NOTES

A Machete for the Patent Thicket: Using *Noerr-Pennington* Doctrine's Sham Exception to Challenge Abusive Patent Tactics by Pharmaceutical Companies

Outrageous drug prices have dominated news coverage of the American healthcare system for years. Yet despite widespread condemnation of skyrocketing drug prices, nothing seems to change. Pharmaceutical companies can raise drug prices with impunity because they hold patents on their drugs, which give them monopolies. These monopolies are only supposed to last twenty years, and then competing lower-cost drugs like generics can enter the market, driving down the costs of pharmaceuticals for all. But pharmaceutical companies have created "patent thickets," dense webs of overlapping patents surrounding one drug, which have artificially extended the companies' monopolies for years or even decades after a drug's initial patent expires. These problems will only be exacerbated as the pharmaceutical industry increasingly focuses on biologic drugs, which already provide more opportunities to acquire multiple patents on one drug than traditional small-molecule drugs.

Patent law's weapons in the fight against patent thickets, namely litigation and inter partes reviews (an abbreviated process for challenging patent validity), have proven to be inadequate—a scalpel when the public needs a machete. Antitrust law, which polices anticompetitive behavior and corrects market failures, is the ideal weapon to fight the pharmaceutical industry's exploitation of patent law. The Noerr-Pennington *doctrine, which immunizes parties from antitrust liability when a party "petitions" the government, currently stands in the way of an antitrust solution to the patent-thicket problem. "Petitions" eligible for* Noerr-Pennington *antitrust immunity include patent applications and patent-infringement lawsuits, so the pharmaceutical industry can wield the* Noerr-Pennington *doctrine as a sword against potential antitrust challenges. The* Noerr-Pennington *doctrine has a narrow "sham exception," where* Noerr-Pennington *antitrust immunity is pierced when a*

party's petitions are "mere shams" to interfere with the operations of a competitor. Unfortunately, after two Supreme Court decisions about the sham exception, the circuit courts have disagreed on the sham exception's operation, leaving potential antitrust plaintiffs, such as consumers and government regulators, with uncertain prospects for challenging patent thickets under antitrust law.

This Note proposes that courts adopt an approach to reconcile the Supreme Court decisions wherein courts apply a stricter standard for invoking the sham exception when an antitrust plaintiff challenges a single sham petition and a looser standard when an antitrust plaintiff challenges a pattern of sham petitions. Further, this Note proposes a general framework for analyzing patent proceedings under the looser pattern standard. This solution strikes a balance between protecting parties' First Amendment petitioning right and discouraging abuse of the patent law system for anticompetitive effect. If successful, antitrust challenges can lead to quicker market entry for lower-cost drugs and allow more people to benefit from innovative and life-altering drugs.

INTRODUCTION

The world's second-best-selling drug of all time is Humira.[1] Humira can treat a variety of autoimmune conditions, including rheumatoid arthritis, Crohn's disease, and plaque psoriasis, among others.[2] Humira is on track to become and remain the best-selling drug in history through 2024, with a projected revenue of $240 billion.[3] AbbVie Inc. ("AbbVie"), the company that owns the patents for Humira, has built its business off Humira's bounty.[4] In 2019 alone, AbbVie earned $19.2 billion in worldwide net revenues from Humira, which accounted for 58% of AbbVie's total net revenues for that year.[5] AbbVie achieves these record-busting revenues for Humira not by quantity sold but by price: Humira's price doubled in just six years.[6] In 2012, Humira cost $19,000 a year per patient; by 2018, Humira's price had reached

1. The heart drug Lipitor is the current best seller with $164.43 billion in sales through 2018, but years of generic Lipitor competitors have eaten away at Lipitor's dominance. Angus Liu, *Top 10 All-Star Drugs in 2024: Humira's Captain, but Who Else Makes the Roster?*, FIERCEPHARMA (Aug. 15, 2019, 11:51 AM), https://www.fiercepharma.com/pharma/top-10-all-time-biggest-selling-drugs-by-2024#:~:text=Heart [https://perma.cc/QH7H-BW5A]. Humira's revenue dominance will end in 2024 because multiple Humira competitors will enter the market throughout 2023. *See infra* note 17 (discussing the entrance of Humira competitors in the market).

2. HUMIRA, https://www.humira.com (last visited Dec. 23, 2021) [https://perma.cc/KC9P-4QHZ].

3. Liu, *supra* note 1.

4. *See* Sy Mukherjee, *Protect at All Costs: How the Maker of the World's Bestselling Drug Keeps Prices Sky-high*, FORTUNE (July 18, 2019, 5:31 AM), https://fortune.com/longform/abbvie-humira-drug-costs-innovation/ [https://perma.cc/M89A-MK69] ("Humira isn't just AbbVie's bestselling drug, it is its everything-drug."). Moreover, AbbVie did not "aggressively pursue the replenishment of their [product] pipeline," and its spending on research and development is near the bottom of the twelve global biopharma companies. *Id.* AbbVie's reliance on Humira has come at a cost to its shareholders: "AbbVie's stock has plunged more than 27% in the past 12 months, underperforming most of its peers." *Id.*

5. AbbVie Inc., Annual Report (Form 10-K) 10, 70 (Feb. 21, 2020). Humira also accounted for 61% of AbbVie's total net revenues in 2018 and 65% of AbbVie's total net revenues in 2017. *Id.*

6. Danny Hakim, *Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher.*, N.Y. TIMES (Jan. 6, 2018), https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html [https://perma.cc/ER3M-BPRX].

$38,000 a year per patient.[7] Moreover, AbbVie explicitly tied its senior-executive bonuses directly to Humira's net revenue between 2015 and 2018.[8] Within the first year that AbbVie introduced this incentive, AbbVie implemented the largest price increases in Humira's history—a 30% increase over a ten-month period. [9] AbbVie can raise Humira's price with impunity because Humira's many patents prevent generic competitors[10] from entering the market and putting pressure on Humira's price.[11]

The original patent for Humira's active ingredient, an antibody called "adalimumab," expired on December 31, 2016.[12] At least four generic competitors to Humira have been approved by the Food and Drug Administration ("FDA").[13] Despite these approvals, no generic competitor has launched in the United States to date.[14] The key to Humira's mind-boggling success is AbbVie's aggressive patent application and litigation strategy, designed to protect Humira from competition.[15] AbbVie allegedly filed 247 patent applications on Humira in the United States alone, obtaining 132 patents.[16] Further, through its aggressive litigation strategy, AbbVie entered into patent-infringement settlement agreements with rival drug manufacturers to ensure that no Humira competitor can launch in the United States until 2023.[17]

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7. *Id.*

8. STAFF OF H. COMM. ON OVERSIGHT & REFORM, 117TH CONG., REP. ON DRUG PRICING INVESTIGATION: ABBVIE—HUMIRA AND IMBRUVICA 9 (Comm. Print 2021) [hereinafter DRUG PRICING INVESTIGATION].

9. *Id.*

10. The "generic" competitors to Humira are actually "biosimilars." *See infra* Section I.B (explaining how biosimilars are the closest equivalent to generics for biologic drugs like Humira).

11. *See* Mukherjee, *supra* note 4 (noting that "[i]n the U.S., pharma companies can charge whatever they want for their products" due to patent exclusivity and the lack of regulation on drug prices).

12. *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 820 (N.D. Ill. 2020).

13. *Id.* at 825.

14. *Id.* at 824–25.

15. *See* Mukherjee, *supra* note 4 (noting that, according to Professor Robin Feldman, "AbbVie [is] a pioneer—not just in medical treatments but also in legal protections").

16. *In re Humira*, 465 F. Supp. 3d at 822. Although AbbVie's actions with Humira are the most blatant use of this patent strategy, reports indicate that the "12 top-selling drugs in the U.S. were protected by an average of 71 patents," which lengthened the average patent monopoly to thirty-eight years, or nearly double the statutory patent term. Bryan Koenig, *7th Circ. to Crawl into Humira 'Patent Thicket' Dispute*, LAW360 (Feb. 23, 2021, 6:58 PM), https://www.law360.com/articles/1351485/7th-circ-to-crawl-into-humira-patent-thicket-dispute [https://perma.cc/X2LG-GYJ2].

17. The earliest potential entrant of a direct Humira competitor is a drug developed by an AbbVie competitor, Amgen, Inc. ("Amgen"), called Amjevita, which was approved by the FDA in 2016. *In re Humira*, 465 F. Supp. 3d at 824. According to the terms of Amgen's patent infringement settlement agreement with AbbVie, Amjevita will launch in the United States in January 2023.

In 2019, the largest grocery union in New York and other indirect purchasers of Humira filed twelve class-action lawsuits against AbbVie in federal district court.[18] The district court consolidated these lawsuits into *In re Humira (Adalimumab) Antitrust Litigation*.[19] The plaintiffs alleged that AbbVie's amassing of an impenetrable "patent thicket" prevented competitors from challenging Humira's dominance, which constituted a violation of federal antitrust law.[20] A patent thicket can be understood as a "dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology."[21] AbbVie allegedly uses its patent thicket to keep artificially extending Humira's patent exclusivity (and, therefore, AbbVie's ability to keep raising prices).[22] The patent thicket has the added bonus of discouraging any potential Humira competitors from challenging Humira's patents because of the sheer amount of patents challengers would need to invalidate.[23]

In June 2020, the district court granted AbbVie's motion to dismiss the class-action complaint.[24] The court held that the *Noerr-Pennington* doctrine immunized AbbVie from antitrust liability, even if AbbVie obtained and litigated its massive patent portfolio in bad faith.[25] The *Noerr-Pennington* doctrine, derived from the First Amendment right to petition, established that courts will immunize parties from antitrust liability for "petitioning" (requesting action from) the government, even when the petitioners intended their actions to have anticompetitive effects.[26] *Noerr-Pennington* petitioning activity can

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Id. The settlement agreements with the other manufacturers provide for entry dates ranging from June 30, 2023 to December 15, 2023. *Id.*

18. Nadia Dreid, *Humira Buyers Say They've Proven AbbVie's 'Patent Thicket,'* LAW360 (Nov. 25, 2019, 9:31 PM), https://www.law360.com/articles/1223265 [https://perma.cc/ZAR3-GXDP]; Jeff Overley, *AbbVie Faces 1st Antitrust Suit over Humira 'Patent Thicket,'* LAW360 (Mar. 18, 2019, 11:11 PM), https://www.law360.com/articles/1140272 [https://perma.cc/TV42-5VHU].

19. Dreid, *supra* note 18.

20. *Id.*

21. Jeffrey Wu & Claire Wan-Chiung Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 CHI.-KENT J. INTELL. PROP. 93, 109 (2020) (quoting 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)).

22. *See In re Humira*, 465 F. Supp. at 827 ("AbbVie was able to delay its competitors and avoid any real examination of the patents' validity long enough to reap a few more years' worth of monopoly profit on its lucrative, patent-protected product, Humira.").

23. *See id.* at 826 ("[Humira competitors said] they had to enter into the settlement agreements because their only other choices were years of expensive litigation over an impassable patent thicket or an at-risk launch likely to result in a hefty damages award.").

24. *Id.* at 853.

25. *Id.* at 830.

26. *See* U.S. CONST. amend. I (guaranteeing citizens the right "to petition the Government for a redress of grievances"); FED. TRADE COMM'N, ENFORCEMENT PERSPECTIVES ON THE *NOERR-PENNINGTON* DOCTRINE 3 (2006), https://www.ftc.gov/sites/default/files/documents/reports/ftc-

include applying for patents, obtaining patents, and filing patent-infringement suits to enforce patents because all of those actions are requests from a party (here, pharmaceutical companies) for the government to perform some action.[27] Thus, the *Noerr-Pennington* doctrine provides patent seekers and patent holders with strong protection from antitrust liability for patent-related activities.

Noerr-Pennington antitrust immunity can be pierced, but the only explicitly recognized exception to the *Noerr-Pennington* doctrine is the narrow "sham exception."[28] The sham exception eliminates *Noerr-Pennington* antitrust immunity in cases where petitioning is a "mere sham" to interfere with the operations of a competitor.[29] As demonstrated by *In re Humira*, however, the sham exception can be almost impossible to invoke in practice. In that case, the court held that the plaintiffs could not invoke the sham exception because AbbVie's activities were not "objectively baseless."[30]

Two Supreme Court cases, *California Motor Transport Co. v. Trucking Unlimited*[31] and *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.* ("*PRE*"),[32] created more challenges for parties trying to invoke the sham exception. *California Motor* and *PRE* proffered different standards for determining whether petitioning is a "mere sham." *California Motor* analyzed a series of proceedings and defined sham petitions as "a pattern of baseless, repetitive claims" filed "regardless of the merits of the cases."[33] *PRE*, on the other hand, involved a single lawsuit and formulated a two-part test with an extremely high bar for successfully invoking the sham exception.[34]

The Ninth Circuit first addressed the seemingly conflicting holdings of *California Motor* and *PRE*. In *USS-Posco Industries v. Contra Costa County Building & Construction Trades Council* ("*Posco*"), the Ninth Circuit held that *California Motor* and *PRE* could be reconciled because they apply in two different situations.[35] The court

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staff-report-concerning-enforcement-perspectives-noerr-pennington-doctrine/p013518enfperspectnoerr-penningtondoctrine.pdf [https://perma.cc/5TXL-V2G9] (explaining the origins of the *Noerr-Pennington* doctrine).

27. *See infra* text accompanying note 150 (noting that *California Motor* extended *Noerr-Pennington* protection to administrative and judicial proceedings).

28. Michael Pemstein, *The Basis for* Noerr-Pennington *Immunity: An Argument that Federal Antitrust Law, Not the First Amendment, Defines the Boundaries of* Noerr-Pennington, 40 T. MARSHALL L. REV. 79, 87 (2014).

29. FED. TRADE COMM'N, *supra* note 26, at 35.

30. *In re Humira*, 465 F. Supp. 3d at 830.

31. 404 U.S. 508 (1972).

32. 508 U.S. 49 (1993).

33. 404 U.S. at 512–13.

34. 508 U.S. at 52–54, 60–61.

35. 31 F.3d 800, 810 (9th Cir. 1994).

reasoned that *PRE*'s exacting standard applied only to cases like *PRE*, where a single sham petition was at issue.[36] *California Motor*, on the other hand, applied in cases where there was an alleged pattern of sham petitions.[37] The Second,[38] Third,[39] and Fourth[40] Circuits all adopted similar reasoning to *Posco* in reconciling *California Motor* and *PRE*. But the First[41] and Seventh[42] Circuits reasoned that the *PRE* two-part test applied in cases with both single and multiple petitions. The Supreme Court has yet to grant certiorari on this issue to decide the circuit split.

This Note proceeds in three parts. First, Part I summarizes the salient elements of patent law, including patent applications, inter partes reviews (an abbreviated process that allows third parties to challenge the validity of previously issued patents),[43] and patent-infringement litigation and settlement agreements. Next, Part I discusses how the pharmaceutical industry's shift to developing biologic drugs such as Humira makes the possibility of patent abuse more prevalent. Finally, Part I outlines the evolution of the *Noerr-Pennington* doctrine and the sham exception. Part II analyzes the circuit split around the reconciliation of *California Motor* and *PRE* and considers the benefits and drawbacks to each side. Part III proposes that the Court adopt the position of the Second, Third, Fourth, and Ninth Circuits in analyzing the sham exception, with some general modifications. Part III further proposes a framework for analyzing proceedings specific to patent law under *California Motor*'s sham exception pattern analysis. The combination of these proposals will allow government regulators and consumers to hack through the patent thickets, which enable skyrocketing drug prices.

I. FROM ANTITRUST, TO BIOLOGICS, TO PATENT LAW

Both antitrust law and patent law seek to promote innovation but in very different ways. Antitrust law protects and promotes competition, and vigorous competition in turn spurs companies to innovate so as to maintain or reach new customers, thereby improving

36. *Id.* at 810–11.

37. *Id.* at 811.

38. Primetime 24 Joint Venture v. Nat'l Broad. Co., 219 F.3d 92 (2d Cir. 2000).

39. Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc., 806 F.3d 162 (3d Cir. 2015).

40. Waugh Chapel S., LLC v. United Food & Com. Workers Union Loc. 27, 728 F.3d 354 (4th Cir. 2013).

41. P.R. Tel. Co. v. San Juan Cable LLC, 874 F.3d 767, 770 (1st Cir. 2017).

42. U.S. Futures Exch., LLC v. Bd. of Trade, 953 F.3d 955, 964 (7th Cir. 2020).

43. Eric C. Cohen, *A Primer on Inter Partes Review, Covered Business Method Review, and Post-Grant Review before the Patent Trial and Appeal Board*, 24 FED. CIR. BAR J. 1, 1 (2014).

their market share.[44] Alternatively, patent law provides incentives to develop innovative technology by providing a limited monopoly to inventors in exchange for disclosure of their inventions to the public.[45] Antitrust and patent law present a paradox because "[a]ctivity that may be encouraged under the patent system frequently raises the suspicion of the antitrust laws by reducing competition."[46] The *Noerr-Pennington* doctrine operates at the intersection of patent and antitrust law by providing antitrust immunity for those petitioning the government to obtain or enforce patents.[47]

The combination of *Noerr-Pennington* antitrust immunity with existing patent law protections, however, has created a perfect cocktail for exploitation. Pharmaceutical companies reap immense profits through increasingly complex patent strategies, such as by creating impenetrable "patent thickets" around one drug to artificially extend their monopolies (and continue raising prices). Finding a way to pierce *Noerr-Pennington* immunity when these tactics have been used is the ideal solution for holding pharmaceutical companies accountable and for creating a pathway to more affordable drugs (absent federal legislation on drug pricing).

Antitrust law is better equipped to fight patent thickets because of who leads the battle. In antitrust suits, plaintiffs, who can be consumers or government regulators, are more likely to continue fighting patent thickets.[48] Consumers and regulators use antitrust litigation to obtain court orders or settlements allowing competitors earlier market entry, in turn significantly driving down consumer drug prices. In contrast, rival pharmaceutical manufacturers who could bring patent proceedings either may be unwilling to enter the fight due to the risk or may concede early in favor of a settlement.[49] Rival pharmaceutical manufacturers essentially face a collective action problem in patent proceedings.[50] If one pharmaceutical competitor wants to fight the patent thicket while the other competitors settle, that

44. Giulio Federico, Fiona Scott Morton & Carl Shapiro, *Antitrust and Innovation: Welcoming and Protecting Disruption*, 20 INNOVATION POL'Y & ECON. 125, 125–26 (2020).

45. W. Nicholson Price II, *The Cost of Novelty*, 120 COLUM. L. REV. 769, 771 (2020).

46. Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 769 (2002).

47. James R. Atwood, *Securing and Enforcing Patents: The Role of* Noerr/Pennington, 83 J. PAT. & TRADEMARK OFF. SOC'Y 651, 652–53 (2001).

48. Wu & Cheng, *supra* note 21, at 170.

49. *Id.* at 166–67.

50. Brian J. Love, Shawn P. Miller & Shawn Ambwani, *Determinants of Patent Quality: Evidence from Inter Partes Review Proceedings*, 90 U. COLO. L. REV. 67, 94 (2019).

competitor bears the entire burden of litigation cost and risk.[51] On the other hand, a patent challenge win, which invalidates a patent, would enable *all* competitors to enter the market early.[52] Thus, the interests of consumers and the rival pharmaceutical manufacturers do not align, necessitating the use of antitrust intervention to hack through patent thickets.[53]

This Part will discuss key concepts in patent law and antitrust law as well as issues specific to the pharmaceutical industry. This background will illustrate how patent law and the *Noerr-Pennington* doctrine enable the proliferation of pharmaceutical patent thickets while simultaneously presenting significant obstacles in clearing these thickets. Section A will provide a primer on basic patent law concepts, including patent duration, patent applications, patent prosecutions, inter partes reviews ("IPR"), patent infringement litigation, reverse payment settlements, and patent thickets. Section B will then explain the unique issues of biologic drugs that exacerbate the problems in patent law. Finally, Sections C and D will discuss the evolution of the *Noerr-Pennington* doctrine and the operation of the sham exception, respectively.

A. A Primer on Patent Law and Pharmaceutical Concerns

As noted above, patent law both incentivizes the creation of patent thickets and grants patent holders strong protection against invalidation of the patents in a thicket. This section illustrates the aspects of patent law that make amassing patent thickets easier than invalidating even one invalidly granted patent.

1. Patent Applications and Patent Prosecution

Patent law developed to promote innovation, but innovation's goal is not to simply promote what is "new" but to promote what is "better" or, in other words, to provide a social benefit.[54] Unfortunately, patent law currently incentivizes "new" technology without

51. *Id.*; *see* Zachary Silbersher, *What Are the Lessons from Boehringer's Settlement with AbbVie over its Humira Biosimilar?*, MARKMAN ADVISORS (May 17, 2019), https://www.markmanadvisors.com/blog/2019/5/17/what-are-the-lessons-from-boehringers-settlement-with-abbvie-over-its-humira-biosimilar [https://perma.cc/W5S6-ASW5] (explaining the risks of pursuing patent litigation by noting that if a rival "lost that challenge, then it might [be] boxed out from entering [the market] until all the patents expire," which could be several years after the settling competitors were able to enter the market).

52. Love et al., *supra* note 50, at 94.

53. Silbersher, *supra* note 51.

54. Price II, *supra* note 45, at 771.

emphasizing "better" technology or increasing welfare.[55] In fact, patent law may even incentivize "negative innovation" in the pharmaceutical industry.[56] Negative innovation is where patent law actually incentivizes pharmaceutical companies to bring products to market that can be *affirmatively harmful* to patients.[57] One particularly egregious example involves the drug Imbruvica (also owned by AbbVie).[58] Imbruvica is an anticancer agent, which means that it is toxic by design (to kill the cancer), and AbbVie's recommended dosage was 2.4 times higher than what was needed to achieve its therapeutic effect.[59] The recommended dosage was so high was because the Patent and Trademark Office ("PTO") rejected the lower dosages in the patent application as "obvious" and therefore unpatentable; the PTO would only grant patents for the higher doses.[60] Therefore, patent law actually created the incentive "to pursue a higher, more toxic dose rather than the lower doses the FDA suggested be explored."[61] Patent law incentives combine with inefficient markets to encourage a proliferation of pharmaceutical patents for "new" drugs, not necessarily "better" drugs.[62]

Negative innovation is not the only market failure that patent law causes. In the United States, patents can be obtained by anyone who "invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" and follows the statutory procedures.[63] Once the government grants the patent, the patent owner has exclusive rights to make, use, or sell the invention in the United States for a term of twenty years from the application filing date.[64] The value of the patent arises

55. *Id.*

56. Robin C. Feldman, David A. Hyman, W. Nicholson Price II & Mark J. Ratain, *Negative Innovation: When Patents Are Bad for Patients*, 39 NATURE BIOTECHNOLOGY 914, 914 (2021).

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.* at 915.

61. *Id.*

62. "New" here includes minor tweaks to existing drugs which receive patents. These minor tweaks constitute "new" technology but do not necessarily improve results for patients. For example, to avoid losing its monopoly on Prilosec at the end of its original patent term, AstraZeneca isolated one molecule from Prilosec's mixture, obtained a patent, and received FDA approval in the form of Nexium. *Id.* at 801–02. Nexium has been tremendously profitable for AstraZeneca but has not shown significant therapeutic benefit over Prilosec. *Id.*

63. 35 U.S.C. § 101.

64. Note that the patent term starts from the date of application and not the date the patent is issued. For example, if the PTO issues a patent three years after an application was filed, then that patent owner effectively has a shorter term—seventeen years instead of twenty years. 35 U.S.C. § 154. This timing is particularly important in the pharmaceutical context because lengthy FDA approval processes can cut a pharmaceutical patent's effective term shorter still. For

precisely from this period of exclusivity: the patent owner can charge extremely high prices while no competitors can enter the market.[65] Of course, patents have no inherent value if there is no market demand for the underlying invention, which means that "[p]atent law relies on the market to sort out the value of inventions."[66] Markets significantly underperform, however, when choosing superior pharmaceutical technologies because "[e]fficient markets require informed consumers who can choose goods."[67] Because pharmaceutical consumption is split among patients, doctors, and insurers and these consumers lack quality information, pharmaceutical markets cannot perform efficiently.[68] Thus, markets cannot remedy the problem of patent law's perverse incentives for pharmaceuticals.

Further study of the patent process reveals more problems. The process to obtain a patent, called patent prosecution, continues to skew incentives for patent seekers. Patent prosecution is ex parte, or not adversarial, and the applicant owes a "duty of candor and good faith" to the PTO during patent prosecution.[69] Each individual involved in the patent prosecution must disclose "all information known to that individual to be material to patentability."[70] Notwithstanding this "duty of candor and good faith," patent applicants in the United States can restart the patent-prosecution process by filing a continuation application or a request for continued examination ("RCE").[71] While continuation applications and RCEs operate slightly differently, both processes give the inventor another chance to mature their patent application into a fully issued patent.[72] For ease of discussion, this Note

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instance, until the Hatch-Waxman Act was enacted, the average effective patent life of a small-molecule drug was only eight years. Henry Grabowski & John Vernon, *Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act After One Decade*, 10 PHARMACOECONOMICS 110 (1996); Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 13 (2018).

65. Erika Lietzan & Kristina M.L. Acri née Lybecker, *Distorted Drug Patents*, 95 WASH. L. REV. 1317, 1319–21 (2020).

66. Price II, *supra* note 45, at 772.

67. *Id.* at 773.

68. *Id.* There are two main causes of inefficient markets for pharmaceutical patents. First, "patients, doctors, and insurers split the consumer functions of selecting, paying for, and benefiting from goods," and each player has divergent incentives. *Id.* Second, information about various pharmaceuticals' quality is "frequently poor or unavailable." *Id.*

69. 37 C.F.R. § 1.56(a) (2021); *see also* Atwood, *supra* note 47, at 652 ("The ex parte nature of the patent-application process, and the powerful legal weapons given to an inventor once a patent issues, can make the PTO and the federal courts unwitting participants in powerfully anticompetitive schemes.").

70. 37 C.F.R. § 1.56(a).

71. The fact that the PTO can never truly reject an application is unique to the United States. Michael D. Frakes & Melissa F. Wasserman, *Does the U.S. Patent and Trademark Office Grant Too Many Bad Patents?: Evidence from a Quasi-Experiment*, 67 STAN. L. REV. 613, 625 (2015).

72. *Id.*

will refer to continuation applications and RCEs collectively as "continuations." There is currently no limit on how many continuations an inventor can file.[73] With no means to limit continuations, the only way for the PTO to reduce its crushing workload is by granting patents.[74] Generally speaking, as long as an inventor pursues a patent application long enough, at least one patent will be issued.[75]

Continuations also grow patent thickets because they allow pharmaceutical companies to obtain multiple derivative patents with only minor distinctions from the original patent.[76] While the PTO can object when it believes a patent seeker is seeking a "double patent" on already patented (or patent-pending) inventions, the patent seeker can "cure" the PTO objection by filing a "terminal disclaimer."[77] A terminal disclaimer means "that all the purportedly 'double patents' will expire at the same time," so the patent holder cannot extend the patent term with these double patents.[78] For instance, one analysis noted that AbbVie had eight formulation patents with terminal disclaimers or, in other words, eight patents derived from a single patent with a single expiration date.[79] The problem for competitors seeking to invalidate these eight patents is that the competitor must individually fight each patent because the invalidation of one does not affect the validity of the others.[80] Each derivative patent with a terminal disclaimer ensures that a competitor will need to expend more time and money to fight the patent thicket, with greater risk.[81]

Growing patent thickets through multiple patent applications and continuations is not cheap, of course, and a conservative estimate

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73. *Id.* at 626.

74. *See id.* at 616 ("[T]he [PTO] currently faces a crushing backlog of over 600,000 patent applications, of which close to forty percent constitute repeat filings . . . . [T]he PTO could attempt to decrease the incentives of applicants to file repeat applications (and hence concomitantly decrease its backlog of applications) by biasing its grant rate upward.").

75. Love et al., *supra* note 50, at 89–90. In fact, about 75% of all patent applications eventually result in at least one patent. Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 181, 182 (2008).

76. Zachary Silbersher, *Why Was the Humira "Patent Thicket" Antitrust Case Against AbbVie Dismissed?*, MARKMAN ADVISORS (June 10, 2020), https://www.markmanadvisors.com/blog/2020/6/10/why-was-the-humira-patent-thicket-antitrust-case-against-abbvie-dismissed [https://perma.cc/VC9G-HR83].

77. Silbersher, *supra* note 51.

78. *Id.*

79. *Id.* It should be noted that the eight formulation patents with terminal disclaimers are by no means the only overlapping patents in Humira's patent thicket. In fact, AbbVie's 132 patents can be traced back to just twenty root patents. *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 823 (N.D. Ill. 2020).

80. Silbersher, *supra* note 51.

81. *Id.*

of the cost per patent is $100,000.[82] The seeds sown by these patents, however, grow into a magnificent harvest for pharmaceutical companies like AbbVie. Even assuming that AbbVie spent twice the conservative estimate, or $200,000, for each of its 247 patent applications, AbbVie would have spent just under $50 million on growing its patent thicket.[83] Fifty million dollars is an enormous amount of money, but for AbbVie, who made $19.2 billion in worldwide net revenues from Humira in 2019 alone, $50 million is a drop in the bucket.[84] For pharmaceutical companies like AbbVie, spending millions to reap billions of profit on drugs like Humira is well worth the investment.

2. Inter Partes Reviews

While the previous section discussed how pharmaceutical companies can acquire numerous patents, this section and the next section discuss the tools patent law provides to invalidate patents that should not have been granted. The first method of invalidating patents is the inter partes review or IPR. Congress grew concerned that the PTO was granting "too many invalid patents that unnecessarily drain consumer welfare, stunt productive research, and unreasonably extract rents from innovators" because the PTO could never fully reject the unlimited continuations that applicants could file.[85] To combat these concerns, Congress enacted the Leahy-Smith America Invents Act in 2011, which created IPRs—a faster and cheaper alternative to patent litigation.[86] IPRs allow a third party (the "petitioner") to challenge the validity of previously issued patents in fast-tracked proceedings before the Patent Trial and Appeal Board ("PTAB").[87] Because the proceedings

82. *Id.*

83. *See supra* text accompanying note 16 (discussing AbbVie's patent portfolio).

84. *See supra* text accompanying note 5 (discussing revenues from Humira). While AbbVie could argue that not all pharmaceutical patents end up creating blockbuster drugs like Humira and the cost of patent applications could just be sunk costs, that argument does not hold water. The PTO issued more than 90% of Humira's U.S. patents *after* 2014, when Humira had already been on the market for twelve years. *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 822 (N.D. Ill. 2020).

85. Frakes & Wasserman, *supra* note 71, at 615; *see also* Cohen, *supra* note 43, at 3 ("Congress's intent was to provide a 'faster, less costly alternative [ ] to civil litigation to challenge patents.' ").

86. Cohen, *supra* note 43, at 1.

87. To begin the process, the petitioner files a petition to institute the IPR and pays the required fees. 35 U.S.C. § 311. The minimum required fees for an IPR consist of an initial request fee of $19,000 and another fee of $22,500 if the proceeding is instituted. 37 C.F.R. § 42.15 (2021). If more than twenty claims are being challenged, there are additional fees. *Id.* By statute, an IPR lasts a maximum of eighteen to twenty-four months. Joseph W. Dubis, Note, *Inter Partes Review:*

are fast-tracked, petitioners can only challenge a patent on some (not all) invalidity grounds.[88]

IPRs have two critical junctures: institution and final written decision. The PTAB's "institution" decision is a non-appealable, intermediate decision issued within six months of the initial IPR filing.[89] The institution decision hinges on whether the PTAB believes the petitioner has "a reasonable likelihood" of prevailing on at least one claim.[90] If the PTAB "institutes" the claim, the IPR will continue to reach a final written decision on the validity of the patent claims.[91]

The institution decision has become the most critical step of the IPR.[92] Once the PTAB institutes an IPR proceeding, the PTAB's final determination will result in cancellation of all instituted claims about 70% of the time.[93] Congress intended IPRs to be a faster and cheaper way than litigation for companies to invalidate patents, but IPRs have become a victim of their own success. The high "kill rate" of instituted claims caused one former Federal Circuit judge to lament that the PTAB was "acting as [a] death squad[ ], killing property rights."[94] The PTAB responded to the criticism of IPRs by decreasing the rate of institutions, even declining institutions in cases where the petitioner satisfied all statutory requirements.[95] These concerns belie the fact that IPRs work exactly as Congress designed—"targeting patents with indicia of relatively low quality" and invalidating patents that should never have been granted in the first place.[96]

A Multi-Method Comparison for Challenging Patent Validity, 6 CYBARIS INTELL. PROP. L. REV. 107, 110, 120 (2015).

88. Petitioners can challenge a patent "for lack of novelty, or as obvious in light of prior patents or other 'printed publications.' " Love et al., *supra* note 50, at 99. In order to challenge a patent on other possible invalidity grounds, a petitioner would need to go through district court litigation instead. *Id.*

89. Cohen, *supra* note 43, at 8.

90. Dubis, *supra* note 87, at 116 (quoting 35 U.S.C. § 314(a)); Cohen, *supra* note 43, at 8.

91. 35 U.S.C. § 318(a).

92. Love et al., *supra* note 50, at 108.

93. *Id.* at 104.

94. *Id.* In fact, the assumption that patent claims will be cancelled after an institution decision is "often sufficient to destroy the majority of a claim's licensing value." *Id.* at 104, 108. *But see* Dubis, *supra* note 87, at 145 ("[T]he invalidation rates in [IPRs] are no worse than in . . . patent litigation. If anything, the invalidation rates for [IPRs] may be more favorable to the patent owner than in the previously available [version of IPRs].").

95. *See* Dubis, *supra* note 87, at 144 ("[IPRs] were initially instituted at a rate of 96 percent but have subsequently subsided to approximately 78 percent."); Joel D. Sayres & Reid E. Dodge, *Unfettered Discretion: A Closer Look at the Board's Discretion to Deny Institution*, 19 CHI.-KENT J. INTELL. PROP. 536, 538 (2020) ("[T]he [PTAB] has increasingly identified circumstances in which it will *not* institute IPR, even where a petitioner satisfies the statutory threshold for institution set forth in 35 U.S.C. § 314(a) . . . .").

96. Love et al., *supra* note 50, at 164.

3. Patent-Infringement Litigation and Reverse-Payment Settlements

In contrast to IPRs, patent challengers (or potential infringers) have a much harder road to invalidate patents through litigation. Patent-infringement litigation is generally lengthier and more expensive than IPRs. Patent litigation typically takes about 2.7 years and can range from $500,000 to $3 million compared to an IPR's two-year and $250,000 median cost.[97] Moreover, courts presume the validity of the patents in question, and challengers must prove their case with clear and convincing evidence.[98] The fact that most IPR petitions are filed defensively shows that patent-litigation defendants often turn to IPRs as a cheaper alternative to litigation.[99]

Due to the complex, lengthy, and costly nature of patent litigation, parties often settle such litigation before a court can reach a final decision on the merits.[100] While the judicial process often favors settlements, the pharmaceutical industry has pioneered reverse-payment settlements to help extend their monopolies.[101] Reverse-payment patent settlements (also called pay-for-delays) involve brand-name drug manufacturers settling patent-infringement suits with the alleged infringers—generic or biosimilar drug manufacturers.[102] These settlements result in brand-name drug manufacturers paying a fee *to the alleged infringers* in return for the infringers staying out of the market for a certain time period.[103] This "reverses" the typical direction of settlement payments, where the infringer would normally have to pay a fee to the patentee.[104] In essence, reverse-payment settlements involve the patent owner paying a kickback to its competitors from its increased monopoly profits to ensure the extension of its monopoly.[105]

The Supreme Court confronted the issue of pharmaceutical reverse-payment settlements in the landmark decision *FTC v. Actavis,*

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97. Wu & Cheng, *supra* note 21, at 149; Jonathan H. Ashtor, *Opening Pandora's Box: Analyzing the Complexity of U.S. Patent Litigation*, 18 YALE J.L. & TECH. 217, 223, 227 (2016); Dubis, *supra* note 87, at 120.

98. Cohen, *supra* note 43, at 15; *see* 35 U.S.C. § 282(a) (establishing the presumption of validity and that the party seeking to invalidate a patent has the burden of proof).

99. *See* Dubis, *supra* note 87, at 143 (noting that 90% of IPR filers were involved in concurrent litigation and that IPRs became "an intermediate proceeding of the overall litigation").

100. *See* Gregory Dolin, *Reverse Settlements as Patent Invalidity Signals*, 24 HARV. J.L. & TECH. 281, 293 (2011) (noting that about 80% of patent suits are settled).

101. Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay for Delay*, 18 CHI. KENT J. INTELL. PROP. 249, 250 (2019).

102. *Id.* at 249.

103. *Id.*

104. *Id.*

105. A. Paul Heeringa, *Dodging Antitrust Bullets in Patent Settlement Agreements: Lessons Learned from the "Reverse Payment" Dilemma*, 5 DEPAUL BUS. & COM. L.J. 265, 273 (2007).

Inc.[106] In *Actavis*, the Court rejected the premise that patent rights are immune from antitrust scrutiny.[107] The Court held that pharmaceutical reverse-payment settlement agreements can violate antitrust laws.[108] In so holding, the Court concluded that reverse payments have potential anticompetitive effects because the patent owner is purchasing the right that it already claims to have but would lose if the patent were held invalid or not infringed upon by the generic manufacturer.[109] The Court declined to make reverse-payment settlement agreements per se unlawful, however, preferring instead to subject them to antitrust law's more comprehensive "rule of reason" analysis.[110] Thus, in *Actavis*, the Court struck a balance between anticompetitive concerns and allowing the pharmaceutical industry autonomy to structure its settlements as it wished. Even reverse-payment settlements are available if the parties are willing to take on risk of antitrust liability. Ultimately, the patent owner and challenger both benefit from these reverse-payment settlements—but the consumer loses by having to pay higher drug prices for a longer period.[111]

4. Patent Thickets

As mentioned earlier, pharmaceutical companies often use "patent thickets" to extend patent monopolies on their drugs past the initial expiration of the patents.[112] A company creates a patent thicket when it obtains "multiple patents that cover a single product or

106. 570 U.S. 136 (2013).

107. *See id.* at 141 (rejecting the Eleventh Circuit's holding that reverse-payment settlements were "immune from antitrust attack so long as [their] anticompetitive effects fall within the scope of the exclusionary potential of the patent").

108. *Id.* at 147.

109. *Id.* at 153–54.

110. *Id.* at 158–59. Antitrust law's "rule of reason" is a flexible standard that follows from the idea that, although some business conduct might technically be a "restraint of trade" and thus a violation of the Sherman Act, Congress only intended to penalize "unreasonable" restraints of trade. *See* Herbert Hovenkamp, *The Rule of Reason*, 70 FLA. L. REV. 81, 85 (2018) (describing the origins of the "rule of reason"). Otherwise, the Sherman Act would outlaw all ordinary business contracts because each contract is technically a restraint of trade, no matter how small. *Id.* Therefore, the rule of reason is a fact-intensive inquiry into "a restraint's overall competitive effect," market circumstances, and a general cost-benefit analysis of the restraint in question. Maurice E. Stucke, *Does the Rule of Reason Violate the Rule of Law?*, 42 U.C. DAVIS L. REV. 1375, 1379 (2009).

111. *Actavis*, 570 U.S. at 154.

112. An interrelated concept is that of "evergreening." Evergreening involves a pharmaceutical company obtaining multiple patents that cover different aspects of a drug in order to extend market exclusivity of the drug. Wu & Cheng, *supra* note 21, at 109–10. Patent thickets and evergreening often go hand-in-hand, but, for simplicity, this Note will only refer to patent thickets.

technology."[113] In more visual terms, 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."[114]

Patent thickets can be so effective at deterring competition because the sheer number of patents in a patent thicket makes any kind of litigation too risky for the challenger. As noted in Section I.A.1, pharmaceutical companies can obtain multiple patents with only slight variations, stemming from just one patent, but competitors must challenge each patent individually in IPRs or patent litigation.[115] Invalidity of one patent does not invalidate the others.[116] Further, if even one patent claim survives the litigation and is ruled as infringed, then the patent owner can seek injunctive relief to stop competitors' sale of biosimilars.[117] In addition, the potential monetary damages can be so high that competitors will not risk patent infringement. For instance, after a federal judge affirmed a patent-validity ruling in favor of one pharmaceutical patent holder, the competitor that challenged the patent had to pay a $1.6 billion settlement.[118] Thus, the extreme monetary risk that pharmaceutical competitors face with patent thickets deters rational companies from challenging patent thickets.

Finally, if a competitor does decide to fight a patent thicket, the cost to clear a patent thicket (even excluding the damages discussed above) can be prohibitively expensive. Even the allegedly lower cost IPR for invalidating patents has a median cost of $250,000 for a single IPR final decision.[119] As an example, assuming Humira had ninety-two core patents at its peak and each IPR decision cost the median price, a patent challenger would have to spend $23 million and prevail on every decision to be able to enter the market.[120] At the same time, if the competitor actually prevails and invalidates some or all of the patents,

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113. *Id.* at 109 (quoting Ian Ayres & Gideon Parchomovsky, *Tradable Patent Rights*, 60 STAN. L. REV. 863, 864 (2007)). *But see* Adam Mossoff, *The Rise and Fall of the First American Patent Thicket: The Sewing Machine War of the 1850s*, 53 ARIZ. L. REV. 165, 166–67 (2011) (describing a patent thicket as multiple patents covering a single product or technology being owned by *different companies*). This Note will be using the definition of "patent thickets" that describes one company obtaining multiple patents for a single technology.

114. Wu & Cheng, *supra* note 21, at 109 (quoting 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)).

115. *See supra* text accompanying notes 76, 80–81.

116. *See id.*

117. Wu & Cheng, *supra* note 21, at 148. *See In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 844 (N.D. Ill. 2020) ("[I]t only takes one valid, infringed patent to render all the rest—whether invalid, infringed, or not—irrelevant for purposes of cause-in-fact analysis.").

118. *See* Uri Y. Hacohen, *Evergreening at Risk*, 33 HARV. J.L. & TECH. 479, 481 (2020) (describing Teva Pharmaceutical's patent infringement settlement, which favored Pfizer).

119. Wu & Cheng, *supra* note 21, at 149.

120. *Id.*

the patent holder never has to disgorge their monopoly profits from the invalid patents even if they could have or should have known that such patents were invalid.[121] Thus, the patent holder has every incentive to obtain as many patents as it can to deter would-be competitors and to extend the timeframe of any litigation challenging its patents. Each day that courts do not deem a pharmaceutical company's patents invalid is another day the pharmaceutical company can reap more monopoly profits with no risk of disgorgement.

B. Biologic Drugs and Biosimilars: The Future of Medicine

The potential abuses of the patent system described above have only worsened with the changing technology of the pharmaceutical industry. Most early twentieth-century pharmaceuticals were small-molecule drugs created from chemical compounds.[122] Once the active ingredient in a small-molecule drug was identified, the drug could be easily synthesized in a variety of ways.[123] This fact made the creation of low-cost generic versions possible once the initial patents on the brand-name small-molecule drug expired.[124] The development of generic versions of small-molecule drugs could cost about $2 million.[125] While the pharmaceutical industry began its abusive patent practices during the small-molecule drug era, these practices accelerated with the advent of more complex biologic drugs in the late twentieth century.

Biologics, short for biological products, promised new medical breakthroughs but also facilitated the explosion of pharmaceutical patent thickets.[126] Pharmaceutical companies manufacture biologics by harvesting material from genetically modified cell lines and purifying that material through a complex and lengthy process.[127] Because biologics are created from living material, which is sensitive to environmental changes, the manufacturing process must be very precise, or the end-product could be significantly altered.[128] Thus, for

121. Hacohen, *supra* note 118, at 481–82.

122. Examples of small-molecule drugs are the heartburn drugs, Prilosec and Nexium, and the blood thinner, Plavix. Carrier & Minniti III, *supra* note 64, at 5.

123. Wu & Cheng, *supra* note 21, at 99.

124. *Id.*; Carrier & Minniti III, *supra* note 64, at 6.

125. Carrier & Minniti III, *supra* note 64, at 9.

126. *See id.* at 3 (discussing different types of abusive tactics that pharmaceutical companies have used in the small-molecule drug setting).

127. *See id.* at 5 (explaining the biologics process and that it began being explored in 1976 with a breakthrough by Genentech, which found a way to genetically engineer DNA in living cells).

128. Wu & Cheng, *supra* note 21, at 100.

biologics, "the process is the product, and the product is the process."[129] This fact allows pharmaceutical companies to "file patents on obscure steps in the production and manufacturing process, or [various formulations]."[130] Humira, for example, has more than thirty patents on drug administration, more than twenty-five patents for its various formulations, more than fifty patents on its manufacturing process, and about twenty patents on the "delivery devices" that customers use to inject Humira into their bodies.[131] The ability to legitimately patent multiple features of one drug provided cover for pharmaceutical companies to grow impenetrable patent thickets around a single drug like Humira.

Another factor complicating the emergence of generic versions of biologics is the fact that biologics cannot be precisely replicated.[132] Instead, biologic-drug manufacturers can only create "biosimilars"—a biologic that is "highly similar" to an already approved biologic "notwithstanding minor differences in clinically inactive components."[133] The cost of developing a biosimilar version of a biologic drug, up to $200 million, completely dwarfs the $2 million cost to develop generic versions of small-molecule drugs.[134] Thus, the enormous cost of developing biosimilars combined with the risk of dealing with a patent thicket and potentially devastating monetary damages for infringement can ward off biosimilar challengers.

Despite the high price tags for biologics development, pharmaceutical companies have increasingly switched their focus from inventing new small-molecule drugs to inventing new biologics, with some planning to receive up to half of their revenues from biologic drugs.[135] The pharmaceutical industry reaps multiple benefits from such a switch: the average daily cost of a biologic far exceeds that of a

129. Dov Hirsch, Note, *The Riddle of the Mysterious Patent Dance Wrapped in an Enigma: Is the Patent Dance of the BPCIA Optional or Mandatory?*, 27 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 645, 652 (2017).

130. Mukherjee, *supra* note 4.

131. *Id.*

132. Carrier & Minniti III, *supra* note 64, at 3. Biologics cannot be precisely replicated because each step in the production process can affect the living components in the biologics process. A helpful analogy is to think of biologics creation like winemaking: even if wineries use the same grapes to make the same type of wine, the wines can turn out very differently based on minor differences in the process like when the grapes are harvested, whether they are crushed or pressed, differences in fermentation, etc.

133. Wu & Cheng, *supra* note 21, at 104 (quoting 42 U.S.C. § 262(i)(2)(A)).

134. Carrier & Minniti III, *supra* note 64, at 9.

135. JIE JACK LI, BLOCKBUSTER DRUGS: THE RISE AND DECLINE OF THE PHARMACEUTICAL INDUSTRY 172–73 (2014).

small-molecule drug;[136] due to their complex nature, biologics provide pharmaceutical companies with more opportunities to amass multiple patents on a single drug;[137] and price erosion from the entry of biosimilars is much less than that from the entry of generics.[138] Biologic drugs also promise vast quality of life improvements for those with autoimmune diseases, those with cancer, and other patients who "previously had no available treatment options"—but only if consumers can afford to use them.[139]

C. The Evolution of the Noerr-Pennington *Doctrine*

As seen in earlier sections, the advent of biologics like Humira has made the formation of patent thickets easier, and patent law both incentivizes the formation of patent thickets and makes them very difficult to effectively challenge.[140] Further, patent law relies on markets to regulate the value of patented inventions, but inefficient markets in the pharmaceutical industry have distorted the value of drug patents.[141] Antitrust law aims to remedy inefficient markets by "correct[ing] market failures brought about by lack of competition" and by "disciplin[ing] activities that seek to limit [competition]."[142] Unfortunately for consumers, the *Noerr-Pennington* doctrine, which provides antitrust immunity when parties petition the government for action—including by seeking and enforcing patents—stands in the way of antitrust law's possible remedies for pharmaceutical market failures.

The *Noerr-Pennington* doctrine originated with the Supreme Court case *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.* in 1961.[143] In *Noerr*, the Court held that the Sherman Act, which prohibits monopolization attempts and agreements restraining trade, cannot prohibit efforts to influence the passage or enforcement of

136. *See* Carrier & Minniti III, *supra* note 64, at 9 (noting that the average daily cost of a biologic is $45 while the average daily cost of a small-molecule drug is $2).

137. *See* Wu & Cheng, *supra* note 21, at 155–56 (arguing that because the scope of each biologic patent is smaller than that of small-molecule patent, companies tend to obtain more patents to cover all the different aspects of the biologic).

138. *See* Carrier & Minniti III, *supra* note 64, at 10 (predicting that the entry of biosimilars will not erode cost as much as the entry of small-molecule drugs because pharmaceutical companies need to recoup the much greater development costs for biosimilars).

139. Alex Hyde, *What Are Biologics?*, BIOANALYSIS ZONE (May 13, 2020), https://www.bioanalysis-zone.com/biologics-definition-applications/ [https://perma.cc/8FH8-2VG9].

140. *See supra* Sections I.A (discussing patent law) and I.B (discussing biologics).

141. *See supra* text accompanying notes 65–68.

142. Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 OHIO ST. L.J. 467, 475 (2015).

143. 365 U.S. 127 (1961).

laws.[144] The Court reasoned that antitrust laws like the Sherman Act could not interfere with the First Amendment right "to petition the Government for a redress of grievances."[145] Therefore, antitrust laws cannot prevent parties from attempting to get new laws passed or attempting to enforce existing laws, even if the practical effect of such efforts would cripple competitors.[146]

A few years later, in *United Mine Workers v. Pennington*, the Supreme Court extended *Noerr* antitrust immunity beyond the legislative arena to acts seeking to influence executive action.[147] The Court held that even "joint efforts"[148] attempting to instigate action by executive officials would be shielded by *Noerr*, despite any anticompetitive motives.[149] Finally, in *California Motor*, the Supreme Court reasoned that the right to petition includes access to the courts and administrative agencies and extended *Noerr* protection to such proceedings.[150] In other words, *Noerr* protected the rights of parties to file lawsuits or initiate administrative proceedings.[151] Thus, the *Noerr-Pennington* doctrine allows parties to use the processes of all three branches of government to achieve anticompetitive effects while immunized from antitrust liability.[152]

A hypothetical may help illustrate how the *Noerr-Pennington* doctrine operates in practice. Assume that Brand Name and Generic are competitors in the pharmaceutical industry. Brand Name has lobbied aggressively for legislation or regulations to be enacted that, in effect, would target only Generic's business. Brand Name's express intent is ensuring that Generic cannot create a generic competitor to Brand Name's marquis drug. Brand Name has also reported Generic to

144. *Id.* at 138; 15 U.S.C. § 1 ("Every contract, combination . . . , or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal."); 15 U.S.C. § 2 ("Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony.").

145. U.S. CONST. amend. I; *Noerr*, 365 U.S. at 138.

146. *See Noerr*, 365 U.S. at 139 ("It is neither unusual nor illegal for people to seek action on laws in the hope that they may bring about an advantage to themselves and a disadvantage to their competitors.").

147. 381 U.S. 657, 670 (1965) ("Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition.").

148. "Joint efforts," or, in other words, an agreement between competitors, are one of the key elements of Sherman Act § 1 violations. The involvement of two parties rather than one party is one of the main distinguishing features between Sherman Act § 1 and § 2. *See* 15 U.S.C. § 1 (Combinations in restraint of trade are illegal.); 15 U.S.C. § 2 (Independent attempts or acts of monopolization are illegal.).

149. *Pennington*, 381 U.S. at 670.

150. Cal. Motor Transp. v. Trucking Unlimited, 404 U.S. 508, 510 (1972).

151. *Id.*

152. *See id.* ("Certainly the right to petition extends to all departments of the Government.").

the FDA for safety violations, again with the express intent of delaying Generic's competing drug. Finally, when these efforts prove unsuccessful, Brand Name sues Generic for patent infringement, claiming that Generic's new drug infringes upon Brand Name's patent for its marquis drug. Generic may, as part of its defense, bring a counterclaim against Brand Name for Sherman Act antitrust violations for attempted monopolization. Alternatively, Generic could bring its own suit against Brand Name for Sherman Act antitrust violations. Either way, in response, Brand Name can argue that the *Noerr-Pennington* doctrine immunized all of Brand Name's actions, and Generic's claims should be dismissed. Under these circumstances, Brand Name would likely get Generic's claims dismissed even if Brand Name brazenly and publicly declared its anticompetitive intentions for its actions. Unless Generic can adequately plead that Brand Name's activities fall within the sham exception or one of the other exceptions to the *Noerr-Pennington* doctrine, Generic's claims will be dismissed.[153]

As can be seen from this illustration, while Brand Name may be the plaintiff in the original action, in a *Noerr-Pennington* context, the roles will be reversed. Thus, this Note describes a party who brings an antitrust claim as the "antitrust plaintiff" (even though the same party may have been the defendant originally). On the other hand, an "antitrust defendant" is a party who invokes *Noerr-Pennington* as a defense. Consequently, the antitrust plaintiff has the burden of proving that the sham exception applies to the antitrust defendant's actions to overcome *Noerr-Pennington* immunity and move past the pleadings.

D. Operation of the Sham Exception to Noerr-Pennington

As the Court set the foundation for the *Noerr-Pennington* doctrine in *Noerr*, the Court simultaneously laid the groundwork for the sham exception. In *Noerr*, the Court noted that "[t]here may be situations in which a publicity campaign, ostensibly directed toward influencing governmental action, is a *mere sham* to cover what is actually an attempt to interfere directly with the business relationships of a competitor and the application of the Sherman Act would be justified."[154]

153. *See* Atwood, *supra* note 47, at 653 ("[T]he basic teaching of the *Noerr/Pennington* doctrine is that petitioning the government . . . is immune from challenge under the antitrust laws. . . . [But] [t]here are exceptions to this immunity principle.").

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

The Court first explicitly recognized a case coming within the "sham" exception in *California Motor*.[155] In *California Motor*, a group of interstate-highway carriers filed multiple petitions to hamper the applications of in-state highway carriers for additional operating rights or transfer of existing rights.[156] In response, the in-state carriers filed an antitrust suit alleging that the interstate carriers conspired to weaponize administrative and judicial proceedings against the in-state carriers.[157] The Court noted that the interstate carriers "instituted the proceedings and actions . . . with or without probable cause, and regardless of the merits of the cases," which implied that some of the proceedings could have merit but overall still constituted a sham.[158] This is because "sham proceedings" could emerge as "a *pattern* of baseless, repetitive claims . . . which leads the factfinder to conclude that the administrative and judicial processes have been abused."[159] A pattern of sham claims is problematic because numerous claims against a party could effectively strip that party's "meaningful access" to the courts and agencies.[160] In essence, the party being petitioned against cannot use the same governmental processes as the petitioner because it is too busy fighting off sham petitions.[161]

While the *Noerr-Pennington* doctrine holds that a petitioner's anticompetitive intent is irrelevant and still grants antitrust immunity to the petitioner, *California Motor* used intent in its sham exception analysis.[162] With respect to the sham exception, it is the intent to deprive competitors of the use of governmental processes that eviscerates *Noerr-Pennington* immunity, *not* a petitioner's general anticompetitive intent to harm its opponents.[163] This is because the First Amendment petitioning right works both ways, and courts must balance each party's countervailing rights.[164] The *Noerr-Pennington* doctrine protects the right of parties to use governmental processes to

155. 404 U.S. at 516.

156. *Id.* at 509.

157. *Id.*

158. *Id.* at 512.

159. *Id.* at 513 (emphasis added).

160. *Id.* at 512.

161. *Id.*

162. *Id.*

163. *See id.* ("[A] purpose or intent [to deprive competitors of meaningful access to the agencies and courts], if shown, would be 'to discourage and ultimately prevent the respondents from invoking' the processes of the administrative agencies and courts and thus fall within the [sham] exception to *Noerr*.").

164. *See id.* at 515 ("First Amendment rights may not be used as the means or the pretext for achieving 'substantive evils' which the legislature has the power to control.").

petition.[165] But if those parties are using governmental processes to stop competitors from petitioning, then the petitioners have violated their competitors' First Amendment rights, and *Noerr-Pennington* no longer provides immunity to the petitioners.[166] The Court thus concluded that if the alleged "pattern of baseless repetitive claims" in the complaint proved true, then "a violation of the antitrust laws has been established."[167]

Over twenty years later, the Court revisited the sham exception in *PRE*. *PRE* involved a *single* lawsuit brought by motion picture owners for copyright infringement against hotel owners.[168] The alleged copyright infringement consisted of the hotel owners allowing guests to rent and view videodiscs in their rooms.[169] The hotel owners counterclaimed for antitrust violations, alleging that the copyright infringement suit was "a mere sham that cloaked underlying acts of monopolization and conspiracy to restrain trade."[170] The Court held that "an *objectively reasonable* effort to litigate cannot be sham regardless of subjective intent."[171] In coming to this conclusion, the *PRE* Court reasoned that *California Motor*'s sham exception analysis required courts to "separate[ ] *objectively reasonable* claims from 'a pattern of *baseless*, repetitive claims.' "[172] Therefore, *PRE* emphasized that the sham exception required an indispensable objective component in discerning petitions as shams.

The *PRE* Court formulated a two-part test for drawing the line between "objectively reasonable" claims and baseless claims that would invoke the sham exception.[173] In step one, the court evaluates whether a suit is "*objectively baseless* in the sense that no reasonable litigant could reasonably expect success on the merits."[174] In a footnote, the majority also clarified that "[a] winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham"; in other words, a winning lawsuit cannot be "objectively baseless."[175]

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165. *See id.* at 510 ("Certainly the right to petition extends to all departments of the Government.").

166. *See id.* at 512 (holding that if a petitioner is using governmental processes to discourage its competitors from invoking governmental processes, the petitioner's activities fall within the sham exception and do not have *Noerr-Pennington* immunity).

167. *Id.* at 513, 515.

168. Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 51–52 (1993).

169. *Id.*

170. *Id.* at 52.

171. *Id.* at 57 (emphasis added).

172. *Id.* at 58 (quoting *Cal. Motor*, 404 U.S. at 513) (emphasis added).

173. *Id.* at 60–61.

174. *Id.* (emphasis added).

175. *Id.* at 60 n.5.

Only if the suit is "objectively baseless" does the court move on to step two and examine the litigant's subjective motivation.[176] A subjective motivation to use the governmental process itself (rather than the outcome of the process) as an anticompetitive weapon would invoke the sham exception.[177] Thus, while *California Motor* frontloaded its sham exception inquiry to focus on the intent to weaponize government process against competitors, *PRE* focused more on the objective nature of the actions before reviewing the weaponization of government processes.

Justice Stevens, concurring in the *PRE* judgment only, noted that potential shams were more likely to fall through the cracks under *PRE*'s two-part test than under *California Motor*'s analysis. In Justice Stevens's view, while *California Motor* viewed shams as a "pattern of *baseless*, repetitive claims," those claims did not necessarily have to be "objectively baseless."[178] He reasoned that "objectively unreasonable" claims could also fit into a "pattern of baseless, repetitive claims."[179] "Objectively unreasonable" claims are those where a plaintiff could have "some reason to expect success on the merits but because of its tremendous cost would not bother to achieve that result without the benefit of collateral injuries imposed on its competitor by the legal process alone."[180] Justice Stevens argued that *California Motor* provided room for "objectively unreasonable" claims to be included in the sham exception because when analyzing a "pattern of baseless, repetitive claims," courts considered claims filed "*regardless* of the merits."[181] Therefore, the "objectively baseless" step in *PRE* may filter out too many possible shams that would be "objectively unreasonable," but not "objectively baseless."

II. THE *NOERR-PENNINGTON* SHAM EXCEPTION CIRCUIT SPLIT AND ITS IMPLICATIONS

As discussed above, *California Motor* has a less rigorous standard for sham petitions of identifying a "pattern of baseless,

176. *Id.* at 60–61.

177. *Id.* Justice Stevens noted in his concurrence that an anticompetitive abuse of governmental processes could be when litigation is initiated "to impose a collateral harm on the defendant by, for example, impairing his credit, abusing the discovery process, or interfering with his access to government agencies." *Id.* at 68 (Stevens, J., concurring).

178. *Id.* at 67–68 (Stevens, J., concurring).

179. *Id.* at 67–69 (Stevens, J., concurring).

180. *Id.* at 68–69 (Stevens, J., concurring).

181. Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 512 (1972); *see Pro. Real Est. Invs., Inc.*, 508 U.S. at 73 ("Repetitive filings, some of which are successful and some unsuccessful, may support an inference that the process is being misused.").

repetitive claims" filed "regardless of the merits" than *PRE* does.[182] *PRE*'s initial requirement that the petitions be "objectively baseless" wherein no reasonable litigant had any reasonable expectation of success on the merits is a high bar before even getting to the remainder of the two-part test.[183] As Justice Stevens's concurrence pointed out, the gulf between *California Motor*'s and *PRE*'s standards for finding a sham petition can lead to differing outcomes depending on which standard the court applies.[184] The seeming conflict in the operation of the sham exception in *California Motor* and *PRE* caused a circuit split. The Ninth Circuit (later followed by the Second, Third, and Fourth Circuits) reasoned that *California Motor*'s lower bar for shams should apply to a pattern of meritless proceedings. In contrast, the First Circuit (later followed by the Seventh Circuit) argued that *PRE*'s high bar for shams should apply to all proceedings regardless of the number.

For ease of discussion, this analysis will refer to these disparate treatments of the sham exception as the Ninth Circuit approach and the First Circuit approach, respectively. Section A will first dissect and reconcile the alleged conflict in the analyses of *California Motor* and *PRE*. Section B will analyze the Ninth Circuit approach, and Section C will analyze the First Circuit approach. Section D will integrate patent thicket concerns into the analysis of the sham exception. Finally, Section E will discuss the stare decisis considerations in reconciling these decisions.

A. Reconciling the "Conflict" Between California Motor *and* PRE

While the differences in the analyses of the sham exception by *California Motor* and *PRE* have been called conflicting, the cases may be read in harmony. Importantly, the *PRE* majority did not explicitly overrule *California Motor* and, in fact, relied on *California Motor* throughout its analysis.[185] In *PRE*, the majority noted that "the sham exception contains an indispensable objective component."[186] The Court further noted that "we have repeatedly reaffirmed that evidence of anticompetitive intent or purpose alone cannot transform otherwise legitimate activity into a sham."[187] In contrast, *California Motor* concentrated on the intent of petitioners (i.e., the antitrust defendants)

182. *See supra* text accompanying note 158–159.

183. *See supra* text accompanying notes 173–177 for a description of *PRE*'s two-step test for the sham exception.

184. *See supra* text accompanying notes 178–179.

185. *Pro. Real Est. Invs., Inc.*, 508 U.S. at 56–58 (1993).

186. *Id.* at 58.

187. *Id.* at 59.

to deprive their competitors (i.e., the antitrust plaintiffs) of the use of governmental processes through their petitions.[188] But *California Motor* contemplated a case with a *pattern* of petitions, not the *single* petition at question in *PRE*. Patterns can be objectively observable when there are multiple petitions.[189] Moreover, when multiple petitions have effectively barred the petitioners' competitors from governmental processes, the competitors have objective evidence of the subjective intent at question in *California Motor*.[190] Thus, if *California Motor* is read to require a *pattern* of petitions to invoke the sham exception, not just multiple petitions, *California Motor* and *PRE* are not in conflict on *PRE*'s "objective criteria" requirement.

PRE is also noteworthy because it does not discuss in detail the use of petitions to bar the antitrust plaintiff from meaningful access to agencies and the judiciary.[191] In *California Motor*, the Court spent considerable time discussing the potential blockage of access to government processes.[192] Again, the fact that *PRE* deals only with a single petition provides an explanation. It is difficult to conceive how any single petition could effectively "bar" a competitor's access to the same court or agency in the way that *California Motor*'s pattern of petitions allegedly did.[193] Thus, *PRE* did not consider the potential bar of access to governmental processes because it was unnecessary to consider in the context of that case.

Finally, *PRE*'s and *California Motor*'s differing standards on whether "objectively baseless" or "objectively unreasonable" claims invoke the sham exception can also be explained. *PRE* requires a petition to be "objectively baseless" because when dealing with only one petition, there is unlikely to be any objective evidence that the petition is a sham except in the most egregious cases.[194] Only one sham petition is probably insufficient to harm a competitor's business to the point that

188. Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 512 (1972).

189. *See id.* at 513 ("One claim, which a court or agency may think baseless, may go unnoticed; but a pattern of baseless, repetitive claims may emerge . . . .").

190. *See* Waugh Chapel S., LLC v. United Food & Com. Workers Union Loc. 27, 728 F.3d 354, 364 (4th Cir. 2013) ("Of course, the subjective motive of the litigant and the objective merits of the suit are relevant, but other signs of bad-faith litigation . . . may also be probative of an abuse of the adjudicatory process.").

191. *See Pro. Real Est. Invs., Inc.*, 508 U.S. at 57 (quoting *California Motor*'s language about barring access to government processes, but not elaborating or discussing that element).

192. *See, e.g.*, *Cal. Motor*, 404 U.S. at 511–12 (claiming that the antitrust defendant's actions essentially "usurp[ed] [the] decisionmaking process" by barring the antitrust plaintiffs' meaningful access to adjudicatory tribunals).

193. *Cf. id.* at 518 (Stewart, J., concurring) (describing the multiple allegations of abuse of the administrative and judicial process by the antitrust defendants).

194. *See Pro. Real Est. Invs., Inc.*, 508 U.S. at 58 (noting that "the sham exception contains an indispensable objective component").

it constitutes an antitrust violation. In contrast, in *California Motor*, the pattern of petitions provides more data points for the court to analyze and more possibilities for gathering objective evidence of a sham.[195] For instance, the number of petitions could impose a financial burden on the competitor that the court can quantify.[196] Multiple petitions could also be used to effectively delay a competitor's entry into the market or to interfere with an important part of a competitor's business.[197] Thus, using a lower standard like "objectively unreasonable" for a pattern of petitions makes sense.

B. The Ninth Circuit Approach: A Lower Bar for a Pattern of Sham Petitions

In *Posco*, the first federal appellate court case to confront the sham exception after *PRE*, the Ninth Circuit adopted a bifurcated approach to reconciling *California Motor* and *PRE*. *Posco* involved a non-unionized contractor, the antitrust plaintiff, who was awarded a major construction contract.[198] Labor unions, the antitrust defendants, allegedly filed automatic protests to requests for permits, filed multiple lawsuits against the antitrust plaintiff, and engaged in lobbying activities against the antitrust plaintiff.[199] The Ninth Circuit noted, however, that the antitrust defendants prevailed in fifteen of the twenty-nine suits that the antitrust plaintiff alleged to be part of the pattern of sham petitions, "a batting average exceeding .500."[200] The Ninth Circuit held that the antitrust plaintiff had not met its burden of showing that the alleged conduct was a sham because of the antitrust defendants' high win rate; thus, *Noerr-Pennington* immunized the antitrust defendants' conduct.[201]

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195. *See Cal. Motor*, 404 U.S. at 518 (Stewart, J., concurring) (describing the multiple factual allegations behind the case).

196. *See, e.g.*, Inserra Supermarkets, Inc. v. Stop & Shop Supermarket Co., 240 F. Supp. 3d 299, 308 (D.N.J. 2017) (describing how the antitrust defendants' petitions had delayed the necessary government approvals that the antitrust plaintiff sought, which forced the antitrust plaintiff to pay $100 thousand per month in rent for years before even being able to begin development of its competing supermarket).

197. *See, e.g.*, Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc., 806 F.3d 162, 167–70 (3d Cir. 2015) (describing the antitrust defendants' multiple petitions appealing the permits and rezoning of a competitor trying to open a full-service supermarket in the same town when that competitor would lose the real estate if it did not obtain all required permits within a certain time).

198. USS-Posco Indus. V. Contra Costa Cnty. Bldg. & Constr. Trades Council, 31 F.3d 800, 804 (9th Cir. 1994).

199. *Id.*

200. *Id.* at 811.

201. *Id.*

Although the Ninth Circuit did not find that the conduct in *Posco* fell within the sham exception (and thus vulnerable to antitrust liability), the Ninth Circuit provided a new blueprint for courts to reconcile *California Motor* and *PRE*. *PRE*'s two-step test applies in situations where a single proceeding is at question and *California Motor* applies in a series of proceedings.[202] The Ninth Circuit reasoned that this bifurcated approach made sense because "the filing of a whole series of lawsuits and other legal actions without regard to the merits has far more serious implications than filing a single action, and can serve as a very effective restraint on trade."[203] Further, in a series of lawsuits some may turn out to have merit by chance, but, as in *California Motor*, the intent to impede competitors' access to governmental processes is the sham exception's overriding consideration.[204] The *Posco* Court reasoned that *California Motor*'s dominant inquiry is "prospective": Did the antitrust defendant make the petitions "not out of a genuine interest in redressing grievances, but . . . undertake[ ] [them] essentially for purposes of harassment"?[205] In evaluating this question, the Ninth Circuit focused on the antitrust defendants' win-loss ratio as discussed above.[206]

The Second, Third, and Fourth Circuits all adopted similar reasoning to *Posco* in reconciling *California Motor* and *PRE*.[207] These later decisions explored the dimensions of *California Motor*'s pattern test. The Fourth Circuit reasoned that *PRE* is "ill-fitted" for a series of proceedings because a judge can more easily determine whether a single claim is objectively baseless than review a parade of state and administrative proceedings for baselessness.[208] The Fourth Circuit also built on *Posco*'s formulation of the win-loss percentage to note that there is "no particular win-loss percentage that a litigant must achieve" to successfully invoke the sham exception.[209]

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202. *Id.* at 810–11.

203. *Id.* at 811; *see supra* text accompanying notes 200–201 (discussing the win-loss ratio in *Posco*).

204. *Posco*, 31 F.3d at 811.

205. *Id.*

206. *Id.*

207. *See* Hanover 3201 Realty, LLC v. Vill. 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."); Waugh Chapel S., LLC v. United Food & Com. Workers Union Loc. 27, 728 F.3d 354, 363 (4th Cir. 2013) ("[W]e agree with the distinction adopted by our sister circuits."); Primetime 24 Joint Venture v. Nat'l Broad. Co., 219 F.3d 92, 101 (2d Cir. 2000) ("[*Pro. Real Est. Invs., Inc.*'s] two-step inquiry, however, applies to determining 'whether a single action constitutes sham petitioning.' ") (quoting *Posco*, 31 F.3d at 811).

208. *Waugh Chapel*, 728 F.3d at 364.

209. *Id.* at 364–65.

Both the Third and Fourth Circuits emphasized that courts should also conduct a "holistic evaluation" to look for "other signs of bad-faith litigation."[210] The Third Circuit emphasized that when considering evidence of bad faith, courts should look to "the magnitude and nature of the collateral harm imposed on plaintiffs by defendants' petitioning activity (e.g., abuses of the discovery process and interference with access to governmental agencies)."[211] Bad-faith indicators can be considered objective manifestations of a subjective intent to usurp the government processes to harm competitors rather than seeking an actual redress of grievances.[212]

The Third Circuit provided a prime example of bad-faith indicators. In *Hanover 3201 Realty*, the antitrust plaintiff entered into an agreement to build a Wegmans supermarket on its property on the condition that it secure all necessary permits and approvals before it could break ground on the project.[213] The antitrust defendants, ShopRite and its subsidiary, allegedly tried to prevent the entry of Wegmans as a competitor supermarket in the town by filing numerous administrative and court challenges to the antitrust plaintiff's permit applications.[214] In particular, the antitrust defendants submitted an amended request for an adjudicatory hearing five months after their initial request citing "new" proposed facts that the antitrust defendants allegedly already knew at the time of their initial request.[215] The Third Circuit reasoned that adding these "new" facts months later suggested that the antitrust defendants were not interested in redressing any grievances but in delaying the antitrust plaintiff from opening a competing business.[216] Additionally, the antitrust defendants' ecological consultant touted its ability to delay the antitrust plaintiff's environmental permit approval in an e-mail.[217] While the antitrust defendants also had some successes, when the Third Circuit reviewed the overall context of the antitrust defendants' actions, it held that the sham exception was applicable, and *Noerr-Pennington* did not immunize the antitrust defendants' conduct.[218] Thus, bad-faith indicators, such as the ones on display in *Hanover 3201 Realty*, help

210. *Id.*; *See Hanover 3201 Realty*, 806 F.3d at 181 (citing *Posco*, 31 F.3d at 811).

211. *Hanover 3201 Realty*, 806 F.3d at 181 (citing *Posco*, 31 F.3d at 811).

212. *Id.*

213. *Id.* at 166.

214. *Id.*

215. *Id.* at 181.

216. *Id.*

217. *Id.* at 182.

218. *Id.* at 182–83 ("That Defendants have had some insignificant success along the way does not alter the analysis when reviewing a pattern or series of proceedings.").

illustrate the abuse of government processes discussed in *California Motor*.

One of the main concerns of the Ninth Circuit approach, however, is that the *California Motor* analysis leaves many open questions. For instance, what counts as a "petition"? When do a series of petitions become a "pattern"? What counts as a win or a loss? Are there any other pertinent criteria? Moreover, courts may need to sift through a large number of proceedings to answer these questions.[219] Administrative proceedings may also add complexity since "the presiding tribunal in those cases had no occasion to [document] the baselessness of the suit because . . . it had no inkling that the action [constituted part of] a possible campaign of sham litigation."[220] While the *California Motor* Court noted that it "may be a difficult line to discern and draw," courts cannot abdicate their duty to adjudicate these cases because of their complexity.[221]

C. The First Circuit Approach: The High Bar of PRE *Always Applies*

Unlike the Ninth Circuit approach, the First Circuit in *Puerto Rico Telephone Co. v. San Juan Cable LLC* reasoned that *PRE* was not necessarily limited to cases dealing with a single petition.[222] The First Circuit noted that "[o]ne large lawsuit or intervention in an agency proceeding can impose much more of a burden on a competitor than might a series of smaller claims."[223] Of course, while one large lawsuit or agency proceeding *could* impose a huge burden on a competitor, a sham petition under *PRE* is one that is "objectively baseless."[224] If a petition is "objectively baseless" such that "no reasonable litigant could reasonably expect success on the merits," then one sham proceeding should not impose the type of burden that would cause significant anticompetitive harm because the relevant court or agency should swiftly dismiss such proceeding. [225]

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219. Waugh Chapel S., LLC v. United Food & Com. Workers Union Loc. 27, 728 F.3d 354, 364 (4th Cir. 2013).

220. *Id.*

221. *See* 404 U.S. 508, 513 (1972); *see also* Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 75 (1993) (Stevens, J., concurring) ("The difficulty of determining the true purpose [of the antitrust defendant's petitions] is great but no more so than in many other areas of antitrust law.").

222. 874 F.3d 767, 771 (1st Cir. 2017) ("[T]he court in [*Pro. Real Est. Invs., Inc.*] wrote nothing to suggest that its ruling would have been different had the defendant filed a series of objectively reasonable suits.").

223. *Id.* at 772.

224. *Pro. Real Est. Invs., Inc.*, 508 U.S. at 60–61.

225. *Id.*

Puerto Rico Telephone had another oddity that made it a unique and less generally applicable case. In *Puerto Rico Telephone*, the district court determined that each of the antitrust defendant's filings was objectively reasonable and that the antitrust plaintiff waived any challenge to those findings.[226] Thus, the First Circuit confronted a case with a series of filings, all of which were objectively reasonable as a matter of law.[227] The First Circuit concluded that if every filing in a large series of filings was objectively reasonable, then they failed to see "how a jury could reasonably conclude that the party was filing petitions 'regardless of the merits of the cases,' " as required by *California Motor*.[228] Judge Barron's concurrence further noted that the majority opinion did not necessarily foreclose the approach taken by the other circuits because the majority opinion relied "on a more record-based, case-specific line of reasoning."[229]

Despite Judge Barron's concurrence, the Seventh Circuit, relying on *Puerto Rico Telephone*, explicitly rejected that *California Motor* "provides a separate rubric to use whenever a 'pattern' of sham filings is alleged."[230] In *U.S. Futures Exchange, L.L.C. v. Board of Trade*, the Seventh Circuit began its analysis by noting that "[t]he sham exception is 'extraordinarily narrow.' "[231] The Seventh Circuit noted that the *PRE* Court draws its two-part test directly from the language in *California Motor*: courts must "draw the 'difficult line' that *separates out* objectively reasonable claims from patterns of '*baseless*, repetitive claims' before finding a sham."[232] *U.S. Futures Exchange* dealt with an alleged pattern of petitions in the *legislative* arena, however, not judicial or administrative proceedings.[233] As the Seventh Circuit reasoned, legislative petitions may be subject to a higher standard than judicial petitions because " 'subjecting the same defendant to antitrust liability because it engaged in numerous unsuccessful attempts' to petition a legislative body 'would eviscerate the Petition Clause.' "[234] The ability to petition representatives to enact legislation is necessary to the functioning of a representative democracy and forms the very

226. *P.R. Tel.*, 874 F.3d at 769–70.

227. *See id.*

228. *Id.* at 772 (quoting Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 512 (1972)).

229. *Id.* at 773 (Barron, J., concurring).

230. U.S. Futures Exch., L.L.C. v. Bd. of Trade, 953 F.3d 955, 964 (7th Cir. 2020).

231. *Id.* at 963.

232. *Id.* at 964 (quoting *Cal. Motor*, 404 U.S. at 512).

233. *Id.* at 963.

234. *Id.* (quoting Kottle v. Nw. Kidney Ctrs., 146 F.3d 1056, 1061 (9th Cir. 1998)).

foundation of the rights in the First Amendment's Petition Clause.[235] In comparison, the right to use courts and administrative proceedings to hold others to account, while crucial, is necessarily more limited because the government has to balance the countervailing rights of both plaintiffs and defendants.

Neither the First nor Seventh Circuits addressed a case with similar facts to *California Motor*, *Posco*, or the cases analyzed by the other circuit courts. Both the First and Seventh Circuit opinions rejecting a separate sham analysis under *California Motor* for a pattern of petitions dealt with atypical situations. In the First Circuit, the antitrust plaintiff acquiesced to the district court's finding that all petitions in question were objectively reasonable.[236] On the other hand, in the Seventh Circuit, the antitrust claim dealt with legislative petitions, not judicial or administrative petitions.[237] In fact, no circuit court has required the *PRE* two-step test to be applied in a case that resembles the facts of *California Motor*.

Additionally, the Seventh Circuit's analysis contained two other flaws that hamper its effectiveness. First, the Seventh Circuit claimed that the First Circuit completely rejected the Ninth Circuit approach of looking for patterns of sham cases.[238] The First Circuit's decision, however, rested its conclusion on much narrower grounds, as discussed above.[239] Second, *U.S. Futures Exchange* also dealt with a *single* proceeding, which meant that the *California Motor* analysis would never have been appropriate in that case.[240] Thus, the Seventh Circuit's rejection of the Ninth Circuit approach is arguably dicta.[241] Taken together, these flaws undermine the persuasiveness of the Seventh Circuit's argument and the First Circuit approach.

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235. *See id.* at 966 ("Proving sham petitioning in a legislative context like this is virtually impossible."); U.S. CONST. amend. I (guaranteeing citizens the right "to petition the Government for a redress of grievances"); *see also Cal. Motor*, 404 U.S. at 510 (explaining that in a representative democracy, "the whole concept of representation depends upon the ability of the people to make their wishes known to their representatives").

236. P.R. Tel. Co. v. San Juan Cable LLC, 874 F.3d 767, 769–70 (1st Cir. 2017).

237. *U.S. Futures Exch.*, 953 F.3d at 963.

238. *See id.* at 964 (claiming that *Puerto Rico Telephone* rejected the notion of a separate rubric for a pattern of petitions).

239. *See supra* text accompanying notes 226–229 (discussing the limited reach of *Puerto Rico Telephone*'s holding).

240. *See U.S. Futures Exch.*, 953 F.3d at 965–66 ("This case . . . involves a single legislative proceeding within which Defendants made multiple efforts . . . regarding one overarching issue. . . . [M]ultiple filings, submissions, or other efforts [do not] transform one lawsuit or proceeding into many.").

241. *See id.*

D. Patent Thickets and the Sham Exception

Patent thickets pose several unique obstacles for plaintiffs wishing to bring antitrust claims against patent holders under the sham exception. If courts follow the First Circuit approach of analyzing each petition in a vacuum, then patent holders could probably successfully invoke the *Noerr-Pennington* doctrine every time.[242] First, judicial economy would be implicated by the First Circuit approach to patent thickets. Antitrust plaintiffs would need to bring separate antitrust claims for each allegedly sham petition.[243] *In re Humira*, decided by a district court in the Seventh Circuit, followed the First Circuit approach and demonstrates how problematic this approach might be.[244] If antitrust plaintiffs challenged all 247 patent applications, eighteen IPRs, and nine patent infringement settlements, the court would have to consider 274 separate claims and analyze each independently under the *PRE* two-step test.[245]

Second, no one claim standing on its own would likely withstand antitrust scrutiny. For example, because patents restrict competition by design, using one patent, even if invalidly granted, would probably not be deemed as unduly hindering competition.[246] Moreover, when only one patent is at issue, competitors could challenge the validity of such patent through IPR or litigation and actually prevail.[247] Potential plaintiffs do not need antitrust claims to challenge one patent; only when a party aggregates an excessive number of patents do IPRs or litigation become too risky to pursue.[248] The cumulative effect of the patent thicket and aggressive patent infringement litigation effectively bars competitors from the use of governmental processes, such as IPRs and patent litigation, as *California Motor* warned.

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242. *See supra* Section II.C (citing the Seventh Circuit's description of the sham litigation as "extraordinarily narrow").

243. *See supra* text accompanying notes 76, 80 (explaining how each patent must be invalidated separately even if they are derivative patents with minor differences stemming from one continuation application).

244. *See In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 830 (N.D. Ill. 2020).

245. *See id.* at 822, 824, 831 (detailing the petitions made by AbbVie in order to allegedly protect AbbVie's patent thicket for Humira).

246. *See* Carrier, *supra* note 46, at 768 ("[M]any acts undertaken by patentee monopolists or agreements between patentees and licensees restrict competition *by their very operation*.") (emphasis added).

247. *See supra* Section I.A.3-4 (explaining the benefits and drawbacks of challenging patents via IPRs or litigation).

248. *See supra* text accompanying notes 119–121 (describing the risks and financial outlay required to challenge a patent thicket through IPRs or litigation and providing the Humira patent thicket as a specific example).

AbbVie's patent strategy with Humira has shown how AbbVie has been able to effectively bar Humira's competitors from accessing governmental processes to challenge the patent thicket around Humira. Boehringer Ingelheim ("Boehringer"), one of the world's largest pharmaceutical companies, developed a Humira biosimilar called Cyltezo, which obtained FDA approval in 2017.[249] In 2017 (after Humira's core patent on adalimumab had expired), AbbVie filed a lawsuit against Boehringer claiming seventy-four instances of patent infringement.[250] Boehringer fought AbbVie in court for two years, but Boehringer eventually gave up and settled with AbbVie in May 2019.[251] Boehringer was the ninth company to settle patent litigation with AbbVie over a Humira biosimilar.[252] In discussing its decision to settle with AbbVie after protracted litigation, Boehringer cited "the inherent unpredictability of litigation" and "the substantial costs . . . and ongoing distraction to our business."[253] Boehringer's settlement after two years of vigorously fighting AbbVie's patent thicket and the myriad other Humira biosimilar settlements illustrate how pharmaceutical competitors cannot, or will not, effectively fight patent thickets using available patent law tools.

Third, if the *PRE* Court's reasoning that "[a] winning lawsuit is by definition [objectively reasonable]" is extended to patent applications, then the sham exception could be eviscerated with respect to patents altogether.[254] Courts could reason that any patent application that resulted in a granted patent is objectively reasonable by virtue of the PTO's grant.[255] This would mean that most patent applications (and all patent thickets) would by default have *Noerr-Pennington* antitrust immunity.[256]

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249. *AbbVie and Boehringer Ingelheim Settle Over Biosimilar Adalimumab*, AJMC CTR. FOR BIOSIMILARS, https://www.centerforbiosimilars.com/view/abbvie-and-boehringer-ingelheim-settle-over-biosimilar-adalimumab (last visited Oct. 3, 2021) [https://perma.cc/W434-UPQH].

250. Mukherjee, *supra* note 4.

251. Colin Kellaher, *AbbVie, Boehringer Settle U.S. Patent Dispute over Drug Humira*, WALL ST. J. (May 14, 2019, 12:24 P.M.), https://www.wsj.com/articles/abbvie-boehringer-settle-u-s-patent-dispute-over-drug-humira-11557851079?st=l34q18a498j0ich&reflink=desktopwebshare_permalink [https://perma.cc/X3H2-YN3T].

252. Mukherjee, *supra* note 4.

253. *Id.*

254. Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 n.5 (1993).

255. Even if the patents were later invalidated, the fact that the PTO granted the patents in the first place probably means that they don't clear *PRE*'s high bar of being "objectively baseless" such that no reasonable applicant would expect a patent to be granted. *See id.* (providing guidance on which petitions are considered objectively reasonable).

256. *See supra* text accompanying note 152.

The Ninth Circuit approach better addresses patent thicket concerns outlined above. One antitrust claim could cover the entire spectrum of alleged anticompetitive behavior, from patent applications to patent infringement settlements.[257] And because the court is analyzing a pattern of behavior for anticompetitive issues, the court can spend less time reviewing each petition individually. Moreover, the aggregation of the petitions can better show the anticompetitive nature of the actions than reviewing each petition individually. As discussed above, the Ninth Circuit approach still contains an objective component (which the *PRE* Court argued was necessary to the sham exception analysis) in calculating the win-loss ratio of the petitions.[258] Thus, patent thickets like those in *In re Humira* are better suited for analysis under the Ninth Circuit approach.

E. Stare Decisis Considerations

Finally, despite the reasoning of the First and Seventh Circuits, the Supreme Court did not expressly overrule *California Motor*'s precedent in *PRE*.[259] The doctrine of stare decisis should be considered when discussing how to handle precedential cases like these. Stare decisis stands for the presumption that precedent should be followed unless the court has a compelling reason to overrule it.[260] The Supreme Court has stated that "[i]f a precedent of this Court has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, the Court of Appeals should follow the case which *directly controls*, leaving to this Court the prerogative of overruling its own decisions."[261] The *PRE* Court made multiple references to the *California Motor* decision, but never stated that it was overruling *California Motor* in whole or in part.[262] Stare decisis for the sham exception requires lower courts to follow whichever Supreme Court decision more closely resembles the facts of the case at hand or "directly

257. *See, e.g.*, *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 822, 824, 831 (N.D. Ill. 2020) (describing the antitrust plaintiff's allegations about AbbVie's various patent activities).

258. *See supra* text accompanying notes 189–190 (noting that requiring a "pattern" of sham petitions would provide multiple data points that can be objectively observed).

259. *Pro. Real Est. Invs., Inc.*, 508 U.S. at 56–58.

260. Amy L. Padden, Note, *Overruling Decisions in the Supreme Court: The Role of a Decision's Vote, Age, and Subject Matter in the Application of Stare Decisis after* Payne v. Tennessee, 82 GEO. L.J. 1689, 1689 (1994).

261. Rodriguez de Quijas v. Shearson/American Express, Inc., 490 U.S. 477, 484 (1989) (emphasis added).

262. *Pro. Real Est. Invs., Inc.*, 508 U.S. at 56–58.

controls."[263] Thus, the lower courts should not assume that the test announced in *PRE* has replaced the *California Motor* analysis. The Ninth Circuit's bifurcated approach best respects the bedrock principle of stare decisis as articulated by the Supreme Court by allowing both the *California Motor* and *PRE* analyses to stand.

Actavis provides another stare decisis consideration. In *Actavis*, the Supreme Court specifically rejected granting antitrust immunity to patent owners who remained within the "scope of [their] patent."[264] Yet, the *In re Humira* Court revived this rejected reasoning by holding that only one valid patent was needed to immunize AbbVie from antitrust scrutiny.[265] To extend the logic of that opinion, AbbVie would thus be immunized from antitrust liability no matter how many illegitimate patents it obtained as long as Humira had one core valid patent at the center of the patent thicket. The anticompetitive harm allegedly perpetrated by AbbVie, however, did not stem from a single patent. [266] The accumulation of a host of patents caused the anticompetitive harm because competitors could not even discover if a valid patent did exist in the midst of the patent thicket. If pharmaceutical companies could obtain one valid patent to immunize a range of illegitimate and anticompetitive patents, *Actavis*'s rejection of antitrust immunity based on simply being a patent owner would be eviscerated.

Additionally, the First Circuit approach of applying the two-step *PRE* test to each individual patent proceeding in a vacuum makes it impossible for a challenger to prevail because patents have a presumption of validity, making them "objectively reasonable."[267] Such an approach again conflicts with *Actavis* because patent owners would essentially be granted antitrust immunity by virtue of simply obtaining

263. *See Rodriguez de Quijas*, 490 U.S. at 484 (holding that lower courts must follow the Supreme Court precedent with the most similar facts and let the Supreme Court overrule its own decisions expressly).

264. FTC v. Actavis, Inc., 570 U.S. 136, 141 (2013) (rejecting the Eleventh Circuit's holding that reverse payment settlements were "immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent").

265. *See In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 844 (N.D. Ill. 2020) ("[I]t only takes one valid, infringed patent to render all the rest—whether invalid, infringed, or not—irrelevant for purposes of cause-in-fact analysis.").

266. For instance, if AbbVie only had one or two valid patents on Humira and no patent thicket, AbbVie's competitors could theoretically figure out how to "patent around" AbbVie's valid patents and, thus, bring a competing drug into the market earlier. Alternately, if Humira had fewer patents, then competitors could better analyze which patents were ripe for attack and could better bear the risk of attempting to invalidate those patents.

267. *See Pro. Real Est. Invs., Inc.*, 508 U.S. at 60–61 (noting that the first step in the *PRE* test requires the antitrust plaintiff "to disprove the challenged lawsuit's *legal* viability" before moving on to the rest of the test).

a patent.[268] In *Actavis* and its rejection of scope-of-the-patent antitrust immunity, the Court explicitly opened the door for possible antitrust scrutiny of patent proceedings.[269] Thus, the Ninth Circuit approach better adheres to *Actavis* because that inquiry acknowledges that some of the patent proceedings could have merit but still allows for some antitrust scrutiny.[270]

III. A FRAMEWORK FOR ANALYZING PATENT PROCEEDINGS UNDER THE *CALIFORNIA MOTOR* PATTERN ANALYSIS

This Note proposes adopting a modified version of the bifurcated approach to the sham exception used by the majority of circuits. Section A proposes some general updates to the *California Motor* pattern analysis to ensure consistency of analysis in the lower courts. Section B provides a framework to analyze patent law-specific proceedings under the *California Motor* pattern analysis. This will provide specific guidance for plaintiffs seeking to challenge pharmaceutical patent thickets and other common tactics of the pharmaceutical industry under the sham exception. Finally, Section C discusses the implications of and counterarguments to this solution.

The main benefit of this solution is that it provides a viable alternative to attacking patent thickets outside of patent law, which has proved incapable of addressing the patent thicket problem. With the sham exception, challengers can attack the entire patent thicket at once instead of making piecemeal hacks at each patent through IPRs or expensive, lengthy litigation. This is because the sham exception analysis under *California Motor* focuses on the overall pattern of anticompetitive behavior. Using the sham exception to attack pharmaceutical patent thickets, if successful, would disincentivize pharmaceutical companies from creating these thickets in the first place to avoid potential antitrust liability. Reduced patent thickets would also lower burdens on the PTO, allow generics and biosimilars to enter the market sooner, and reduce drug prices for consumers, due to the increased market competition.

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268. *See* 570 U.S. at 141 (rejecting antitrust law immunity when a patent owner's actions fell within the scope of the patent).

269. *See id.* (holding that reverse payment settlements made by patent owners can sometimes violate antitrust laws); USS-Posco Indus. v. Contra Costa Cnty. Bldg. & Constr. Trades Council, 31 F.3d 800, 811 (9th Cir. 1994) ("The inquiry in such cases is prospective: Were the legal filings made, not out of a genuine interest in redressing grievances, but as part of a pattern or practice of successive filings undertaken essentially for purposes of harassment?").

270. *See supra* Section II.B (describing the Ninth Circuit approach of applying the *California Motor* sham analysis in cases where there was a pattern of filings made "without regard to the merits").

A. General Proposed Updates to the California Motor *Pattern Analysis*

As noted above, this Note proposes a modified version of the Ninth Circuit's bifurcated approach to the sham exception analysis. First, if only a single petition is at question, then the *PRE* two-step test should be used to analyze the sham exception claim. If, however, a case involves multiple petitions, instead of going straight to *California Motor*, the court should determine whether the petitions constitute a "pattern." If the court determines that the multiple petitions constitute a pattern, then the court would proceed under *California Motor*'s sham exception analysis. On the other hand, if the court determines that the multiple petitions do not constitute a pattern, then the court would proceed to analyze the petitions under *PRE*'s more exacting standard.

When analyzing multiple petitions, one way courts can discover a pattern is to see if the petitions take a logical progression. Typically, if people study a section of a pattern, they can then predict the next steps in that pattern. Similarly, if the antitrust defendant's petitions follow a predictable path or illustrate progress towards a specific anticompetitive goal, then the petitions probably constitute a pattern. *Livingston Downs Racing Association v. Jefferson Downs Corp.* illustrates this point.[271] In that case, the antitrust plaintiff attempted to open a rival racetrack for horse racing and betting operations; in order to do this, the antitrust plaintiff had to obtain licenses from the state racing commission and secure voter approval for the racetrack in a referendum election.[272] The antitrust defendants wanted to deter the rival racetrack from becoming operational and followed a predictable course of action to stymie the antitrust plaintiff every step of the way: lobbying the racing commission to deny the antitrust plaintiff the required licenses; "campaigning against the new racetrack in the referendum election; filing lawsuits contesting the legitimacy of both the referendum election and the [antitrust plaintiff's licenses]; and intervening in the various lawsuits [the antitrust plaintiff] filed in an attempt to obtain [the required licenses]."[273] The long delays caused by the antitrust defendants' lobbying and legal challenges eventually caused the antitrust plaintiff's financing to fall through, "scuttling their plans entirely."[274] As can be seen here, the antitrust defendants

271. *See* 192 F. Supp. 2d 519 (M.D. La. 2001) (noting that repeated petitions in state courts, apparent temporizing, and overzealous pursuit of certain actions gave rise to the inference that the defendants were using the legal process as a weapon).

272. *Id.* at 522.

273. *Id.*

274. *Id.*

followed a logical progression to challenge the rival racetrack's opening through every possible avenue, evidencing a pattern of petitions.

Finally, if the court determines that the multiple petitions in question constitute a pattern, the court should holistically examine the petitions, the parties' circumstances, and any bad faith indicators to determine whether the pattern constitutes a sham. A host of bad faith indicators could overcome minor successes, or a lack of bad faith indicators may require more serious successes to be deemed a sham. Other indicators like actual collateral harm suffered as a result of the antitrust defendant's petitions could also be a strong factor in determining that the actions should be deemed a sham.

B. Patent Law Considerations Under the California Motor *Pattern Analysis*

The unique and complex nature of patent law and proceedings makes analysis under the *California Motor* framework difficult, particularly with respect to the threshold questions described above. This section provides guidance on how to analyze patent applications, IPRs, and reverse payment settlements in order to ensure consistent results under *California Motor*.

Patent applications pose an interesting issue under the *California Motor* pattern analysis. The term "patent applications" can include brand new patent applications as well as continuations, which tie back to previous patent applications.[275] One could make an argument that continuations should be lumped together with the original application and all counted as one petition. But continuations result in a restarting of the patent prosecution process and a full reconsideration of the merits of the application by the government examiners.[276] Thus, each continuation should be treated as a separate petition. This approach could also help to ease the burden on the PTO by encouraging inventors to file higher quality applications early on and discouraging them from filing multiple continuations on the same claims.[277]

Next, IPRs contain two major PTAB decisions that need to be analyzed: (1) the initial institution decision and (2) the final written decision about the patent's validity. The final written decision should

275. *See supra* Section I.A.1 (explaining the difference between new patent applications, continuation applications, and RCEs).

276. *See* Frakes & Wasserman, *supra* note 71, at 625 n.46 (explaining the consequences of filing either a continuation application or an RCE).

277. *See id.* at 616 (noting that PTO's backlog contained over 600,000 applications of which close to 40% were repeat filings).

count as a win or a loss because both parties have had a chance to argue their case, present evidence, and have a tribunal weigh the arguments before coming to a decision, which can be appealed.[278] Further, an invalidity decision under an IPR has the same outcome as an invalidity decision in litigation—the patent is cancelled.[279] On the other hand, this Note proposes that institution decisions should not be counted as a win or a loss for the reasons provided below.

While the institution decision can end the IPR proceeding, the institution decision is not the final word on a patent's validity. The patent can still be challenged in district court litigation on other grounds or even be the subject of an IPR by a totally new party.[280] Moreover, before the PTAB institutes an IPR proceeding, the challenger, not the patent owner, has the burden of proof to establish "a reasonable likelihood that the [challenger] would prevail."[281] Of course, patent owners also do not have the presumption of validity in IPRs that they have in litigation, but the thumb is still on the scale for the patent owners prior to institution.[282] When *Posco* first established the win-loss ratio as a criterion under the *California Motor* analysis, the Ninth Circuit specified as part of its calculation that the wins were decisive because the plaintiff (i.e., the antitrust defendant) had the burden of proof and still won.[283] Because patent owners do not bear the burden of proof before institution in IPRs, institution decisions should not be used in the win-loss ratio.

In re Humira provides an example of why using institution decisions in a calculation is problematic. Although the court in *In re Humira* held that *PRE* was the proper test, the court reasoned that AbbVie would have prevailed under *California Motor* too.[284] The court used AbbVie's record in the IPRs as partial evidence for this proposition.[285] Challengers filed eighteen total IPR petitions on various Humira patents.[286] Of these, all five that made it past institution resulted in losses for AbbVie (the PTAB found three patents invalid and

278. *See supra* Section I.A.2 (describing IPR procedures).

279. On the contrary, if a patent is found valid in a final written decision, then the petitioner is estopped from challenging the patent in court on any grounds that it could have raised in the IPR. Love et al., *supra* note 50, at 102.

280. *Id.*

281. Dubis, *supra* note 87, at 116 (quoting 35 U.S.C. § 314(a)).

282. Cohen, *supra* note 43, at 15.

283. USS-Posco Indus. v. Contra Costa Cnty. Bldg. & Constr. Trades Council, AFL-CIO, 31 F.3d 800, 811 (9th Cir. 1994).

284. *See In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 830 (N.D. Ill. 2020) (reasoning that the claim of sham petitioning would not succeed in other circuits, including the Ninth Circuit, which uses the *California Motor* test).

285. *Id.* at 831.

286. *Id.*

AbbVie terminated the other two patents after institution).[287] The PTAB declined to institute the other thirteen petitions, which the court counted as wins for AbbVie.[288] By the court's calculation, AbbVie won thirteen out of eighteen petitions, a success rate of 72.2%.[289] Since AbbVie did not succeed even once on the merits of its patents during eighteen IPRs and all challenges that proceeded to a decision on the merits resulted in losses for AbbVie, immunizing AbbVie from antitrust liability on the basis of that record seems misguided at best.

Finally, although settlements normally count as wins for the antitrust defendant, this Note proposes that reverse payment settlement agreements should be counted as losses. In *Catch Curve, Inc. v. Venali, Inc.*, the court noted that patent owners usually seek injunctions, damages, license fees, or some combination thereof in patent litigation.[290] Thus, when Catch Curve, as the patent owner, settled its suits and received license fees, these settlements counted as wins in the sham analysis because the patent owner received one of the outcomes that it was seeking through the litigation.[291] Reverse payment settlements, of course, reverse the traditional flow of payments.[292] A patent owner launching patent infringement litigation against a challenger could have sought an injunction or license fees in court, but instead *pays a competitor* not to compete. This patent owner does not end up with a settlement in its favor but is ostensibly worse off than before it initiated the lawsuit. Counting such a settlement as a win is illogical. And if such settlements count as wins, pharmaceutical companies would have even greater incentives to game potential win-loss scenarios by paying off all challengers in settlements.

Counting reverse payment settlements as losses would also follow the *Actavis* precedent. The Supreme Court noted the anticompetitive effects that reverse payment settlements could have in practice.[293] The Court refused to create a per se rule making all reverse payment settlements unlawful, and this approach would similarly not rule out such settlements.[294] Parties could still enter into such settlements, but each reverse payment settlement would increase their antitrust liability risk. This approach would encourage pharmaceutical companies not to enter into (or at least to limit) such agreements to

287. *Id.*
288. *Id.*
289. *Id.*
290. No. CV 05-04820 (AJWx), 2008 WL 11334024, at *8 (C.D. Cal. Nov. 3, 2008).
291. *Id.*
292. *See supra* Section I.A.3 (describing reverse payment settlement agreements).
293. FTC v. Actavis, Inc., 570 U.S. 136, 153–54 (2013).
294. *Id.* at 158–59.

avoid creating a record of losses to be used against them in potential *Noerr-Pennington* cases.

C. Implications and Counterarguments

If AbbVie can brazenly exploit the patent law system with its Humira patent thicket, other pharmaceutical companies and industries may follow suit and create their own patent thickets.[295] A proliferation of patent thickets would result in a reduction in innovation, higher costs to consumers, and a crushing burden on the PTO. Moreover, if companies realize that they have virtual immunity to antitrust laws because the sham exception is nearly impossible to invoke, their anticompetitive behavior will worsen.

Pharmaceutical companies argue that these patent law tactics are needed because biologic drugs cost hundreds of millions of dollars to develop, and they need to recoup these costs.[296] Pharmaceutical companies, however, recoup their research and development costs in a myriad of ways through taxpayer funding. For instance, the U.S. government, through the National Institutes of Health ("NIH"), "play[s] a very major role in the early stages of almost every drug that gets developed and approved by the [FDA]."[297] Government funded research contributed to the development of "all 210 new drugs approved by the U.S. Food and Drug Administration between 2010 and 2016."[298] Yet, the government usually does not demand any ownership rights as a requirement for funding research, which leaves pharmaceutical companies to take the windfall.[299]

Taxpayers also help fund the development of new drugs through multiple tax incentives. The tax code provides tax credits for research and development, which includes credits available to all companies and

295. *See, e.g.*, J. Peter Paredes, *Written Description Requirement in Nanotechnology: Clearing a Patent Thicket?*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 489, 490 (2006) (warning that a growing patent thicket in nanotechnology could delay the commercialization or development of nanotechnology); *see also* Silbersher, *supra* note 51 ("Other . . . pharmaceutical companies are surely watching [Boehringer's settlement with AbbVie]. It is now a no-brainer to follow AbbVie's patent plan . . . for Humira. Namely, if you're launching a biologic drug, cover it with as many patents as possible. . . . Pursue lots of overlapping patents with barely distinguishable inventions.").

296. *See supra* Section I.B (discussing the intricacies of biologic drug development).

297. David E. Mitchell, Opinion, *Taxpayers Fund Research and Drug Companies Make a Fortune*, N.Y. TIMES (Mar. 24, 2021), https://www.nytimes.com/2021/03/24/opinion/coronavirus-vaccine-cost-pfizer-moderna.html?smid=url-share [https://perma.cc/CZ94-SVGN].

298. *Id.*

299. *Id.*

credits specifically for pharmaceutical companies.[300] For any research and development costs that pharmaceutical companies cannot recoup through tax credits, the tax code also allows companies to deduct research and development expenditures as business expenses.[301]

Taxpayers also subsidize the high costs of biologics through Medicare and Medicaid spending on these drugs. For example in 2016, Medicare and Medicaid paid a total of $3.3 billion for Humira alone, which accounted for about 31% of Humira's total U.S. sales in that year.[302] Medicare and Medicaid spending increases the demand for prescription drugs, which in turn encourages pharmaceutical companies to develop new drugs.[303] Thus, Medicare and Medicaid spending helps subsidize pharmaceutical company profits (and indirectly fund new research and development) through its spending on prescription drugs.

Additionally, despite the various research and development support that large pharmaceutical companies receive and their astronomical drug prices, it is small pharmaceutical companies that are mostly responsible for new drug development.[304] Small drug companies developed over 70% of the nearly three thousand drugs in phase III clinical trials.[305] Perhaps more shocking, "[s]ince 2009, about one-third of the new drugs approved by the [FDA] have been developed by pharmaceutical firms with annual revenues of *less than $100 million*."[306] Meanwhile, large pharmaceutical companies like AbbVie only spend a fraction of their revenues from blockbuster drugs like Humira on research and development. Case in point: in 2018, AbbVie spent only $5.1 billion on research and development, but earned $19.9 billion in worldwide net revenues from Humira alone in the same year.[307] Studies have also indicated that "[i]ncreases in pharmaceutical industry competition have been found to *increase* firms' R&D spending."[308] This implies that pharmaceutical companies' dire

300. CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 20 (2021), https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf [https://perma.cc/AH3A-6KMK].

301. *Id.*

302. INITIATIVE FOR MEDICINES, ACCESS AND KNOWLEDGE, OVERPATENTED, OVERPRICED SPECIAL EDITION: HUMIRA 6 (2020), https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf [https://perma.cc/4U5K-68AD].

303. CONG. BUDGET OFF., *supra* note 300, at 2.

304. "Small" is a relative term here. The Congressional Budget Office defined small drug companies as "those with annual revenues of less than $500 million." *Id.*

305. *Id.*

306. *Id.* (emphasis added).

307. Mukherjee, *supra* note 4; AbbVie Inc., *supra* note 5, at 31.

308. CONG. BUDGET OFF., *supra* note 300, at 4 (emphasis added).

warnings about the necessity of patent thickets to fund research may be overblown.

Pharmaceutical companies also argue that FDA approval requirements significantly cut into the effective life of patents, which means that without extending the patent terms, pharmaceutical companies' patent exclusivity may not last long enough to recoup their development costs.[309] The answer to this problem is not, however, allowing the industry to create an end run around the patent system. If pharmaceutical companies can circumvent patent terms, then as rational actors, they will put most of their investments toward innovation in creating new patents and extending the patent terms for their existing pharmaceuticals rather than innovating new drugs. Why spend hundreds of millions of dollars developing a new biologic that may not pass clinical trials when pharmaceutical companies can focus on extending the exclusivity of an already approved and profitable drug? Indeed, AbbVie provides a prime example of this behavior with its Humira patents. AbbVie filed nearly 50% of its Humira patent applications from 2014 onwards—only two years or less before the original Humira patent expired.[310] Allowing patent thickets to proliferate perverts patent law's normal innovation incentives to the public's detriment. Antitrust liability could ensure that pharmaceutical companies continue to innovate and create new drugs.

Finally, allowing the possibility for *Noerr-Pennington* immunity to be pierced in the case of abusive patent tactics will not ensure victory for antitrust plaintiffs against pharmaceutical companies.[311] Successful invocation of the sham exception will allow antitrust plaintiffs the opportunity to develop their cases and move them beyond the motion to dismiss stage.[312] Antitrust plaintiffs, however, still need to be able to prove their case, and this is no mean feat.[313] The sham exception can

309. *See supra* note 64 and accompanying text (explaining how patent terms can be effectively shortened because the patent term starts running at the date of the application and not when the patent is issued or when the drugs are actually approved by the FDA).

310. INITIATIVE FOR MEDICINES, ACCESS AND KNOWLEDGE, *supra* note 302, at 4.

311. *See* Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 61 (1993) ("Proof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim.").

312. *E.g.*, *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 853 (N.D. Ill. 2020) (granting defendants' 12(b)(6) motion to dismiss).

313. *See* Daniel E. Rauch, *Sherman's Missing "Supplement": Prosecutorial Capacity, Agency Incentives, and the False Dawn of Antitrust Federalism*, 68 CLEV. ST. L. REV. 172, 193 (2020) ("Antitrust prosecutions are famously resource-intensive, lasting years and costing substantial amounts of money."); William Kolasky, *Reinvigorating Antitrust Enforcement in the United States: A Proposal*, 22 ANTITRUST 85, 85 (2008) ("It has been more than fifteen years since the Supreme Court last decided an antitrust case in favor of a plaintiff. Over this fifteen-year period, plaintiffs have gone 0-for-16, with not a single plaintiff winning an antitrust case in the Supreme Court since the first George Bush was president.").

make antitrust scrutiny of pharmaceutical patent thickets possible. Moreover, the specter of antitrust liability may be enough to incentivize pharmaceutical companies to change their ways without the intervention of litigation or legislation. Although at the time of writing, Congress has recently unveiled new legislation to combat the drug pricing problem, the passage, contents, and potential impact of such legislation on drug prices remains uncertain.[314] Given that Congress has tried and failed to pass drug pricing legislation under both Republican and Democratic leadership, allowing pharmaceutical companies to face antitrust liability by piercing *Noerr-Pennington* immunity may still be the best hope for lower drug prices.[315]

CONCLUSION

What this technical discussion of the science of biologics, the ins and outs of patent law, and their intersection with antitrust law leaves out is the human cost of outrageous drug pricing. Biologics have amazing therapeutic potential because they often treat chronic, painful autoimmune diseases or cancer that may not be treatable with traditional small-molecule drugs. But consumers are often left to choose between relief from a crippling disease or paying the bills. One piece of testimony during a recent Congressional hearing on AbbVie's pricing practices for Humira underscores the stakes of this battle:

> [Humira] costs more than my car payment. More than my business insurance. More than my food bill each month. But I made the decision to suck it up and pay because the drug worked. But after months of successful pain and symptom management on Humira, . . . AbbVie raised the price [and] [m]y new monthly payment was going to be almost $1,100 a month. I simply could not afford it any longer. . . . It was already too expensive for me at $750 per month. I couldn't afford the 40% price hike.[316]

Pharmaceutical companies' exploitation of patent law to amass impenetrable patent thickets around a single drug like Humira to

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314. Jonathan Weisman & Emily Cochrane, *Democrats Add Drug Cost Curbs to Social Policy Plan, Pushing for Vote*, N.Y. Times, https://www.nytimes.com/2021/11/02/us/politics/prescription-drug-prices-medicare.html?smid=url-share (last updated Nov. 6, 2021) [https://perma.cc/S9F2-HQG3] (describing the contents of the most recent version of the drug pricing bill unveiled in November 2021). Even if this legislation passes, the effect on drug pricing may be modest without other levers like antitrust liability pressuring pharmaceutical companies to reasonably price their products.

315. *See, e.g.*, Paige Winfield Cunningham, *The Health 202: Congress Failed to Pass a Drug Pricing Overhaul. So It Set Another Deadline.*, WASH. POST (Dec. 17, 2019), https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2019/12/17/the-health-202-congress-failed-to-pass-a-drug-pricing-overhaul-so-it-set-another-deadline/5df7c57a88e0fa32a5140777/ [https://perma.cc/L79H-KJQC] (describing how Congress failed to pass major legislation to lower drug prices in 2019 but set another deadline in May 2020 to get the legislation passed).

316. DRUG PRICING INVESTIGATION, *supra* note 8, at 15–16.

artificially extend their monopoly comes at the expense of American consumers. The pharmaceutical industry's shift to biologic drugs, which are more complex and already lend themselves to multiple patents for a single drug, will aid in this strategy. With skyrocketing price tags to develop new biosimilars followed by expensive, lengthy, and uncertain patent infringement lawsuits, pharmaceutical competitors will probably not push cheaper biosimilar alternatives forward. Patent law has proved to be ill-suited to the challenge of hacking through these patent thickets, providing a scalpel when consumers need a machete. Thus, consumers need antitrust law to step into the void. Potential plaintiffs, however, must overcome the *Noerr-Pennington* doctrine in order to wield antitrust law in these circumstances. Use of the narrow sham exception to *Noerr-Pennington* may be the best solution to fight pharmaceutical companies' abuse of the patent system.

For the sham exception to be an effective "machete" to hack through the patent thicket, the sham exception circuit split needs to be resolved. The Ninth Circuit approach to the sham exception reconciled *California Motor* and *PRE* by reasoning that *PRE*'s two-part test only applied in cases involving a single petition and *California Motor*'s looser standard applied to cases with multiple petitions. In contrast, the First Circuit approach to the sham exception argued that the *PRE* two-part test applied in all situations.

This Note proposes adopting a modified version of the Ninth Circuit approach and proposes a general framework for analyzing patent proceedings under the *California Motor* pattern analysis. This solution strikes the balance between protecting parties' First Amendment petitioning right and discouraging abuse of governmental processes for anticompetitive effect, particularly in patent law. If successful, antitrust challenges can lead to a quicker market entry for biosimilar competitors, driving down biologic prices and allowing more people to benefit from these life-altering drugs.

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