen sought Sandoz's biosimilar application under § 1782 was that the Biosimilars Act's confidentiality restrictions prevented Amgen from using, in the European litigation, the identical version that Amgen had received from Sandoz in the patent dance. Yet, under § 1782, whether a document is usable in the foreign proceeding is beyond the scope of the court's inquiry. *See In re*: Request from Vienna, 2023 WL 6278815, at *5. The only issue for the court to decide under § 1782 is whether the § 1782 applicant—here, Amgen—can *obtain* certain documents, not whether it can actually *use* those documents in a foreign proceeding. Although the eligibility criteria required that Amgen *desire* to use the

C. PATENT ABUSES

The second phase of biologic patent dispute resolution also offers the brand biologic an opportunity to prolong the negotiation and litigation process. Each additional day, week, or month spent engaged in the process reaps the brand another day, week, or month of monopoly profits. As a general matter, monopoly profits can be significant enough to justify strategic behavior to create such delay.[265]

As noted earlier, the second phase begins when the brand notifies the biologic that marketing of the biosimilar will begin in 180 or more days.[266] At this point, the brand may seek a preliminary injunction blocking the manufacture and/or sale of the biosimilar until resolution of the infringement status of any patents that were on the Initial Brand or Biosimilar Lists but were omitted from the Negotiated or Failed-Negotiation Lists.[267] These omitted patents may include new patents that were issued after the Initial Brand List was provided to the biosimilar manufacturer, and, therefore, must be included in the Supplemental Brand List.[268]

The Supplemental Brand List must be provided to the biosimilar within 30 days of a new patent's issuance.[269] However, the brand can continue to apply for and receive new patents after the Initial Brand List is provided,[270] creating

documents in a foreign proceeding, the court was barred under § 1782 from deciding whether Amgen could actually *use* the documents in that foreign proceeding.

In short, with respect to the biosimilar application, Amgen's § 1782 application could not have gotten Amgen any evidence that Amgen did not already have. The issue of whether Amgen could use that evidence in the European litigation should be decided not by the District of Delaware (where the § 1782 action was pending), but rather either the District of New Jersey (where the phase-one litigation was pending) or the European courts (where Amgen was intending to seek preliminary injunctive relief). But insofar as Amgen's § 1782 application sought Sandoz's biosimilar application, it would appear that Amgen already had all the relief it was entitled to obtain.

265. For example, one drug that received a five-month delay was able to earn over $600 million in monopoly sales, roughly $120 million per month. FELDMAN & FRONDORF, *supra* note 21, at 96–97. Even if there are other drugs available to treat the same issue addressed by the monopoly drug, the effects of those available substitutes are already reflected in the sales statistics.

266. *See supra* note 154 and accompanying text.

267. *See supra* note 156 and accompanying text.

268. Carrier & Minniti, *supra* note 107, at 37.

269. *Id.* at 18 n.162.

270. Rai & Price, *supra* note 67, at 20. In practice, the biosimilar can guard against sharp practice by requiring the brand to enter into a private confidentiality agreement with an anti-prosecution provision. *See* Van de Wiele, Kesselheim & Sarpatwari, *supra* note 200; *cf.* 42 U.S.C. § 262(l)(1)(A) (authorizing parties to agree on supplemental confidentiality rules for the patent dance's exchange of information).

the potential opportunity for an eleventh-hour delay of the biosimilar's entry to market. This type of behavior rewards a brand's efforts to abuse the patent system, which can take the form of cultivating patent thickets and using late-issued patents. The following Sections will describe how these behaviors play out in greater detail.

1. Patent Thickets

Patent thickets, a technique familiar in the non-biologic space, develop when firms amass large numbers of overlapping patents to increase risk of infringement for competitors.[271] Patent thickets serve to deter generic and biosimilar applicants through the threat of endless litigation, and some of the patents may extend the lifespan of the brand's patent protection in relation to the product.[272] Drug-makers create patent thickets by seeking protection for minor or frivolous modifications and patenting those modifications rather than by making legitimate innovations related to the drug.[273] The dearth of a comprehensive public list of all biologic patents related to drugs in the Purple Book[274] makes patent thickets particularly difficult for biosimilar applicants and antitrust regulators to detect. In addition, their deployment in the biologic patent dispute resolution process can be devastating.[275]

Lack of transparency prevents the biosimilar company from confirming the existence of a thicket prior to engagement in the patent dance. In addition, the two-phase structure of patent dispute resolution ensures that, one way or

271. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2001) ("[A patent thicket is] a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology."); KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46679, THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES IN DRUG PRICING 52–53 (2024) ("[Patent thicket may] describe one incumbent manufacturer's practice of amassing a large number of patents relating to a single product, with the intent of intimidating competitors from entering the market, or making it too costly and risky to do so.").

272. In a practice known as "evergreening," drug manufacturers that have already patented a drug's base compound obtain additional patents covering different aspects of the drug in an effort to prolong their market control for that drug. *See generally* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIS. 590 (2018); Robin Feldman, *Understanding 'Evergreening': Making Minor Modifications of Existing Medications to Extend Protections*, 41 HEALTH AFFS. 801 (2022).

273. Jeffrey Wu & Claire Wan-Chiung Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 CHI.-KENT J. INTELL. PROP. 93, 138 (2019).

274. *See supra* Section III.B.1.

275. *See infra* text accompanying notes 276–283.

another, each patent in the thicket has a chance to lengthen the biosimilar's time to market.

Of course, these threats hinge on the biosimilar company's decision to continue with the patent dispute resolution process set out in the Biosimilars Act once the existence of a patent thicket becomes apparent. Daunted by both the literal and temporal cost of bringing each patent in a thicket to court, the biosimilar may well choose to settle instead—thereby opening the door to pay-for-delay and other collusive agreements, as described above.

Litigation surrounding AbbVie's Humira (adalimumab), a biologic used to treat rheumatoid arthritis, provides an illustration of these tactics. In 2014, two years before Humira's primary patent would expire, AbbVie began to file aggressively for additional patents on the drug: Out of the 247 patent applications filed on Humira, 220 were filed at least one year after its commercial launch[276] and 122 of them—approximately 50% of all applications filed—were applied for after 2013, two years before the primary patent's expiration.[277] One analysis found that AbbVie asserted at least 20 method-of-manufacturing patents against biosimilar applicants that were filed more than a year after Humira was launched[278] and thus were of dubious validity.[279] Furthermore, AbbVie's patent thicket protecting Humira was significantly thicker in the United States than in Europe—AbbVie had accumulated more than three times the number of patents in the United States than in Europe.[280]

When biosimilars emerged on the drug, AbbVie asserted large numbers of patents against them.[281] By reaching settlements with every challenging biosimilar maker since 2016, AbbVie effectively delayed until 2023 the market entries of all six adalimumab biosimilars that have received FDA approval.[282]

276. W. Nicholson Price II & Arti K. Rai, *How Logically Impossible Patents Block Biosimilars*, 37 NATURE BIOTECH. 862, 862 (2019).

277. I-MAK, OVERPATENTED, OVERPRICED: HUMIRA 3–4 (2021), https://www.i-mak.org/wp-content/uploads/2021/09/i-mak.humira.report.3.final-REVISED-2021-09-22.pdf.

278. Price & Rai, *supra* note 276, at 862.

279. *See id.* (arguing that the method-of-manufacturing patents that were filed more than a year after Humira launched were invalid if that method was already used in manufacturing Humira or improperly asserted in blocking biosimilar entry, as biosimilars can find an alternative method that is not covered in the asserted patent).

280. Stacie Ropka, Ted Mathias & Chantelle Ankerman, *Failure to Launch: The Patent Thicket Delay of US Biosimilars*, LAW360 (Oct. 9, 2019), https://www.law360.com/articles/1206946/failure-to-launch-the-patent-thicket-delay-of-us-biosimilars.

281. *Id.*

282. Jason Laday, *Market Gears Up for Biosimilar Boom in 2023 as Humira Exclusivity Draws to a Close*, HEALIO (June 18, 2021), https://www.healio.com/news/rheumatology/20210617/

Although the specific financial terms of the settlements have not been disclosed to the public, commentators have asserted that Humira's patent thicket fostered a legal environment perfect for pay-for-delay.[283]

AbbVie may have created a patent thicket to buy itself time—seven years—for a "product hop." With a product hop, a brand extends its monopoly over a particular market with the introduction of a newly patented formulation for the same condition and shifting the market to the new product.[284] Indeed, in 2019, AbbVie released two new rheumatoid arthritis drugs to which the company may aim to shift Humira's consumer base. This would discourage customers from trying biosimilars that may come to market.[285]

As exemplified by AbbVie's strategic actions, patent thickets may hinder biosimilar entry even more effectively than they hinder generic entry due to a combination of opacity and brand control over the patent dispute resolution process.[286]

2. Late-Issued Patents

Late-issued patents present another way for brands to use the patent dispute resolution process to their advantage. Recall that the brand submits a Supplemental Brand List of patents if any relevant patents are issued after the brand has submitted its Initial Brand List.[287] The brand must furnish the biosimilar with its Supplemental Brand List no later than thirty days after the brand receives the new patent.[288] The biosimilar then has thirty days to return a statement to the brand asserting whether the patent is invalid or not infringed by the biosimilar's product.[289]

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market-gears-up-for-biosimilar-boom-in-2023-as-humira-exclusivity-draws-to-a-close (reporting that AbbVie reached settlements with all six FDA approved adalimumab biosimilars, delaying their market entry until 2023); *see also* I-MAK, *supra* note 277, at 8 (stating that the first biosimilar alternative to Humira would not enter the U.S. market until 2023); Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249, 278–79 (2019) (providing examples of cases where Humira reached settlements with potential biosimilar entrants, delaying biosimilar market-entry until 2023).

283. Feldman & Misra, *supra* note 282, at 277–79.

284. Laday, *supra* note 282.

285. *Id.*

286. Wu & Cheng, *supra* note 273, at 167.

287. *See supra* notes 134–135 and accompanying text.

288. *See supra* notes 134–135 and accompanying text.

289. Although 42 U.S.C. § 262(l)(7) ambiguously describes when the patents on the Supplemental Brand List can be litigated, at least one practitioner suggests that patents on the Supplemental Brand List can be litigated only in phase two. *See* APRIL ABELE ISAACSON, THOMSON REUTERS PRAC. L., BIOLOGICS PRICE COMPETITION & INNOVATION ACT

These conditions incentivize the brand biologic to hold off on filing for some patents, or to engage in any behavior with the USPTO that could delay granting the patent, until after the relevant product faces the prospect of biosimilar competition. After the biosimilar has applied for approval and the first few exchanges of patent lists have concluded, the brand can then apply for and obtain additional patents and submit a Supplemental Brand List.[290] Thus, even if every single patent the brand includes on its Initial Brand List is successfully invalidated by the biosimilar in phase one, the brand is not without options in phase two: The brand can stop the biosimilar from making or selling its product on the grounds that its freshly issued patents, listed on the Supplemental Brand List, have not yet been litigated. In this way, even patents that the brand knows will not stand up to challenge can be a source of monopoly profit as they stall the biosimilar's entry to market.

This method of late filing represents an update to the use of "submarine patents," patents that experienced years of delay between filing and issuance due to the filer's intentional manipulation of their processing at the USPTO. Firms deployed submarine patents in their heyday to surprise new innovators with infringement claims, often after an industry that had been in its nascence at the time of filing became more established. Submarine patenting worked because prior to 1995, patent lifespans in the United States began when the patents were issued, rather than when the patent applications were filed, as is the case today. In addition, prior to 1995, all patents remained secret until issuance, enabling filers to keep any patents-in-progress hidden from

(BPCIA): LITIGATION CONSIDERATIONS 6 (2022), https://ktslaw.com/en/Insights/Publications/2022/3/Biologics-Price-Competition-Innovation-Act-BPCIA-Litigation-Considerations. However, as noted above, if the Supplemental Brand List is provided before the Negotiated List is negotiated (or the Failed-Negotiation Lists are exchanged), a textual and logical analysis concludes that patents on the Supplemental Brand List can be litigated in phase one as well, especially given that the Biosimilars Act characterizes the Supplemental Brand List as a "supplement" to the Initial Brand List. *See supra* notes 179–182 and accompanying and following text. The only standard a patent must meet in order to qualify for inclusion on the Supplemental Brand List is to be worthy of the biologic's "[reasonable]" belief that "a claim of patent infringement could reasonably be asserted" on its basis. *See* 42 U.S.C. § 262(l)(7)(B) (providing that any patents that were issued after provision of the Initial Brand List and that the brand reasonably believes to be assertable against the biosimilar applicant shall be included in the Supplemental Brand List).

290. 42 U.S.C. § 262(l)(7). If a new patent is issued to the biologic manufacturer during the patent dance, the manufacturer must inform the biosimilar applicant within 30 days. However, this 30-day requirement applies when a patent is *issued*, not when the patent application is *filed*, meaning patents that are obtained after the Initial Brand List is provided could still have been applied for beforehand.

competitors.[291] Applicants, therefore, could engage in various tactics of regulatory manipulation to delay the issuance of their patent, allowing them to choose a time for the patent to issue that would afford them competitive advantages in the market.[292] However, in December 1994, Congress enacted the Uruguay Round Agreements Act, incorporating into law the agreements from the Uruguay Round of the General Agreement on Tariffs and Trade.[293] The following year, the United States joined the World Trade Organization.[294] Under the Uruguay Round Agreements Act and other subsequent statutory reforms, patent terms were modified to end twenty years from the date when patent applications were filed rather than seventeen years from the date when the patents were issued,[295] and patent applications were made public after eighteen months.[296] These reforms effectively killed the ability to create new submarine patents.[297]

Although late-issued patents introduced during the biologic patent litigation process cannot strictly be deemed submarine patents, they work in an analogous manner to stymie biosimilar innovators with unexpected infringement claims. This new form of submarine patent can do the greatest

291. Carrier & Minniti, *supra* note 107, at 38.

292. *Id.*; *see also* Minniti, *supra* note 159, at 172–73, 186–90 (noting the severity of the threat of submarine patents for biosimilars specifically, due to the multitude of patents involved and the new emergence of the sector).

293. Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994).

294. *U.S. in the World Trade Organization*, LIBR. OF CONG., https://guides.loc.gov/united-states-trade-policy/world-trade-organization (last visited Mar. 1, 2024).

295. Uruguay Round Agreements Act § 532(a); 35 U.S.C. § 154(a)(2). *See* Karin L. Tyson & Robert W. Bahr, *Patent Term Guarantee Overview*, U.S. PAT. & TRADEMARK OFF. (Aug. 10, 2011), https://www.uspto.gov/patents/laws/american-inventors-protection-act-1999/patent-term-guarantee-overview ("[T]he Uruguay Round Agreements Act amended 35 U.S.C. § 154 in June of 1995 to change the term of utility and plant patents from ending seventeen years from the date of patent grant to ending twenty years from the filing date of the application . . . .").

296. 35 U.S.C. § 122(b)(1)(A); American Inventors Protection Act of 1999 (AIPA), Pub. L. No. 106-113, § 4502, 113 Stat. 1501, 1501A-561 (1999).

297. Many true submarine patents filed before 1995 took decades to make their way through the USPTO. *See* Dennis Crouch, *Old-School Submarine Patents*, PATENTLY-O (Dec. 14, 2010), http://patentlyo.com/patent/2010/12/old-school-submarine-patents.html. As of 2014, 450 remained pending with the USPTO, some of which were for biologic drugs. Dennis Crouch, *Old Application; New Patents*, PATENTLY-O (Jan. 18, 2014), https://patentlyo.com/patent/2014/01/old-patents.html; *see also* Minniti, *supra* note 159, at 187–88 (describing the threat to biosimilars posed by the 450 submarine patents pending at USPTO as of 2014, and noting that a recent case involved a biologic for which a patent application was filed in 1995 but patents did not issue till 2011 and 2012).

damage in the second phase of the patent dance as the basis for preliminary injunction motions.

IV. RE-ALIGNMENT: SHIFTING THE STEPS

Multiple factors may be contributing to the slow entry and uptake of biosimilars in the United States. On the subject of pricing, some evidence suggests that middle players may be contributing to higher biosimilar prices in the United States in comparison to Europe.[298] For example, some biosimilars reportedly have tried to launch at lower prices in the United States, but were subsequently forced to raise their prices.[299] Middle players refused to contract for the drugs at the substantially lower prices because of insufficient ability to extract revenue.[300] In theory, that insufficiency may stem from the inability to extract revenue from rebates, or from fees based on the higher pre-rebate price of the drug, or both. The Biosimilars Act did not anticipate or address supply-chain issues such as these.

Similarly, other areas of the Biosimilars Act, outside of intellectual property disclosure and the patent dance, also contribute to sluggishness in this market. The length of the data exclusivity that the Biosimilars Act grants to brand biologics in the first place is one such area.[301] During this twelve-year period,

298. *See* Sarah J. Tribble, *Why The U.S. Remains The World's Most Expensive Market For 'Biologic' Drugs*, CAL. HEALTHLINE (Jan. 28, 2019), https://californiahealthline.org/news/why-the-u-s-remains-the-worlds-most-expensive-market-for-biologic-drugs/ (noting that biosimilars on average cost higher in the United States than in Europe and asserting that tactics like rebate traps can artificially decrease biosimilar intake and increase prices).

299. Sandoz initially launched Omnitrope, a follow-on protein to Amgen's Genotropin (somatropin), at a substantial price discount. But Sandoz tried to sell Omnitrope through "specialty pharmacies," which, unlike managed care organizations, make profit as a percentage of a drug's sales price. As a result, the low price of Omnitrope adversely affected the revenue of the specialty pharmacies. So Sandoz had to *increase* the price of Omnitrope to achieve market penetration. Some years later, after the Biosimilars Act created the biosimilar pathway, Sandoz sought approval for Zarxio (filgrastim-sndz), a biosimilar to Amgen's Neupogen (filgrastim). As to whether Zarxio would be priced lower than Neupogen, a Sandoz executive said simply that the subject of price was "challenging" and that his company learned its lesson from Omnitrope. *See* Sue Sutter, *Biosimilar Pricing: Sandoz Vows Not to Make* Omnitrope *'Mistake' with Filgrastim*, PINK SHEET (Dec. 22, 2014), https://pink.citeline.com/PS056542/Biosimilar-Pricing-Sandoz-Vows-Not-To-Make-emOmnitropeem-Mistake-With-Filgrastim.

300. *See* Sutter, *supra* note 299.

301. 42 U.S.C. § 262(k)(7)(A) ("Approval of [a biosimilar application] may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under [42 U.S.C. § 262](a)."); *Background Information: List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/biosimilars/

the FDA may not approve any biosimilar application that uses the brand biologic as its reference product.[302] Furthermore, the Biosimilars Act provides the brand with four years of regulatory exclusivity during which a biosimilar may not even apply for approval.[303] Finally, all of the patent disclosure in the world will not help if the patents themselves do not provide the necessary information.[304] Nevertheless, the patent dance remains at the heart of the Biosimilars Act, and it fails to function in an effective manner. Those failings can be remedied.

At the outset, we would note that the logic of trying to focus the parties on what matters among the avalanche of patent rights and numerous claims within those patents may make sense. In fact, some patent judges and jurisdictions try to streamline portions of patent cases by asking the parties to focus on a subset of the possible issues first, in the hopes that resolving these will bring the parties closer to a resolution.[305] Nevertheless, the appeal of encouraging two particular parties to resolve a dispute ignores the broader interests of society, which reach well beyond those two parties and that moment of time. Rather, society's interests center on encouraging a broad range of competitors to prepare to enter the field, both when the brand's patents expire and across time.

Entry preparation, however, requires full and complete rights information. To that end, the Hatch-Waxman Act provides a model that can be adapted to the biologic circumstances.[306] For example, we suggest that brand biologic

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background-information-list-licensed-biological-products-reference-product-exclusivity-and (last updated Aug. 3, 2020).

302. 42 U.S.C. § 262(k)(7)(A).

303. *Id.* § 262(k)(7)(B) ("A[biosimilar application] may not be submitted to the Secretary until the date that is 4 years after the date on which the [brand] product was first licensed under [42 U.S.C. § 262](a).").

304. *See supra* Sections II.C, III.B (describing insufficiency of biologic patent disclosure).

305. A number of district courts have adopted local rules limiting the number of claim terms that may be submitted to the court for claim construction in a single case. *E.g.*, N.D.N.Y. PAT. R. 4.4(b) ("No more than ten (10) patent terms or phrases may be presented to the Court for construction, absent prior leave of Court upon a showing of good cause."); D. MASS. R. 16.6(e)(1)(C) ("The parties may jointly present to the court no more than 10 claim terms for construction . . . ."); N.D. CAL. PAT. R. 4-1(b) ("The parties shall also jointly identify the 10 terms likely to be most significant to resolving the parties' dispute, including those terms for which construction may be case or claim dispositive."). In jurisdictions where no specific local patent rule limits the number of claim terms that the court will construe, certain judges may impose their own limits. *See, e.g.*, Hearing Components, Inc. v. Shure, Inc., No. 9:07CV104, 2008 WL 2485426, at *1 (E.D. Tex. June 13, 2008) ("In order to secure the just, speedy and inexpensive determination of this action pursuant to Fed.R.Civ.P. 1, the court ORDERS that the parties shall elect no more than ten (10) disputed claim terms for construction.").

306. *See* Drug Price Competition and Patent Restoration Act of 1984, *supra* note 19.

companies could be required to submit all patent and exclusivity rights to the FDA at the time of the drug's approval, along with a requirement to supplement that information with any new rights acquired. The FDA, in turn, could be required to publish that information in the Purple Book. The system could be structured in a use-it-or-lose-it form, such that biologic companies could not assert rights in relation to a drug if they failed to list those rights. This would give prospective biosimilars a more robust view of the potential rights at the time when they are contemplating entering the fray.

Providing disclosure upfront would remove some of the temptations that parties have to maneuver the patent dance so that information is not released to future competitors. If the information is already out there, the benefit of hiding loses its power to distort choices along the way.

For enacting such a reform, the general choreography of the patent dance could remain in place. The litigation structure could continue to allow the biosimilar to choose how many patents would become the focus of the litigation. This limits the brand's ability to overwhelm the biosimilar with endless numbers of legal claims, each of which may be of questionable validity.

In addition, the Biosimilars Act should provide some advantage for the first-moving biosimilar that gets FDA approval and gets to market. One could model such a provision after the 180-day exclusivity that is available under Hatch-Waxman for first-filing generics who successfully challenge rights.[307] Although policy makers would be well advised to learn from and adjust to the Hatch-Waxman history of pay-for-delay agreements, a first-mover advantage could be designed to avoid the strategic behaviors that developed to tiptoe around the Hatch-Waxman Act's language and provisions.

A simpler and cleaner solution than trying to design around the strategic behaviors of pay-for-delay could be a period of exclusivity for the first-moving biosimilar to get FDA approval, regardless of whether any rights-challenging occurs. Currently, the first interchangeable to get FDA approval receives a period of exclusivity, which protects it against entry by subsequent interchangeables.[308] That provision could be expanded to all first biosimilars who get FDA approval.

Finally, additional small adjustments could be made to ensure a functioning patent dance, including standardizing whether injunctive relief—preliminary or otherwise—is available. Disincentives also could be created for parties who

307. 21 U.S.C. § 355(j)(5)(B)(iv) (describing the 180-day exclusivity period for the first-filing generics with a Paragraph IV certification).

308. 42 U.S.C. § 262(k)(6) (stipulating the length and nature of "[e]xclusivity for first interchangeable biological product").

would move outside the process. These could deter parties from finding the need and incentive to sidestep the systems created.

Together, these changes could provide a pathway for moving forward with a more successful Biosimilars Act. Although it may be tempting to scrap the entire patent dance, starting from scratch would wipe away all that we may have learned about the goals and strategic behaviors of the parties. Sometimes the devil you know may be better than the devil you don't. By leaving the essential process in place while making a few key changes, the Biosimilars Act, with its central feature of the patent dance, could become a more effective conduit for bringing competition to the increasingly important market for biologic medicine.

V. CONCLUSION

As numerous commentators have asserted, biologics are currently a driving force behind high drug prices. According to the most recently available information,[309] biologics account for only 2% of all prescriptions in the United States but 37% of the drug spending.[310] Combating these prices and ensuring more affordable access to medications will require greater competition in the biologic market from cheaper alternatives. Congress attempted to achieve this objective by passing the Biosimilars Act in 2010 to create an easier market entry pathway for follow-on drugs known as biosimilars. The Biosimilars Act, however, has proven to be much less successful than the older cousin on which it was patterned, the Hatch-Waxman Act. A key part of this dismal performance can be traced to the control over patent disclosure that the Biosimilars Act vests in drug companies. To avoid disclosure of patent and manufacturing information to other drug companies, biologic and biosimilar makers alike can easily evade the disclosure contemplated by the Biosimilars Act.

In particular, the strategies employed by brand companies adapt some of the forms of gameplaying familiar in the non-biologic space to the conditions of biologic manufacture and patent dispute resolution, as well as taking on

309. Josh Nathan-Kazis, *'Biosimilars' Were Supposed to Tame Costs for Drugs Like Humira. It Isn't Working.*, BARRON'S (Feb. 21, 2023), https://www.barrons.com/articles/biosimilar-drug-costs-humira-a5f42f37.

310. *Id.*; David L. Carl, Yannic Laube, Miquel Serra-Burriel, Huseyin Naci, Wolf-Dieter Ludwig & Kerstin N. Vokinger, *Comparison of Uptake and Prices of Biosimilars in the U.S., Germany, and Switzerland*, 5 JAMA NETWORK OPEN (2022) (noting the statistically disproportionate level of spending on biologics in the United States); Avik Roy, *Biologic Medicines: The Biggest Driver of Rising Drug Prices*, FORBES (Mar. 8, 2019), https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/?sh=66bfc61c18b0 (describing biologics as a primary driver of high drug prices).

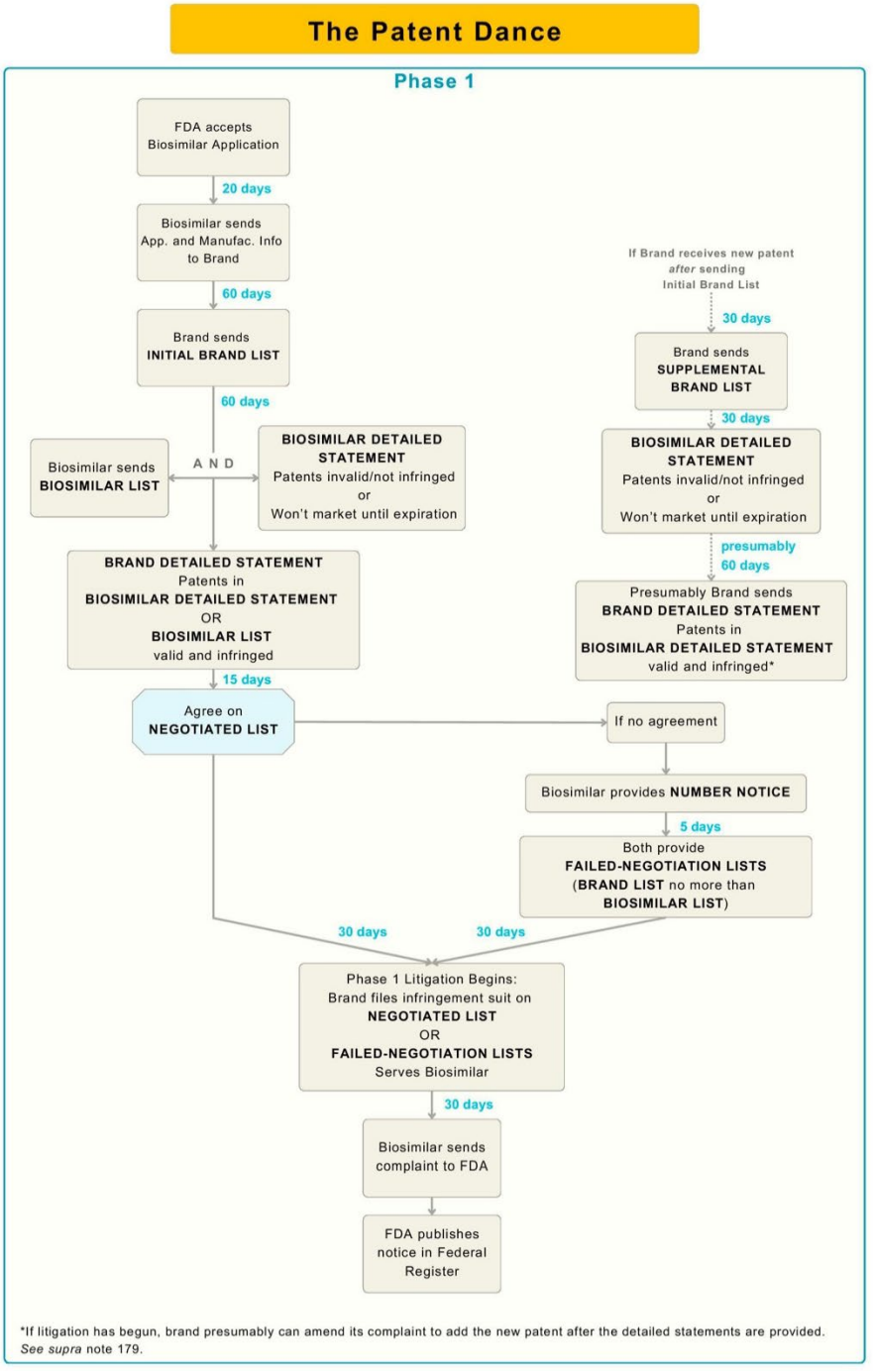
entirely new strategic behaviors. All of these behaviors will remain enticing to drug-makers as long as the biologic regulatory regime not only incentivizes brands to shroud their patents in darkness but offers them ample opportunity to continue to do so.

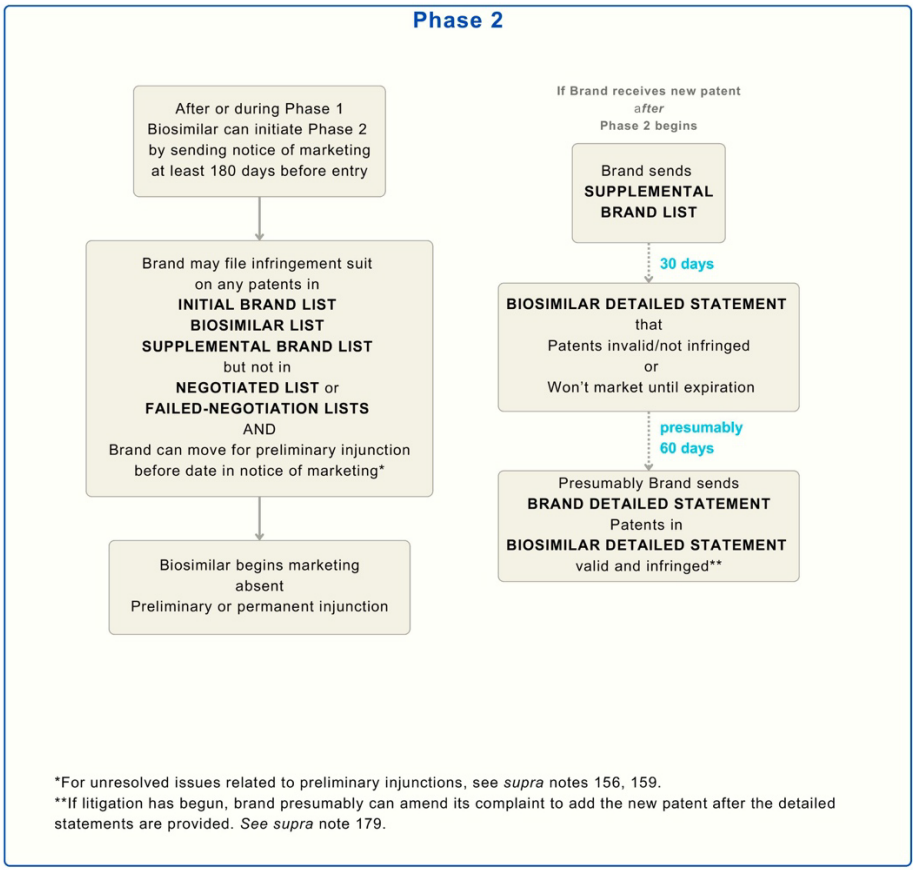
VI. APPENDIX

A. PATENT DANCE NOMENCLATURE

Numerical Legal Name	**Simple Language Used in This Article**
3A List	Initial Brand List
3B List	Biosimilar List
7AB List	Supplemental Brand List
4AB List	Negotiated List
5A Notice	Number Notice
5B Lists	Failed-Negotiation Lists
Subparagraph B Statement	Biosimilar Detailed Statement
Paragraph 3(C) Statement	Brand Detailed Statement

B. PATENT DANCE FLOWCHART





*For unresolved issues related to preliminary injunctions, see *supra* notes 156, 159.
**If litigation has begun, brand presumably can amend its complaint to add the new patent after the detailed statements are provided. *See supra* note 179.