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Cover Page Footnote

*J.D., 2022, Fordham University School of Law; B.A., 2014, Williams College. The views, mistakes, and opinions in this Note are my own. There are many people who I'd like to thank for helping me with this Note—firstly, Professor Mark R. Patterson for his guidance, edits, and thoughtful conversations; Professors Wendy Luftig and David A, Zarett for their class on health care and the law that inspired this Note; and most certainly the editors and staff of the Fordham Intellectual Property, Media, and Entertainment Law Journal for their edits and diligent work (especially Caroline Vermillion, Ziva Rubinstein, Nicole Kim, and Grace L. Sullivan). Many thanks to family and friends who supported me in my transition from lab work into law school. Lastly, many thanks are owed to Gleb Sagitov, who has patiently listened to me talk about these ideas for years, offered counterarguments, and made me laugh many times throughout the writing process. This would not be possible without all of you.

In the Thick(et) of It: Addressing Biologic Patent Thickets Using the Sham Exception to *Noerr-Pennington*

Anna Zhou*

A biologic patent thicket occurs when a pharmaceutical company acquires a "dense web" of patents and other intellectual property rights regarding a specific product. While applying for multiple patents is permissible, the resulting protections can have antitrust implications. In an industry like biologics, where companies can acquire patent exclusivity and regulatory exclusivity over their products, the process of continuously accumulating these exclusivities seems to be an attempt to keep biosimilars at bay. Keeping competitors out of the market drives up prices and raises questions about how these regulatory and patent pathways are being used.

Recent class action litigation in the Northern District of Illinois, In re: Humira (Adalimumab) Antitrust Litigation, *challenged AbbVie's patent thicket surrounding Humira. This case tried to posit a novel approach to addressing patent thickets using the sham exception to* Noerr-Pennington. *While the Seventh Circuit affirmed the district court's opinion in* Mayor of Baltimore v. AbbVie, Inc., *this Note aims to explore the intersection of antitrust and patent law*

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regarding patent thickets and addresses the use of antitrust law remedies to patent thickets. This Note further argues that, in a case like In re: Humira*, the sham exception to* Noerr-Pennington *should apply, and that courts should consider patent thickets in two ways. First, courts should look at the value of a patent, and when the value is worth less than the cost of prosecuting that patent, the patent should be considered objectively baseless under the* Professional Real Estate Investors *test. Secondly, courts should adopt a more flexible approach when considering a sequence of petitions, like a sequence of accumulated patents, as part of antitrust analysis.*

INTRODUCTION

In 2002, the U.S. Food and Drug Administration ("FDA") approved Humira,[1] a TNF inhibitor.[2] Since then, the drug has been approved to treat Crohn's disease, rheumatoid arthritis, and psoriasis, along with six other conditions.[3] Two decades later, Humira remains the top-selling biologic drug in the world, selling an estimated $19 billion in the United States in 2019.[4] To some, Humira is a biopharmaceutical success story; to others, the drug represents the worst of the pharmaceutical industry.[5] Throughout the past decades, Humira manufacturer AbbVie has aggressively advertised the drug, consistently raised the price of the drug, and defended the drug against the entry of competitors through a lengthy series of litigation.[6]

Humira is an interesting drug because it has, arguably, the densest patent thicket in the entire pharmaceutical industry.[7] A patent thicket is defined as a "dense web of overlapping intellectual property rights" that a competitor "must hack through in order to actually commercialize" a similar product.[8] A pharmaceutical patent thicket occurs when a company, like AbbVie, obtains many patents protecting different elements or aspects of the same product.[9] AbbVie holds approximately 136 patents related to Humira.[10] A patent grants the

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1 Humira® is a registered trademark term granted to AbbVie Biotechnology, Ltd. HUMIRA, Registration No. 2,725,934. It will be referred to as "Humira" throughout this Note.

2 *See Humira®*, https://www.abbvie.com/our-science/pipeline.html [https://perma.cc/RA7L-8U5Z].

3 *See id.*

4 Kyle Blankenship, *The Top 20 Drugs by Global Sales in 2019*, FIERCEPHARMA (Jul. 27, 2020), https://www.fiercepharma.com/special-report/top-20-drugs-by-global-sales-2019 [https://perma.cc/3XJP-3VUZ].

5 *See* Sally Turner, *Humira: The Highs and Lows of the World's Best-Selling Drug*, PHARM. TECH. (Sept. 4, 2020, 9:24 AM), https://www.pharmaceutical-technology.com/features/humira-abbvie-drug/ [https://perma.cc/N3G4-ZP67].

6 *See* Sy Murkherjee, *Protect at All Costs*, FORTUNE, Aug. 1, 2019, at 71–73.

7 *See* Jeffrey Wu & Claire Wan-Chiung Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 CHI.-KENT J. INTELL. PROP. 93, 130 (2019).

8 Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* INNOVATION POL'Y & THE ECON. 119, 120 (Adam B. Jaffe et al., eds., 2001).

9 *See* KEVIN T. RICHARDS ET AL., CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 24 (2020).

10 *See* Murkherjee, *supra* note 6, at 73.

patent holder exclusivity to make, use, and commercialize the patented product for twenty years.[11] However, a series of patents related to the same product can end up extending the exclusivity of that product well beyond the initial twenty-year grant.[12] Biologics manufacturers may also be granted a period of market exclusivity by the FDA upon approval of a drug product.[13] Biologics producers can then leverage the exclusivities offered by the FDA and the patent system to extend the period of monopoly over the particular drug. In the case of Humira, the combined market and patent exclusivity is estimated to end in 2034, thirty years after the drug was originally approved.[14] Because it has no competitors, AbbVie could realistically raise the price of Humira unchecked. And in this instance, AbbVie *has* increased the price of Humira many times throughout the years.[15] While a variety of factors impact pharmaceutical drug pricing, the absence of direct competitors certainly contributes to the rising prices.[16]

Patents are a government-sanctioned monopoly.[17] However, the United States also has a well-developed body of antitrust laws, meant to protect competition.[18] In situations where a pharmaceutical

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11 35 U.S.C. § 154(a)(2).

12 *See* Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG BUSINESSWEEK (Sept. 7, 2017), https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug [https://perma.cc/WQ2S-QPQD].

13 *See* Rebecca S. Eisenberg, *Patents and Regulatory Exclusivity*, *in* THE OXFORD HANDBOOK OF THE ECON. OF THE BIOPHARMACEUTICAL INDUS. 167, 168 (Patricia M. Danzon & Sean Nicholson, eds., 2012).

14 Christopher Rowland, *Why Price of Humira Keeps Rising Despite FDA Approval of Generic Competition*, WASH. POST (Jan. 8, 2020, 7:00 AM), https://www.washingtonpost.com/business/economy/why-humiras-price-keeps-rising-despite-fda-approval-of-generic-competition/2020/01/07/549ed0ce-2e3a-11ea-bcb3-ac6482c4a92f_story.html [https://perma.cc/9K4Z-V7GR].

15 *See id.*

16 *See* FDA, NEW EVIDENCE LINKING GREATER GENERIC COMPETITION AND LOWER GENERIC DRUG PRICES (Dec. 13, 2019), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices [https://perma.cc/TC6H-7KYE].

17 *See* U.S. PAT. & TRADEMARK OFF. (PTO), GENERAL INFORMATION CONCERNING PATENTS, https://www.uspto.gov/patents/basics [https://perma.cc/9LZK-Q3A7].

18 *See* U.S. FED. TRADE COMM'N (FTC), THE ANTITRUST LAWS, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws [https://perma.cc/39U7-UC46].

manufacturer holds exclusive rights to a drug, there may be a way to use antitrust laws to address such a monopoly and potentially lower drug prices.[19] This Note explores the possibility of addressing patent thickets using the sham exception to the *Noerr-Pennington* doctrine, by arguing that courts should view patent thickets in one of two ways. First, courts should look at the value of a patent, and when the value is worth less than the cost of prosecuting that patent, the patent should be considered objectively baseless under the *Professional Real Estate Investors* test. Secondly, courts should adopt a more flexible approach when considering a sequence of petitions, like a sequence of accumulated patents, as part of antitrust analysis. Because antitrust analysis is a fact-specific inquiry,[20] this Note explores these approaches using Humira as an example. Part I provides a background primer on patent law, antitrust law, and laws governing biologic drug approval. Part II explores how these sets of laws intersect in such a way that biologics manufacturers can leverage exclusivity periods to set higher prices for their drugs. Part III explains why determining each individual patent value fits within the sham exception of the *Noerr-Pennington* doctrine. Part IV addresses how courts should view a patent thicket as a sequence of petitions. Finally, Part V provides a brief comment on the complexities of drug pricing and other ways to potentially address high drug prices.

I. A PRIMER ON THE THREE FIELDS OF LAW RELATED TO THE BIOPHARMACEUTICAL INDUSTRY

Many different fields of law govern biopharmaceuticals. To best understand the complex system, this Part aims to briefly introduce patent laws, antitrust laws, and the Biologics Price Competition and Innovation Act of 2009. Fundamentally, it is the convergence of these three different fields that allowed AbbVie to develop such a patent thicket.

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19 *See* Harry First, *Excessive Drug Pricing as an Antitrust Violation*, 82 ANTITRUST L.J. 701, 703–04 (2019).

20 *See* Ohio v. Am. Express Co., 138 S. Ct. 2274, 2284 (2018) ("The rule of reason requires courts to conduct a fact-specific assessment.").

A. Patent Law

Patent law is rooted in the U.S. Constitution, which permits Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[21] Currently, the patent laws describe a trade-off: by disclosing the invention to the public, the inventor also gets exclusive rights to practice the invention.[22] An invention is patentable if it is patentable subject matter,[23] novel,[24] non-obvious,[25] and useful.[26] The patent must also be described in a way that a person skilled in the art can otherwise make and use the invention.[27] Patent applications are submitted to the United States Patent and Trademark Office ("USPTO"), where patent examiners consider the applications for those particular attributes against what is already known to the public, called the prior art.[28] If the patent examiner decides the application fits all statutory requirements compared to the prior art, the inventor is granted the patent and receives a twenty-year exclusivity period to use and practice the patent from the date of application filing.[29]

Not every patent is eligible for the twenty-year exclusivity period—some patents are subject to a terminal disclaimer.[30] A patent is meant to cover a single embodiment or expression of an invention.[31] During examination, the patent examiner may find that the

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21 U.S. CONST. art. 1, § 8, cl. 8.

22 *See* Hoi Wai Jackie Cheng & Mariangela Parra-Lancourt, *Chapter 2: The Fourth Industrial Revolution, Development and Intellectual Property: The World Economic and Social Survey 2018 and Beyond*, *in* INTELL. PROP. L. & THE FOURTH INDUS. REVOLUTION 29, 30–31 (Heath et al., eds., 2020).

23 *See* 35 U.S.C. § 101.

24 *Id.* § 102.

25 *Id.* § 103.

26 *Id.* § 101.

27 *Id.* § 112.

28 *See* PTO, PATENT PROCESS OVERVIEW, https://www.uspto.gov/patents/basics/patent-process-overview [https://perma.cc/KHL6-8QVB].

29 35 U.S.C. § 154(a)(2).

30 *See* U.S. Patent & Trademark Office, Manual of Patent Examining Procedure [hereinafter MPEP] § 1490 (9th ed. Rev. 10, June 2020). The following paragraph is a very basic explanation for the double patenting process. For more information, see generally Daniel Kazhdan, *Obviousness-Type Double Patenting: Why It Exists and When It Applies*, 53 AKRON L. REV. 1017 (2019).

31 *See* MPEP § 806.03 (8th ed. Rev. 9, Aug. 2012).

application covers more than one version or variation of an invention.[32] If so, the inventor can decide to split the application into two separate applications.[33] The first application will proceed through the normal application process and receive the twenty-year exclusivity period.[34] The severed part of the application may still be eligible for patent protection.[35] An inventor can still pursue this split-off application as a patent, but must terminally disclaim it to the original application.[36] This split-off application would be known as a divisional application.[37] Essentially, if both patents are granted, the exclusivity period of the second patent will end the same date as the first patent (otherwise known as the "parent application").[38] Patents are assessed for the elements of patentability against the prior art at the time of filing,[39] which means that a terminally disclaimed patent application will be assessed for those factors based on the filing date of the original patent application.[40] Thus, if any other researchers discover anything related to the invention in the period between the first filing date and the second filing date, such discoveries will not count as part of the prior art that the examiner can use to consider a patent.[41]

B. Antitrust Law

Antitrust laws are meant to "protect the process of competition for the benefit of consumers."[42] While businesses are allowed to pursue commercial success, they must operate within certain parameters set out by the Sherman Act.[43] Under the Sherman Act, firms

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32 *See* MPEP § 804 (9th ed. Rev. 10, June 2020).

33 *See id.*

34 *See* Kazhdan, *supra* note 30, at 1021–22.

35 *See id.* at 1023.

36 *See id* at 1024.

37 *See* 37 CFR 1.53(b), 1.63(d) Divisional-Continuation Procedure, MPEP § 201.06(c) (8th ed. Rev. 9, Aug. 2012), https://mpep.uspto.gov/RDMS/MPEP/e8r9#/e8r9/d0e7252.html [https://perma.cc/7HFC-SKAP].

38 *See* Kazhdan, *supra* note 30, at 1024.

39 *See id.* at 1022.

40 *See* MPEP § 2141.01 (9th ed. Rev. 10, Jun. 2020).

41 *See id.*

42 *See* FTC, THE ANTITRUST LAWS, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws [https://perma.cc/L7YS-L538].

43 *See id.*

are not permitted to conspire with one another to restrain trade,[44] nor are companies permitted to "monopolize, or attempt to monopolize . . . any part of the trade or commerce."[45] Some of these acts are *per se* illegal.[46] However, most other violations of the Sherman Act are subject to a rule of reason, burden-shifting analysis.[47] Under this analysis, an entity accusing a company of anticompetitive conduct or behavior must first show the court that the company has engaged in conduct that has an anticompetitive effect.[48] The accused company can then offer pro-competitive justifications for their conduct.[49] If the accused company successfully provides pro-competitive justification for the conduct, the accuser must then show the court that the conduct's anticompetitive effect outweighs its pro-competitive justifications.[50]

Companies can offer certain rationales to justify otherwise anti-competitive conduct.[51] One such rationale is the *Noerr-Pennington* doctrine, which stipulates that entities petitioning the government are immune from antitrust liability that may result from that petitioning.[52] Petitioning the government can take many forms: litigation, for example, is considered a government petition, as parties are asking the government (in this case, the courts) to resolve a particular dispute.[53] However, this is not to say that all petitioning is immune: courts have also developed a "sham" exception to *Noerr-*

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44 Sherman Antitrust Act of 1890 § 1, 15 U.S.C. § 1.

45 Sherman Antitrust Act of 1890 § 2, 15 U.S.C. § 2.

46 *See* Cont'l T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 49–50 (1977).

47 *See* Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 886 (2007).

48 *See* Ohio v. Am. Express Co., 138 S. Ct. 2274, 2284 (2018).

49 *See id.*

50 *See id.*

51 *See* PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW—AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 658 (2020).

52 *See id.* at ¶ 203d. The *Noerr-Pennington* doctrine comes from two seminal cases, *E.R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). In *Noerr*, railroad companies had organized a campaign to lobby state government officials for legislation that allegedly disadvantaged the trucking industry. Part of that lobbying effort included false advertisements related to trucking. The Supreme Court found that lobbying effort was immune from antitrust liability—essentially that the resulting legislation, despite perhaps having antitrust effects, was not subject to antitrust liability, and the process by which the result was achieved is also not subject. *Noerr*, 365 U.S. at 136.

53 *See* AREEDA, *supra* note 51, at ¶ 203e.

Pennington.[54] Under the sham exception, if the party uses the petitioning process as an anticompetitive tool, the conduct will not be covered by the immunity.[55] The court generally determines whether the petition is used as an anticompetitive tool by determining, first, whether the petition is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits."[56] If the petition is objectively baseless, the court then looks at the petitioning party's subjective intent, focusing on "whether the baseless lawsuit conceals 'an attempt to interfere *directly* with the business relationships of a competitor.'"[57] This test must first be satisfied before the court can assess the anticompetitive effects of the petitioning behavior.[58]

C. The Current Laws Governing Biologic Drug Approvals

Biologics is a catch-all term referring to a wide variety of products, including vaccines, gene therapy, and therapeutic proteins.[59] These products are usually composed of sugars, proteins, or nucleic acids (or some combination of the three), and differ from chemically synthesized small molecule drugs.[60] Biologics usually are developed in living organisms and have special manufacturing requirements as a result.[61] Biologics have become an important part of available therapeutics—in 2019, biologic drugs accounted for forty-three percent of the United States' total spending on medicines.[62] Critical and famous biologics include Humira, Enbrel, and

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54 *Noerr*, 365 U.S. at 144 (1961).

55 *Id.*

56 Pro. Real Estate Invs., Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 (1993).

57 *Id.* (quoting *Noerr*, 365 U.S. at 144).

58 *See id.*

59 *See* FDA, WHAT ARE 'BIOLOGICS' QUESTIONS AND ANSWERS (Feb. 6, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers [https://perma.cc/EF9D-FJUD].

60 *See id.*

61 *See* Susan Berger, *Biologics Are Revolutionizing Care for Some Diseases, but They Are Very Costly*, WASH. POST (Mar. 16, 2015), https://www.washingtonpost.com/national/health-science/biologics-are-revolutionizing-care-for-some-diseases-but-they-are-very-costly/2015/03/16/1ffe46b6-b6ed-11e4-9423-f3d0a1ec335c_story.html [https://perma.cc/L4QD-L56D].

62 MURRAY AITKEN ET AL., IQVIA INSTITUTE, BIOSIMILARS IN THE UNITED STATES 2020–2024 3 (2020).

Remicade, all of which have generated billions of dollars for their respective companies.[63]

The approval process for biologic drug development is similar to that of small molecule drugs; biologic manufacturers must show that the biologic is safe and efficacious, usually through extensive clinical trials.[64] Under normal circumstances, the process can be lengthy and costly.[65] The law recently changed with the passage of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA").[66] As part of the BPCIA, approved products receive twelve years of exclusivity from the FDA—four years of data exclusivity, and a sequential eight years of market exclusivity.[67] Additionally, the BPCIA aims to provide an easier pathway for the approval of generic version of the biologics (called biosimilars).[68] The BPCIA is meant to address two competing interests. On one hand, the Act rewards companies that create new drugs by prohibiting the FDA from even considering a similar product for the first four years.[69] On the other, the Act purposefully incentivizes biosimilar manufacturers to develop competing drugs.[70] The full effect of this Act is still developing—as of February 2023, the FDA has approved forty biosimilar products.[71]

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63 *See* Berger, *supra* note 61.

64 *See* 42 U.S.C. § 262(a)(2)(C). For more information related to the drug approval process, see FDA, DEVELOPMENT & APPROVAL PROCESS | DRUGS (Mar. 28, 2022), https://www.fda.gov/drugs/development-approval-process-drugs [https://perma.cc/F7JB-WTSC].

65 Mark Terry, *The Median Drug Development Cost Is $985 Million, According to New Study*, BIOSPACE (Mar. 4, 2020), https://www.biospace.com/article/median-cost-of-bringing-a-new-drug-to-market-985-million/ [https://perma.cc/96NW-26BK].

66 Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 28 U. ILL. L. REV. 1, 14 (2018).

67 42 U.S.C. § 262(k)(7)(A)–(B). The twelve years of exclusivity granted by the FDA is broken up into two parts. *See* Carrier & Minniti, *supra* note 66, at 15. The first four years are deemed as the data exclusivity period, in which the FDA will not accept any biosimilar application. *See* 42 U.S.C. § 262(k)(7)(B). After these four years end, the second, eight-year period begins. During that time, the FDA can start accepting biosimilar applications but cannot approve the biosimilar application. *See* 42 U.S.C. § 262(k)(7)(A).

68 *See* Carrier & Minniti, *supra* note 66, at 15.

69 *See id.*

70 *See id.* at 14.

71 FDA, BIOSIMILAR PRODUCT INFORMATION (Feb. 25, 2022), https://www.fda.gov/drugs/biosimilars/biosimilar-product-information [https://perma.cc/6QRJ-ASCT].

II. THE COLLISION OF THREE POINTS OF LAW

Together, the BPCIA and the patent laws provide a pathway for drug manufacturers to obtain a monopoly on their products.[72] Drug manufacturers can also obtain patents on different parts of the same drug product; AbbVie, for example, received patent protections over Humira's active ingredient, overall formulation, method of treatment, and manufacturing processes.[73] The accumulation of these patents means that the exclusivity period could potentially extend well beyond the twelve years permitted by the BPCIA.[74] Additionally, the patents related to the drug and production process grant the patent owner the exclusive rights to practice and sell the products related to those patents.[75] This means that drug manufacturers can sue biosimilar manufacturers for potential infringement long after the exclusivity is granted.[76]

As an example, assume a company is creating a drug that is approved by the FDA in 2020. Under the regulatory exclusivity scheme through the BPCIA, that drug is protected by regulatory exclusivity through 2032. Assume that the company has also strategically timed its patent applications for the drug and applied for patent protection in 2018. The patents on the drug, if granted, would expire in 2038. Although these exclusivities would run simultaneously, the company has still functional market exclusivity through 2038, as it could ward off potential competitors through patent infringement lawsuits. If the company were extra strategic, it would stagger its patent applications that protect different elements of the drug (such as active ingredient, formulation, manufacturing process) so that its later patent applications would add additional years beyond 2038 to its market exclusivity.[77]

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72 *See* Carrier & Minniti, *supra* note 66, at 45.

73 *See* Wu & Cheng, *supra* note 7, at 111.

74 *See* Rowland, *supra* note 14.

75 *See* Peter Loftus & Denise Roland, *By Adding Patents, Drugmaker Keeps Cheaper Humira Copies Out of U.S.*, WALL ST. J. (Oct. 16, 2018, 7:00 AM), https://www.wsj.com/articles/biosimilar-humira-goes-on-sale-in-europe-widening-gap-with-u-s-1539687603 [https://perma.cc/TYV5-6PV3].

76 *See* Murkherjee, *supra* note 6, at 73.

77 This example is simplified for the purposes of this Note. Regardless of its relative simplicity, the premise still stands. Drug manufacturers plan their patent applications strategically throughout the drug development process to balance the time limitations of

Given this system, biosimilar manufacturers may not be incentivized to produce biosimilars. The drug approval process is long, and the threat of patent litigation post-approval may effectively remove any financial incentive to produce a biosimilar candidate.[78] The BPCIA anticipates this by providing a shortened pathway for biosimilar approval, as well as a patent resolution process between biosimilars and biologics manufacturers.[79] This patent resolution process—colloquially called the "patent dance"—is triggered shortly after the FDA accepts a biosimilar application.[80] During the patent dance, the biologics and biosimilar manufacturers exchange information related to the drug manufacturing process and the list of patents that the biosimilar manufacturer may infringe.[81] The two companies also try to create licensing agreements related to some of these patents during this time.[82]

After exchanging lists, the two companies negotiate a final list of patents that the biosimilar manufacturer will allegedly infringe.[83] At this point, the biologics manufacturer has thirty days to initiate a lawsuit for patent infringement, and subsequently, the two parties will come to a resolution, either through settlement or full litigation.[84] The biosimilar company can assert defenses, stating that this list of patents includes patents that are unenforceable, invalid, or non-infringing.[85] During this time, the FDA is still assessing the biosimilar drug.[86] If the FDA decides to approve the biosimilar, the biosimilar manufacturer must notify the biologics manufacturer of approval.[87] The biologics manufacturer can then seek a preliminary

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the patent application process as well as extending patent exclusivity for the product as long as possible. For a more in-depth example, see generally Bo Peng & Marta Cavero Tomas, *A Cheat Sheet to Navigate the Complex Maze of Exclusivities in the United States*, 3 PHARM. PAT. ANALYST 339 (2014).

78 *See* Rowland, *supra* note 14.

79 *See* Carrier & Minniti, *supra* note 66, at 17.

80 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, 115 (2019).

81 *See id*. at 115–16.

82 *See id.* at 116.

83 *See id.*

84 *See id.*

85 *See* Carrier & Minniti, *supra* note 66, at 17.

86 *See* Li, *supra* note 80, at 117.

87 *See id.*

injunction to prevent the biosimilar launch until the patent conflicts are resolved.[88] Usually, resolutions are obtained through "private negotiation between the parties."[89]

Ultimately, the patients who take these drugs bear the brunt of this system. Biologics, like Humira, are notoriously some of the most expensive drugs to date.[90] Part of this high price is due to the difficulty in developing and commercializing such products.[91] Biologic manufacturing involves a huge investment upfront, and thus companies that make that investment want a high margin of exclusive profits in return.[92] Combined with the lack of directly competing products, AbbVie can set a high price for biologics, such as Humira.[93] Not only did AbbVie set a high initial price, it continues to raise prices—the U.S. list price of Humira has nearly tripled between 2006 and 2017, marking an annual growth rate of over twelve percent a year.[94] Because each additional year of exclusivity means that AbbVie can receive another year of large profit margins, AbbVie is hugely incentivized to extend their exclusivity for any time that they can. Since the regulatory exclusivity period is set by law, a drug manufacturer, like AbbVie, looks to patents to extend exclusivity.[95] The accumulation of patents has paid off for AbbVie. It has fended off biosimilar challenges until 2023—almost a decade after the regulatory exclusivity period ended, and over half a decade after its key patents expired.[96]

This is not to say that what AbbVie has done with Humira patents is illegal; "AbbVie has exploited advantages conferred on it

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88 *See id.*

89 Carrier & Minniti, *supra* note 66, at 18.

90 *See* Loftus & Roland, *supra* note 75.

91 *See* Ian Haydon, *Biologics: The Pricey Drugs Transforming Medicine*, SCI. AM. (Jul. 26, 2017), https://www.scientificamerican.com/article/biologics-the-pricey-drugs-transforming-medicine/ [https://perma.cc/C66B-4UKN].

92 *See* Nicole Gray, *Why Biosimilars May Not Be the Huge Cost-Saver People Hope*, BIOPHARMADIVE (May 20, 2015), https://www.biopharmadive.com/news/why-biosimilars-may-not-be-the-huge-cost-saver-people-hope/399509/ [https://perma.cc/T6PB-8LV8].

93 *See* Rowland, *supra* note 14.

94 *See* Murkherjee, *supra* note 6, at 72.

95 *See* Loftus & Roland, *supra* note 75.

96 *See id.*

through lawful practices."[97] Certainly, Humira improves the lives of patients and offers many advantages over other products in the market.[98] Yet, it seems abusive for a company to keep leveraging government-granted monopolies to keep out competitors and drive up prices to consumers. And while a mechanism, such as the BPCIA, does exist to encourage biosimilar development, efforts to encourage new biologics through the BPCIA are hampered by patent thickets. Addressing the monopolies that patent thickets present seems to fall within the scope of antitrust law, which states that monopolization is illegal under particular circumstances.[99]

In 2020, class action litigation in the Northern District of Illinois attempted to challenge AbbVie's patent thicket under the antitrust laws.[100] The plaintiffs alleged in the case, *In re: Humira (Adalimumab) Antitrust Litigation*, that AbbVie "cornered the market for Humira (and other biosimilar drugs) through anticompetitive conduct."[101] AbbVie allegedly made it difficult for other biosimilar competitors to enter the market by "obtaining and asserting 'swaths of invalid, unenforceable, or noninfringed patents without regard to the patents' merits.'"[102] However, Judge Shah dismissed these claims,[103] stating that AbbVie acquired these patents through a valid petitioning process that was immunized from antitrust liability under the *Noerr-Pennington* doctrine.[104] The sham exception did not apply because the potential presence of invalid patents does not signal an entirely sham petitioning process.[105] According to Judge Shah, AbbVie's over fifty percent success rate in patent applications did not suggest "plausible acts of sham petitioning."[106] The plaintiffs

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97 *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 819 (N.D. Ill. 2020).

98 *See generally* Glasure, *supra* note 4.

99 Sherman Act of 1890 § 2, 15 U.S.C. § 2.

100 *In re Humira*, 465 F. Supp. 3d at 819.

101 *Id*.

102 *Id.* at 827.

103 *Id.* at 853.

104 *Id.* at 835.

105 *See id.* at 830.

106 *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 830-31 (N.D. Ill. 2020). Judge Shah also assessed AbbVie's success in *inter partes* review (IPR). *Id.* at 831. IPR is an administrative proceeding, in which parties can assert that patents are invalid in front of the Patent Trial and Appeals Board (PTAB). *Id.* According to the record, AbbVie

appealed the decision to the Seventh Circuit, which affirmed the decision of the Northern District of Illinois in 2022.[107]

As noted by Judge Shah, this approach to addressing patent thickets is still considered novel.[108] Thus, any discussion related to the use of the sham exception to *Noerr-Pennington* as a sword against patent thickets is "inherently speculative."[109] The litigation scheme under the BPCIA is still developing, and courts are still shaping the exact contours of the "patent dance."[110] Additionally, the intersection between the rise of biologics and antitrust law is still vaguely defined.[111] Some scholars posit that biologics will become the next "antitrust frontier."[112] Various factors create a perfect storm for abuse, such as the complicated process to bring such drugs to market, an absence of a clear list of patents that protect each biologic, and the use of settlement to resolve complicated patent infringement cases that include promises to refrain from entering the market.[113] Professors Michael Carrier and Carl Minniti argue that antitrust law can, and should, play a more prominent role in regulating biologics, as regulatory frameworks are inadequate.[114] Other scholars seem less enthusiastic about applying antitrust remedies, arguing instead that current patent misuse mechanisms sufficiently prevent abuse.[115] And yet another set of scholars, like Professor Erika Lietzan, propose that antitrust law may not even apply, as there is a risk of decreased biologics innovation which should be a

has been involved in 18 different IPR proceedings involving Humira. *Id.* Of those that were heard by PTAB, AbbVie was successful in three out of five proceedings. *Id.* The PTAB can deny hearings on invalidity for any reason; it is also worth noting that 13 of the 18 proceedings were denied review by PTAB. *Id.*

107 *See* Mayor of Balt. v. AbbVie, Inc., 42 F.4th 709, 716 (7th Cir. 2022).

108 *In re* Humira, 465 F. Supp. 3d at 837.

109 Erika Lietzan, *A Solution in Search of a Problem at the Biologics Frontier*, 2018 U. ILL. L. REV. 19, 20 (2018).

110 *See generally* Li, *supra* note 80.

111 *See* Carrier & Minniti, *supra* note 66, at 1.

112 *Id.*

113 *Id.* at 3–4, 17.

114 *Id.* at 18–19.

115 *See, e.g.*, Daryl Lim, *Biologics as the New Antitrust Frontier: Reflections, Riposte, and Recommendations*, 2018 U. ILL. L. REV. 209, 212 (2018).

larger concern.[116] Regardless, *In re Humira* will have great implications on future litigation and scholarship in this field.

Despite the Seventh Circuit upholding the ruling from the Northern District of Illinois, there must be a different way to define sham petitioning involving patent thickets. This Note posits that the sham exception to *Noerr-Pennington* can and should be used to address biologic patent thickets. Because courts determine the applicability of the sham exception based on a two-part test, this Note's solution is divided accordingly into two sections. The first section examines the objective portion of the test and proposes that courts look at each patent individually to assess the value of the patent compared to the cost of prosecuting that patent. If the value of the patent is less than the cost of prosecuting the patent, even if the entire patent thicket is valuable, then that patent should count as objectively baseless toward the sham petitioning requirement. The second section proposes courts consider the patent thicket as a series of petitions to the government and analyze the second, subjective, prong of the sham exception test. Because a patent thicket is simply an accumulation of patents—and therefore a sequence of petitions to the government—courts should consider the cumulative petitioning process of acquiring the patents as a whole. Courts should then take a more flexible approach to addressing how that sequence of petitions may be considered sham petitioning.

III. ASSESSING THE VALUE OF THE PATENT INDIVIDUALLY

As articulated in *Noerr* and subsequent cases, parties that petition the government for a result are shielded from antitrust liability, even if the outcome of that petition is anticompetitive.[117] However, the petitioning activity can be considered a sham under specific circumstances, as outlined in *Professional Real Estate Developers*.[118] If the petition is objectively and subjectively baseless, it does not receive *Noerr-Pennington* immunity.[119] This section aims to

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116 *See, e.g.*, Lietzan, *supra* note 109, at 21.

117 E.R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 135–36 (1961).

118 Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 51 (1993).

119 *Id.* at 60–61.

describe a way to classify those patents that may be objectively baseless.

A. Current Court Approaches to Sham Petitioning

The sham petitioning exception to the *Noerr-Pennington* doctrine was outlined in *Professional Real Estate Investors v. Columbia Pictures*.[120] The Supreme Court articulated a two-part definition: "[f]irst, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. . . . Under this second part . . . the court should focus on whether the baseless lawsuit conceals 'an attempt to interfere *directly* with the business relationships of a competitor.'"[121]

This definition is sequential; a court cannot move onto the second prong (subjective baselessness) without establishing the first prong (objective baselessness).[122] While *Professional Real Estate Investors* specifically addressed an overly zealous litigant,[123] the sham definition has been subsequently applied to other petitioning situations as well.[124] For example, patent applications are considered petitions to an administrative agency and can be covered under this exception.[125]

Success on the merits is well-delineated in a litigation context. A lawsuit is considered objectively reasonable when the "lawsuit is one 'reasonably calculated to elicit a favorable outcome.'"[126] This reasonable calculation should incorporate "[t]he notion of probable cause, as understood and applied in the commonlaw tort of wrongful civil proceedings."[127] Probable cause is determined by looking at the

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120 *Id.* at 61.

121 *Id.* at 60–61.

122 *Id.* at 60 ("Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation.").

123 *Id.* at 62–66 (discussing the merits of the underlying lawsuit upon which the antitrust claim was based).

124 *See* AREEDA & HOVENKAMP, *supra* note 51, ¶ 210.

125 *See id.* ¶ 204.

126 U.S. Futures Exch., LLC v. Bd. of Trade, Inc., 953 F.3d 955, 964 (7th Cir. 2020) (quoting Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 n.5 (1993)).

127 *See* Prof. Real Est. Invs., 508 U.S. at 62.

relevant facts regarding the case,[128] and in civil proceedings, "requires no more than a reasonable belief that there is a chance that a claim may be held valid upon adjudication."[129] However, this is less defined in an administrative setting: the Supreme Court has simply said that parties cannot make misrepresentations toward adjudicative bodies.[130] Other appellate courts have elaborated, indicating that "a misrepresentation renders an adjudicative proceeding a sham only if the misrepresentation (1) was intentionally made, with knowledge of its falsity; and (2) was material, in the sense that it actually altered the outcome of the proceeding."[131]

B. Implications of this Framework on Patent Applications

It is difficult to apply this adjudicative framework toward patent prosecution: when an inventor applies for a patent, she must act with the "duty of candor and good faith in dealing with the [Patent] Office."[132] As part of these responsibilities, the applicant must disclose all known information of materiality to the USPTO.[133] This is meant to cover all information that the Patent Office may need to make a "proper and independent determination on patentability,"[134] including any information related to "enablement, possible public uses, sales, offers to sell, derived knowledge, prior invention by another, inventorship conflicts, litigation statements, and the like."[135] The duty to disclose information "is not limited to prior art but embraces *any* information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an

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128 *In re* Relafen Antitrust Litig., 346 F. Supp. 2d 349, 360–62 (D. Mass. 2004).

129 *See* Prof. Real Est. Invs., 508 U.S. at 62–63 (internal quotations and corrections omitted).

130 Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 513 (1972) ("Misrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process.").

131 Mercatus Grp., LLC v. Lake Forest Hosp., 641 F.3d. 834, 843 (7th Cir. 2011).

132 MPEP § 2001 (8th ed. Rev. 9, Aug. 2012), https://www.uspto.gov/web/offices/pac/mpep/s2001.html#d0e195585 [https://perma.cc/Z585-8YGK].

133 *Id.*

134 *Id.*

135 *Id.*

application to issue as a patent."[136] While these requirements provide a uniform standard that allows the USPTO to issue more consistent patents,[137] they do not particularly speak to the adjudicative process itself. When a patent applicant begins her application process, she and her lawyer should have already performed some amount of due diligence to determine whether the invention is patentable at all.[138] She then files the application if there is some reason for patentability in the first place, indicating good-faith belief of success on the merits. Accordingly, this lends itself to the conclusion that applicants will only file their applications if they believe that the inventions are patentable and have a chance of success on the merits. Following this logic, from the outset of the prosecution process, no applications can be considered objectively baseless, as the patent applicant considered their beliefs of patentability and likelihood of success.

But this certainly is not the case. There are clearly instances where applicants intend to deceive the USPTO, and antitrust law has carved out a separate exception to the *Noerr-Pennington* doctrine specifically regarding patents—the *Walker-Process* exception.[139] Under the *Walker-Process* exception, a patent owner who obtains a patent through "fraud on the Patent Office" and asserts an infringement lawsuit based on that patent is not exempt from *Noerr-Pennington*.[140] This is because the petition to the government that resulted in the patent, a government-sanctioned monopoly, was done under false pretenses.[141] Generally, courts have interpreted "fraud" as inequitable conduct during the patent application process before

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[136] Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1234 (Fed. Cir. 2003) (internal quotations omitted) (quoting GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001)).

[137] MPEP § 2001.04 (8th ed. Rev. 9, Aug. 2012), https://www.uspto.gov/web/offices/pac/mpep/s2001.html#d0e195585 [https://perma.cc/4C9X-TTFE].

[138] *See* Gene Quinn, *The Cost of Obtaining a Patent in the US*, IPWATCHDOG (Apr. 4, 2015), https://www.ipwatchdog.com/2015/04/04/the-cost-of-obtaining-a-patent-in-the-us/id=56485/ [https://perma.cc/D3SF-2Q6K].

[139] *See* Herbert J. Hovenkamp, The Walker Process Doctrine: Infringement Lawsuits as Antitrust Violations (Sept. 2008) (Legal Studies Research Paper No. 08-36, University of Iowa) (on file with author), at 2.

[140] *See id.* at 1.

[141] *Id*. at 2.

the USPTO.[142] This requires an intent to deceive the examiner during the prosecution process and "that the examiner would very likely not have issued the patent had he or she known the truth."[143] While important for patent litigation and useful in instances where fraud can be established, the *Walker-Process* exception is unhelpful when considering patent applications that may be reasonable but provide no objective purpose.

Recall patents that are split off from their parents, mentioned in Part I.[144] These are also called divisional applications, defined as "a later application for an independent or distinct invention."[145] Generally, this occurs when the examiner indicates that "two (or more) aspects disclosed and claimed in a single application are, in fact, independently patentable inventions."[146] The inventor, then, must decide which claims to pursue as a patent; the claims that are not selected can be withdrawn and submitted as a separate application.[147] The claims in the original patent application that were selected for continued prosecution are called the "parent application," while any patent resulting from the claims severed from the initial application is called the "divisional patent."[148] Divisional patents can be terminally disclaimed and have the same exclusivity ending date as the original patents.[149] Most importantly, applicants can file a divisional application after receiving a "nonstatutory double patenting"

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142 *Id.*

143 *Id.*

144 *See supra* Part I.A.

145 MPEP § 201.06 (8th ed. Rev. 9, Aug. 2012), https://mpep.uspto.gov/RDMS/MPEP/e8r9#/e8r9/d0e7252.html [https://perma.cc/YL3C-AZEA].

146 Sadhana Chitale et al., *Understanding the Basics of Patenting*, 38 NATURE BIOTECHNOLOGY 263, 264 (2020).

147 *Id.*

148 *See* MPEP § 201.04 (8th ed. Rev. 9, Aug. 2012), https://mpep.uspto.gov/RDMS/MPEP/e8r9#/e8r9/d0e6763.html [https://perma.cc/8XJ6-GT3G]; *see also* MPEP § 201.06 (8th ed. Rev. 9, Aug. 2012), https://mpep.uspto.gov/RDMS/MPEP/e8r9#/e8r9/d0e7252.html [https://perma.cc/8E5P-SGT2].

149 *See* MPEP § 201.06(c) (8th ed. Rev. 9, Aug. 2012), https://mpep.uspto.gov/RDMS/MPEP/e8r9#/e8r9/d0e7252.html [https://perma.cc/VS9D-3SCQ].

rejection.[150] This type of rejection occurs when a claim has "subject matter [that] is not patentably distinct from the subject matter claimed in a commonly owned patent."[151] The purpose of such a rejection is "to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later."[152] The standard of examination for these split-off applications is different, as the inventor's own inventions are not considered as prior art.[153]

While the existence of these divisional applications that are terminally disclaimed allow an inventor to protect more of their invention, these applications present difficulties to biosimilar companies. Evidence suggests that biologics manufacturers acquire many of these patents to "continuously broaden the scope" of patents and "make it almost impossible for a generics company to invalidate an entire family."[154] Empirical research also demonstrates this; of Humira's 136 patents, over half are divisional patents or patents subject to terminal disclaimers.[155] Further, within these patent families, there are twenty-one patents related to the formulation of Humira alone, all consisting of the same five components, but varying in protein concentration and the presence of particular pharmaceutical salts required to stabilize the protein.[156] The claims in this particular family "significantly overlap with one another."[157] Importantly, Humira only has two approved formulations in the United States.[158]

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[150] *See* MPEP § 804 (9th. ed. Rev. 10, June 2020), https://www.uspto.gov/web/offices/pac/mpep/s804.html [https://perma.cc/4VH3-6RXZ] (defining double patenting).

[151] *In re* Berg, 140 F.3d 1428, 1431 (Fed. Cir. 1998).

[152] *Id.* at 1431–32.

[153] *See* 35 U.S.C. § 102(b)(2)(C).

[154] Charlotte Kilpatrick, *Divisional Filings at USPTO and EPO 'Legal but Evil'*, MANAGING INTELL. PROP. (Mar. 26, 2020).

[155] *See* Wu & Cheng, *supra* note 7, at 141.

[156] *See id.* at 143–46.

[157] *See id*. at 146.

[158] *See* FDA, HUMIRA® (ADALIMUMAB) INJECTION, FOR SUBCUTANEOUS USE INITIAL U.S. APPROVAL § 11, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125057s410lbl.pdf [https://perma.cc/QH77-2REB]. One formulation consists of 40 mg/mL adalimumab, citric acid, sodium phosphate, mannitol, polysorbate 80, sodium chloride and Water for Injection. *Id.* at 1. This formulation was approved in 2002. The later

Yet, AbbVie has protections to a much larger swath of formulations,[159] some of which AbbVie may never seek approval for sale in the United States or anywhere in the world. According to the current *Noerr-Pennington* paradigm, the applications for each of the twenty-one patents for the different formulations of Humira were considered valid petitions to the USPTO.[160] Under current antitrust analysis, the *Professional Real Estate Investors* analysis would stop here;[161] these applications are probably all valid on their face.

This is where the Seventh Circuit stopped in its analysis of the Humira patents. After all, the court asks, "what's wrong with having lots of patents? If AbbVie made 132 inventions, why can't it hold 132 patents?"[162] There is an ideological debate over whether this large number of Humira patents is indicative of the innovative nature of the product.[163] However, setting aside this debate, this current behavior (filing for applications and accumulating a large number of patents when some of these patents ultimately cover the same thing) runs counter to the purpose of patent law to cover a single product. Continuing to apply for patents that cover the same invention seems abusive, and abuse of a government petitioning process can lend itself to antitrust liability.[164] How, then, can the amount of petitions, which are numerous, be reconciled with the petitions' seeming validity? Under current antitrust doctrine, there is no good way to consider this scenario. Instead, perhaps the law should draw upon other antitrust doctrines as a source of inspiration.

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approved formulation consists of 40 mg/mL Humira, mannitol, polysorbate 80 and Water for Injection. *Id.* at 26.

159 *See* Wu & Cheng, *supra* note 7, at 146.

160 This analysis does not include applications for additional formulations for Humira that were ultimately rejected. There may be even more applications (i.e., more petitions from AbbVie).

161 Pro. Real Estate Invs., Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 (1993).

162 Mayor of Balt. v. AbbVie, Inc., 42 F.4th 709, 712 (7th Cir. 2022).

163 *Compare* Dominic Basulto, *Patents Are a Terrible Way to Measure Innovation*, WASH. POST (July 14, 2015, 8:00 AM), https://www.washingtonpost.com/news/innovations/wp/2015/07/14/patents-are-a-terrible-way-to-measure-innovation/ [https://perma.cc/35PE-V3P5], *with* Bryan Kelly et al., *Measuring Technological Innovation over the Long Run*, (Nat'l Bureau of Econ. Rsch., Working Paper No. 25266, 2020).

164 *See* Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 513 (1972).

C. Objectively Baseless Determined by Patent Value

In other antitrust cases, courts are suspicious when firms set prices of a product below cost and later recoup these lost profits.[165] However, the presence of this loss-leading strategy alone is insufficient to infer anticompetitive intent; parties must still show that the pricing strategy hurt competitors or caused other "real market injury."[166] This structure can be applied to patents, by comparing the value of the patent to the cost of prosecuting that patent. If the cost of prosecuting the patent is greater than the value of the patent, the courts should apply the same suspicion toward this loss-leading patent acquisition and move to the subjective prong of the *Professional Real Estate Investors* test.

The cost of prosecuting a patent is relatively easy to calculate. The USPTO has published a fee schedule, indicating the cost of each office action.[167] Applicants are charged fees based on numbers of claims submitted, for the patent examiner to search the prior art, as well as for examination itself.[168] The applicant is also charged fees for additional interactions with the USPTO, as well.[169] Since the Patent Office recommends that patent applications come through attorneys (and only ones who are registered to practice with the Office),[170] the cost of obtaining a patent often also includes the cost of

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[165] Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 222 (1993). In *Brooke Group*, the loss-leading strategy was imposed by a tobacco company, which allegedly priced its products lower than the cost to make the products. Because other tobacco manufacturers could not match those lower prices, consumers would prefer the lower cost products and not buy from the other manufacturers. This would eventually drive the other companies out of business, and once Brown & Williamson was the only company left, they would raise prices to recoup for the initial losses while driving competitors out of business.

[166] *Id.* at 226.

[167] *See generally* USPTO FEE SCHEDULE (Dec. 29, 2022), https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule [https://perma.cc/G4JQ-WFD7].

[168] *See id.*

[169] *See id.*

[170] *See* FINDING A PATENT PRACTITIONER, https://www.uspto.gov/learning-and-resources/patent-and-trademark-practitioners/finding-patent-practitioner [https://perma.cc/8T26-7CR5]. Applicants can represent themselves pro se, but the Patent Office "always recommends using a registered patent attorney or agent to assist" in applications. FILING A PATENT APPLICATION ON YOUR OWN,

retaining a patent attorney. A survey of patent lawyers indicates that their median charge for filing just one biotechnology or chemical patent application is about $10,000.[171] This does not include fees for any changes made to the application during the prosecution process or other patent filings in other countries, which can drastically increase the cost of prosecuting a patent.[172]

D. Difficulty in Determining Patent Value

Determining the value of a patent, on the other hand, is difficult. While patents are licensed and sold, these tend to be private transactions, and information about the exact calculations and negotiations is difficult to acquire.[173] Another indicator of patent value could be court damages awards in patent infringement cases.[174] Generally, these damages are based on a "reasonable royalty" rate to which the parties would have otherwise agreed absent the act of infringement.[175] However, the patented object is often just a part of the whole product, making it sometimes difficult for courts to calculate the value of the patented part as opposed to the product as a whole.[176] Courts previously adopted the "entire market value" rule, under which a court "assess[es] damages based on the entire market value of the accused product only where the patented feature creates the basis for customer demand or substantially creates the value of the component parts."[177] But the entire market value rule is utilized when an allegedly infringing product contains both patented and

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uspto.gov/patents/basics/using-legal-services/pro-se-assistance-program [https://perma.cc/U7JN-5X65].

171 FRANK L. GERRATANA ET AL., AM. INTELL. PROP. L. ASS'N, REPORT OF THE ECONOMIC SURVEY 2019 35 (2019).

172 *See id.* at 35–36. For a more in-depth analysis of the cost of patent prosecution, see Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495 (2001). Lemley's article was written before the passage of the America Invents Act in 2012. Nevertheless, it provides interesting insight into the cost of prosecuting a patent. For other, more recent (albeit simpler) examples, see Quinn, *supra* note 138.

173 *See* Cristina Odasso et al., *Selling Patents at Auction: An Empirical Analysis of Patent Value*, 24 INDUS. & CORP. CHANGE 417, 418 (2015).

174 *See* 35 U.S.C. § 284.

175 *See* Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp., 879 F.3d 1332, 1348–49 (Fed. Cir. 2018).

176 *See id.* at 1350.

177 AstraZeneca AB v. Apotex Corp., 782 F.3d 1324, 1337 (Fed. Cir. 2015) (internal quotation marks omitted).

unpatented components, as the rule "is designed to account for the contribution of the patented feature to the entire product."[178] Further convoluting this analysis, the Federal Circuit has indicated that the entire market value rule may not apply in a case where a competitor of a generic drug infringed a formulation patent.[179]

If the entire market value rule does apply, this calculation is complicated in situations where multiple patents protect a product, like a pharmaceutical drug. For Humira, most of the drug's success should come from the active ingredient itself, but some patients may prefer this particular TNF inhibitor because of the formulation, or ease of dosing.[180] Determining the portion of Humira sales that relate directly to the patent that protects the autoinjector device, for example, is not an easy task. There are different ways to view the added value of the additional patent in a thicket.[181] In some situations, the value of the overall product can be distributed evenly over the entire pool of patents; in others, where the patents act "strategically" with one another, each patent must be assessed individually.[182] However, the value of Humira may be dependent on the presence of the entire patent thicket, which makes each additional patent more valuable.

When evaluating patent thickets, courts should consider the characteristics of each patent individually. Since Humira has twenty-one different formulation patents,[183] but only markets two separate formulations in the United States,[184] the additional patents that cover formulations that AbbVie does not utilize must have a

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178 *Id.* at 1338.

179 *Id*. at 1338–39. The Federal Circuit did note that, "[w]hile the entire market value rule does not apply to this case, the damages determination nonetheless requires a related inquiry. When a patent covers the infringing product as a whole, and the claims recite both conventional and unconventional elements, the court must determine how to account for the relative value of the patentee's invention in comparison to the value of the conventional elements recited in the claim, standing alone." *Id.* at 1339 (internal citations omitted).

180 *See, e.g.*, Kristin Karlsdottir et al., *A Patients' Perspective Towards the Injection Devices for Humira and Imraldi in a Nationwide Switching Program*, FRONTIERS MED. (Jan. 27, 2022), https://www.frontiersin.org/articles/10.3389/fmed.2022.799494/full [https://perma.cc/2R6U-DRET].

181 *See* ALEXANDER J. WURZER ET AL., VALUATION OF PATENTS 115–16 (2012).

182 *See id.* at 116.

183 *See* Wu & Cheng, *supra* note 7, at 143–46.

184 *See* FDA, *supra* note 158.

lower value. These other patented formulations add no value to the actual product itself, except for the purpose of fending off competitors. This seemed to be of no matter to the Seventh Circuit.[185] While the Seventh Circuit may consider these additional patents to be "neither here nor there,"[186] the reality is that these patents do have implications on how biosimilar manufacturers conduct business. A biosimilar manufacturer who wishes to formulate a competing TNF inhibitor would avoid using any of those combinations to prevent a potential patent infringement lawsuit. This ultimately increases the time, effort, and amount of resources required to find the right formulation and delays the biosimilar's entry into the market, if the biosimilar manufacturer decides to proceed at all. On a broader scale, a court could look at the number of patents with a terminal disclaimer,[187] or patents obtained through divisional applications, to guide the valuation.

IV. VIEWING THE PATENT THICKET AS A SEQUENCE OF PETITIONS

One of the difficulties for Humira's biosimilar competitors simply comes from the sheer number of patents that AbbVie has been able to acquire for the product.[188] Because these patents cover a wide range of formulations, dosing, manufacturing techniques, and methods of treatment,[189] it is likely difficult for competitors to even determine how to start designing a biosimilar and find aspects of the drug that are non-infringing. This challenge in designing and producing biosimilars is known—eight separate companies have settled with AbbVie, as opposed to challenging the patent thicket as part of the BPCIA process.[190]

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185 *See* Mayor of Balt. v. AbbVie, Inc., 42 F.4th 709, 713 (7th Cir. 2022) ("The fact that the 132 patents can be traced to continuation applications from 20 root patents seems to us neither here nor there.").

186 *Id.*

187 *See supra* Part I.A.

188 *See* Rowland, *supra* note 14.

189 *See* Wu & Cheng, *supra* note 7, at 125.

190 *See* Andrew Dunn, *With Boehringer Settlement, AbbVie Completes Humira Sweep*, BIOPHARMA DIVE (May 14, 2019), https://www.biopharmadive.com/news/abbvie-boehringer-ingelheim-settle-humira-patent-biosimilar/554729/ [https://perma.cc/FZ2H-L76U]. Generally, settlements in BPCIA cases involve the biologic company paying the biosimilar manufacturer to delay market entry of the biosimilar until a later date. *See*

In a situation where a company can (and does) accumulate over a hundred patents, and where it is clear that market entry of competitors is delayed as part of this accumulation process, courts should look at this sequence with a more flexible approach toward sham petitioning. This is not to say that the presence of a few "objectively baseless" patents means that the *entire* patent thicket is baseless. Instead, the sequence of petitions should be viewed holistically, and the intent of the company's actions in engaging in this sequence should be considered more heavily in these cases.

A. Current Court Approaches

While a series of petitions may be anticompetitive for the purposes of sham litigation, courts disagree exactly how to assess the series of petitions. In *California Motor Transport Co. v. Trucking Unlimited*, the Supreme Court articulated that a series of repetitive filings can be outside the scope of the *Noerr-Pennington* doctrine.[191] Justice Stevens later elaborated that "[r]epetitive filings, some of which are successful and some unsuccessful, may support an inference that the process is being misused."[192] At the same time, the Court articulated a two-part test for "sham" litigation in *Professional Real Estate Investors*, requiring that a court look at whether a petition is objectively and subjectively baseless.[193] However, this becomes more difficult when applying this test in a sequence of petitions. Courts have yet to determine how many individual instances in a series must be considered objectively baseless before that entire

Carrier & Minniti, *supra* note 66, at 19. The practice, aptly named "pay-for-delay," is known as a reverse payment patent settlement. *See* FTC, PAY FOR DELAY, https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay [https://perma.cc/V4QU-UV4J]. The Supreme Court has recently ruled that the reverse payment settlement may at times be incompatible with antitrust laws. *See, e.g.*, FTC v. Actavis, Inc., 570 U.S. 136, 141 (2013). These types of settlements in the BPCIA space have not yet been litigated. *See* Carrier & Minniti, *supra* note 66, at 21. The Seventh Circuit in *Mayor of Baltimore* did discuss the reverse settlement payments between AbbVie and the eight other pharmaceutical companies. *See Mayor of Balt.*, 42 F.4th at 714–16 (7th Cir. 2022). However, this discussion is irrelevant for the purposes of this Note.

191 *See* 404 U.S. 508, 513 (1972).

192 Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 73 (1993) (Stevens, J., concurring).

193 *See id.* at 60–61.

sequence is deemed objectively baseless for the purposes of sham litigation.

The First and Seventh Circuits impose a strict version of this analysis, and require "patterns of '*baseless*, repetitive claims' before finding a sham."[194] These Circuits hold that each of these petitions must be viewed individually, and that the courts must apply the *Professional Real Estate Investors* test to each filing.[195] Ultimately, these courts find that the focus of this analysis is "not . . . the difference between a single suit and a series of suits, but rather . . . the difference between 'objectively reasonable claims' and 'a pattern of baseless repetitive claims.'"[196] The First Circuit recognized that there were certain pragmatic reasons for filing a series of smaller lawsuits, as a larger suit may generate a bigger burden on the parties involved.[197] Additionally, these courts recognize that the sham exception "has never hinged on the petitioner's subjective intent alone,"[198] indicating that the objective test is required under all circumstances. The sham litigation analysis, then, always begins with a case-by-case assessment of whether each proceeding is objectively baseless.[199]

The Second, Third, Fourth, and Ninth Circuits take a different approach and apply a "more flexible standard . . . when dealing with a pattern of petitioning."[200] The inquiry shifts away from a case-by-case standard, and moves toward a "holistic review that may include looking at the defendant's filing success—i.e., win-loss percentage—as circumstantial evidence of the defendant's subjective motivations."[201] These courts recognize that by bringing a series of lawsuits, as a matter of chance, some of the series may have some sort

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194 U.S. Futures Exch., LLC v. Bd. of Trade, 953 F.3d 955, 964 (7th Cir. 2020) (quoting *Pro. Real Est. Invs.*, 508 U.S. at 58); *id.* at 965 ("We stand with the First Circuit.").

195 *Id.*

196 P.R. Tel. Co. v. San Juan Cable LLC, 874 F.3d 767, 771 (1st Cir. 2017).

197 *See id.* at 772.

198 *U.S. Futures Exch.*, 953 F.3d at 964.

199 *See id.*

200 Hanover 3201 Realty, LLC v. Village Supermarkets, Inc., 806 F.3d 162, 180 (3d Cir. 2015) ("We agree with the approach to *California Motor* and *Professional Real Estate* that has been adopted by the Second, Fourth, and Ninth Circuits.").

201 *Id.*

of merit.[202] Because the ultimate purpose is to determine what is "actually nothing more than an attempt to interfere directly with the business relationships of a competitor,"[203] a court must look at the overall pattern of cases to determine if the sham exception applies.[204] The misuse of the process means that a small number of the petitions that have objective merit are not meant to shield the overall behavior from liability.[205] Courts can look at "other evidence of bad-faith as well as the magnitude and nature of the collateral harm imposed on plaintiffs . . . (e.g., abuses of the discovery process and interference with access to governmental agencies)."[206] In other words, where there is only one petition or application, the objectively baseless standard from *Professional Real Estate Investors* should apply. But where there is a series of petitions, courts should evaluate whether the overall course of behavior is meant to be anti-competitive.

In the recent Humira case, *In re: Humira (Adalimumab) Antitrust Litigation*, the Northern District of Illinois applied the strict approach proposed by the Seventh Circuit.[207] The court identified three different venues that AbbVie potentially misused—the patent prosecutions and other proceedings in front of the USPTO, the biologic licensing and drug approval process before the FDA, and the patent infringement actions in district court.[208] Because of sham exception's strict standards, the plaintiffs were required to allege that each petitioning process was objectively baseless.[209] The court found that both AbbVie's fifty-three percent patent application approval rate and high success rate during *inter partes* review demonstrated that the petitions were not objectively baseless, shielding AbbVie from liability in front of the USPTO.[210] During the patent

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202 *See* USS-POSCO Indus. v. Contra Costa Cnty. Bldg. & Const. Trades Council, 31 F.3d 800, 811 (9th Cir. 1994).

203 E.R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961).

204 *See Hanover 3201 Realty*, 806 F.3d at 180.

205 *Id.*

206 *Id.* at 181.

207 *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 829 (N.D. Ill. 2020).

208 *Id.*

209 *Id.* at 830.

210 *Id.* at 830–31.

dance, AbbVie also resolved patent infringement suits with Amgen and Sandoz.[211] Although AbbVie asserted some patents against Sandoz during the patent dance that may have been objectively baseless, both suits were settled and deemed reasonable by the court.[212] After removing the immunized behavior from the evaluation, the court found that the remaining claims were simply "a few sharp elbows thrown at sophisticated competitors participating in regulated patent and biologic-drug regimes."[213] Although some elements were potentially anticompetitive and suspect under the sham litigation inquiry, the court stated that the entire "alleged monopolization scheme" was not subject to an antitrust injury.[214]

Additionally, the court was hesitant to impose antitrust liability because most petitions involve the patent system.[215] The USPTO reviews patents and, thus, all approved patents are "entitled to a presumption of validity."[216] This presumption, while not "completely unassailable,"[217] is because the Patent Office has already scrutinized the patent for potential invalid claims, and would only grant the patent if it did not find any.[218] Even if the court took a more flexible approach to the sham exception, the Northern District of Illinois felt that the fifty-three percent patent approval rate and the higher rate of success during the *inter partes* review was "too high to plausibly allege sham petitioning as a matter of law."[219] The court also cautioned that, even if the patent examination system is flawed and subject to limits, "the proper fix is not to use antitrust doctrine to launch a collateral attack on 132 patents, thirteen *inter partes* review determinations, multiple patent dance exchanges and at least two patent infringement lawsuits."[220]

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211 *Id.* at 832–33.
212 *Id.* at 833.
213 *Id.* at 834.
214 *Id*.
215 *Id.*
216 *Id.*
217 *Id.* (quoting Chi. Rawhide Mfg. Co. v. Crane Packing Co., 523 F.2d 452, 458 (7th Cir. 1975)).
218 *Id.*
219 *Id.* at 830.
220 *Id*. at 834.

The Seventh Circuit affirmed this decision by the Northern District of Illinois.[221] The court stated that the sheer number of patents covering Humira was not a concern,[222] and reiterated that the fact that most of AbbVie's patents were not challenged in IPR proceedings indicated that the patents were not as weak as the plaintiffs claimed.[223] The Seventh Circuit additionally stated that the fact that the 132 patents issued meant that the "applications cannot be called baseless."[224] And because the concerns of the plaintiffs were directed towards the patents themselves, and not the process of petitioning, the Seventh Circuit felt that *Noerr-Pennington* did not apply.[225] According to the court, the act of applying for patents does "not impose costs on rivals; only issued patents do so."[226]

B. The Flexibility of Using the Flexible Approach

The Northern District of Illinois is not wrong that antitrust law is not a fix to the patent system. However, to simply set aside a question of potential monopolization merely punts the question. The point of antitrust law is to protect against monopolization,[227] and accumulating patents as part of a monopolization scheme falls within the scope of antitrust law. By putting it so indiscriminately, the Northern District of Illinois and the Seventh Circuit both ignore the fact that the *Professional Real Estate Investors* analysis is not the entirety of the antitrust analysis.[228] Instead, after a court deems a behavior suspect, plaintiffs in an antitrust lawsuit still must prove anticompetitive effects; further, the case is still subject to a rule of reason, burden-shifting analysis.[229]

Additionally, it is misguided to rely on the greater-than-fifty percent patent approval rate as indicative of the overall validity of the

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221 *See* Mayor of Balt. v. AbbVie, Inc., 42 F.4th 709, 716 (7th Cir. 2022).

222 *See id.* at 712.

223 *See id.* at 713.

224 *Id.*

225 *See id.* at 714.

226 *Id.* at 713–14. The question of whether patent applications do not impose costs on rivals is outside the scope of this Note.

227 *See* FTC, THE ANTITRUST LAWS, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws [https://perma.cc/5HKK-DDVT].

228 *See* AREEDA & HOVENKAMP, *supra* note 51, at ¶ 208.

229 *Id.*

sequence of patent acquisitions. In fact, there is evidence to show that a patent approval rate of fifty percent is relatively low, as the overall patent grant rate at the USPTO hovers around seventy percent.[230] AbbVie's patent approval rate seems lower still when taking into account the number of terminally disclaimed patents the company has acquired. Of AbbVie's 136 granted patents, seventy-eight have terminal disclaimers relating to nine different parent applications.[231] In effect, these patents—which have a different application process and patentability threshold—play a disproportionate role in AbbVie's overall patent approval rate. The approval rate of parent patents critical to Humira's success is probably even lower than fifty percent in actuality.

Notably, this case represents the first time that USPTO application proceeding win-rates were used as a benchmark for assessing a sequence under *Noerr-Pennington*.[232] Although the win-rate during the patent prosecution process may have been higher than previous cases that applied the win-loss ratio test,[233] the court cannot take the standards set out in those previous cases as a guidepost. All of these previous cases were related to litigation proceedings—none involved patent applications.[234] If the Northern District of Illinois is so hesitant to apply the same antitrust liability standards due to the Patent Office's large penumbra,[235] surely it should also hesitate to apply the same standard regarding the win-loss ratio.

Fundamentally, AbbVie and other biologics manufacturers prioritize long-term business strategies. Their goal of getting a biologic to market involves years of careful planning and analysis.[236] They pursue this goal through a particular strategy and file patent and administrative applications at certain points during the drug

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230 Mark Lemley & Bhaven Sampat, *Is the Patent Office A Rubber Stamp?*, 58 EMORY L.J. 101, 109 (2008).

231 *See* Wu & Cheng, *supra* note 7, at 141.

232 Amici Curiae Brief of 66 Law, Economics, Business, and Medical Professors in Support of Plaintiffs-Appellants at 4, UFCW Local 1500 Welfare Fund v. AbbVie Inc., No. 20-2402, (7th Cir., Oct. 9, 2020).

233 *Id.* at 4–5.

234 *Id.*

235 *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 834 (N.D. Ill. 2020).

236 *See, e.g.*, IQVIA BIOTECH, DRUG DEVELOPMENT STRATEGY & ANALYSIS (2019).

development process.[237] Each of these filings is intentional and strategic. By looking at both elements—patent applications and patent dance litigations—separately, the court misses the overall goal. While each element may not be objectively baseless, the actions together reveal monopolistic intent. Instead, by focusing on each element individually, this runs into the same issue with the *Professional Real Estate Investors* test, mentioned in Part II.[238] Because each element is valid and therefore not objectively baseless, the court would stop at this first part of the analysis regardless. The Northern District and the Seventh Circuit ignored the overall pattern of AbbVie's behavior and missed the forest for the trees, so to speak.

C. The Difficulties in Determining Sequence Threshold

Certainly, in instances where there are hundreds of patents and many different proceedings in front of the Patent Trial and Appeals Board and district courts, it is easy to consider a set of behaviors as a sequence. However, difficulty arises when there are fewer proceedings: what if a company only has a handful of patents and only a few BPCIA patent dance proceedings? This is a sequence in the sense that there is more than one proceeding, but is this truly a sequence? The Third Circuit declined to answer this question, simply stating that "we do not set a minimum number requirement . . . or find that four sham petitions will always support the use of *California Motor*."[239] This strongly indicates why courts prefer to evaluate each instance of petitioning individually and apply the *Professional Real Estate Investors* test. Additionally, it is easier for the courts to apply one standard, as opposed to having two separate standards—one that applies in a sequence and one that does not.

However, concerns about determining a sequence may not apply in the biologics space. Biologics manufacturers tend toward more patent protections as opposed to fewer—generally speaking, the

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[237] *See* Isobel Finnie, *Protecting Biotech IP to Support Deal Value*, BIOPHARMA DEALMAKERS, June 2018, at B2–B4.

[238] *See supra* Part III.B.

[239] Hanover 3201 Realty, LLC v. Village Supermarkets, Inc., 806 F.3d 162, 181 (3d Cir. 2015).

number of patents per drug has increased over time.[240] Currently, the major biologics products on the market have over ninety patents registered per drug.[241] It is unlikely that as more biologics enter the market, the numbers of patents that protect these molecules would significantly decrease. In and of itself, this indicates that the concern about having too few patents in a sequence is misplaced. Additionally, following the Third Circuit's lead,[242] it makes sense for courts to address each sequence on a case-by-case basis.

V. A GLOBAL COMMENT ABOUT DRUG PRICING

Pharmaceutical pricing in the United States is the product of a complicated system.[243] Pharmaceutical companies negotiate with insurance companies and consider a wide variety of factors to determine what price the market will bear for that particular drug.[244] Because biologics require more research and are generally more complicated to produce, they tend to be priced higher in the market.[245] Additionally, the U.S. Government does not directly negotiate pharmaceutical prices, unlike its counterpart governments in other parts of the world.[246] Further, other countries also implement pharmaceutical price controls, while the U.S. Government does not.[247] Product exclusivity plays a part in determining drug price[248] by allowing a manufacturer to leverage their position to negotiate for a higher price. However, exclusivity is by no means the only factor that determines price, and changing the overall exclusivity period granted to a drug, whether through regulatory or patent means, is not going to single-handedly solve drug pricing problems. Evidence from

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240 Lisa Ouellette, *How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOM. TECH. L. REV. 299, 301 (2010).

241 *See* Wu & Cheng, *supra* note 7, at 130.

242 *Hanover 3201 Realty*, 806 F.3d at 181.

243 Julia Belluz, *Why Medicine Costs So Much in America*, VOX (Dec. 18, 2015, 10:40 AM), https://www.vox.com/2015/12/18/10581682/drug-cost-prices-set-us [https://perma.cc/GN62-VHGL].

244 *Id*.

245 *See* Wu & Cheng, *supra* note 7, at 102.

246 *See* Belluz, *supra* note 243.

247 *Id.*

248 *Id.*

Europe suggests that once biosimilars enter the market, the price of the drug decreases.[249] In some countries, Humira prices were slashed almost eighty percent with impending entry of biosimilars.[250] However, it is difficult to disentangle how much of that price decrease is attributable to the entry of biosimilars alone, as opposed to other structural elements related to the European single-payer health systems.[251]

Adapting the measures outlined in this Note will not unilaterally solve expensive drug pricing issues overnight. However, if courts adapt these measures and other proposals are implemented to regulate the accumulation of patents, the combination may impact drug pricing. Measures could include requiring biologics manufacturers to list all patents related to a particular product. In the small molecule space, pharmaceutical companies are legally required to list all of their patents with the FDA in a publication called the "Orange Book."[252] This allows generics manufacturers to easily ascertain all of the patents related to a specific product.[253] Although a similar publication, called the "'Purple Book,'" exists for biologics, there is no requirement to list all of the patents related to the product.[254] This makes it difficult for biosimilar companies to determine the exact metes and bounds that protect a biologic and plan their products.[255] Requiring the FDA to maintain an official list makes it more cost-effective for biosimilar companies to plan their products.[256] Congress is currently considering this idea; however, as of February 2023, the bill has yet to move along to committee.[257]

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[249] Ned Pagliarulo, *Humira Biosimilar Discounting 'Aggressive' as Competition Enters in Europe*, BIOPHARMADIVE (Nov. 2, 2018), https://www.biopharmadive.com/news/humira-biosimilar-discounting-aggressive-as-competition-enters-in-europe/541282/ [https://perma.cc/2Q8X-8ES5].

[250] *Id.*

[251] *See* Belluz, *supra* note 243.

[252] *See* Carrier & Minniti, *supra* note 66, at 12.

[253] *See id.* at 17.

[254] *Id.*

[255] *See* Brian K. Chen et al., *Why Biologics and Biosimilars Remain So Expensive: Despite Two Wins for Biosimilars, the Supreme Court's Recent Rulings Do Not Solve Fundamental Barriers to Competition*, 2018 DRUGS 1777, 1778 (2018).

[256] *Id.*

[257] Biologic Patent Transparency Act, S. 659, 116th Cong. (2019), https://www.congress.gov/bill/116th-congress/senate-bill/659 (last visited March 1, 2023).

Other potential solutions could include administrative changes within the USPTO. Currently, biologic manufacturers can apply for manufacturing process patents.[258] However, some of these applications are filed long after the molecule has been approved.[259] Under U.S. patent law, "certain types of secret use more than a year before" the application date of a patent "can defeat validity."[260] In other words, if a biologics company has been using this manufacturing method for more than a year after a drug is commercialized, the manufacturing method cannot be patented at that time.[261] A simple way to slow patent accumulation is to ensure that the USPTO closely scrutinizes these types of applications to ensure that they comply with the timeline for the disclosure guidelines.

CONCLUSION

There are many different proposals to reform the laws that regulate the pharmaceutical industry. But the approach recommended in this Note is important because, ultimately, it provides an additional route for biosimilar manufacturers to enter the market by way of the courts. While Humira is only one example of a patent thicket, evidence suggests that without checking this type of behavior, biologics companies will continue to accumulate patents to block competing biosimilars.[262]

Courts' current approach to sham litigation—the objectively baseless requirement—inadequately address patent applications. In general, antitrust laws are diametrically opposed to patent laws given their objectives. However, both antitrust and patent laws ultimately try to promote the progression of science and society,[263] but

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[258] Arti K. Rai & W. Nicholson Price II, *An Administrative Fix for Manufacturing Process Patent Thickets*, 39 NATURE BIOTECHNOLOGY 20, 20 (2021).

[259] *Id.*

[260] *Id.*

[261] *Id.*

[262] Eric Sagonowsky, *AbbVie, Already Famous for Its Humira Strategy, Forms Another 'Patent Wall' Around Imbruvia: Report*, FIERCEPHARMA (July 21, 2020), https://www.fiercepharma.com/pharma/abbvie-already-famous-for-its-humira-strategy-forms-another-patent-wall-for-imbruvica-report [https://perma.cc/5G3N-97RV].

[263] *See* Int'l Wood Processors v. Power Dry, Inc., 792 F.2d 416, 427 (4th Cir. 1986) ("[T]he goals of the patent laws and the antitrust laws point toward the same end . . . . The

may need to be reworked in the biotech industry. When evaluating patent thickets, courts should compare the value of the patent against the cost of prosecution to determine whether the patent is objectively baseless, even if the entire patent portfolio has a high value. In patent thicket litigations, courts should adopt the flexible intent standard when looking at a series of petitions to the government. While further steps will still be required to alleviate drug pricing costs for patients, the suggested solutions hopefully will help address some of the high costs for patients. Given rising drug prices, it is imperative that some changes be made in the system and adopting the measures in this Note is one way that courts can participate in the process.

fundamental premise is that the public benefits from a competitive economy that provides for the efficient allocation of resources and increased production at lower prices.").