Molecule Size Doesn't Matter: The Case for Harmonizing Antitrust Treatment of Pay-for-Delay Agreements

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With notoriously the most-expensive drug prices in the world, the United States has failed to use all of the tools in its shed to combat the unending upwards trend. One such important tool is U.S. antitrust law that targets companies that improperly charge monopoly and supracompetitive prices long past their original patent's expiration. Some companies have found a way to game the regulatory approval system by suing would-be generic competitors and then, under the guise of settlement, paying them to delay their market entry — allowing a brand drug manufacturer to maintain their monopoly prices and continue raking in large profits. The Actavis *Supreme Court found these agreements involving reverse payments — also known as pay-for-delay — can violate antitrust laws even in light of the existing patents. This Note argues that in an ongoing case,* In re Humira *that examines reverse payments between biologic drug companies, the district court was right to engage in an* Actavis *analysis but did so improperly.* In re Humira *provides a prime opportunity to strengthen and clarify U.S. jurisprudence on reverse payments and market allocations to reduce ambiguity in an evolving pharmaceutical sphere: biologics and biosimilars. This Note further argues that to harmonize the antitrust treatment of pharmaceuticals — small molecule and biologic — both clear judicial standards and legislation are needed.*

This Note proceeds in four parts. Part II discusses various forms of antitrust abuses that arise in the pharmaceutical sphere and that often accompany reverse payment agreements. It follows with the relevant legal

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and regulatory backgrounds of small and large molecule drugs. Part III then considers the consequences of lax antitrust scrutiny on pharmaceuticals and finishes with an in-depth examination of the In re Humira *litigation. Lastly, Part IV proposes a two-fold solution, legal and legislative, to the problems posed by* Actavis*'s lack of legal clarity. Ultimately, the purpose of this Note is to demonstrate that the way a drug is manufactured, approved, or allowed to compete does not alter the application of antitrust law seeking to rid the market of collusive agreements between rivals.*

I. INTRODUCTION

The United States' drug prices are the highest in the world — a problem on the minds of Republicans and Democrats alike. President Trump has decried U.S. drug companies as "getting away with murder."[1] Numerous Congressional committees have grilled drug company CEOs about their high drug prices and the disproportionate impact of price hikes on the poor.[2] Polling data has also confirmed that the country's soaring pharmaceutical prices are a top concern among all voters.[3] Yet U.S. drug prices stubbornly remain the highest in the entire world, with brand name drug prices averaging 3.2 to 4.1 times those for the same drugs in other countries.[4] The consequences are evident: high drug prices increase government, employer, and household expenditures; reduce employee wages; and force patients to skip doses, split pills, or decide to end much-needed treatment entirely.[5] While politicians argue

1. Carolyn Y. Johnson, *Trump on drug prices: Pharma companies are "getting away with murder"*, WASH. POST (Jan. 11, 2017, 12:26 PM), https//:www.washingtonpost.com/news/wonk/wp/2017/01/11/trump-on-drug-prices-pharma-companies-are-getting-away-with-murder/ [https//:perma.cc/6MNK-8WYV].

2. Leigh Ann Caldwell, *In Senate testimony, pharma executive admits drug prices hit poor the hardest*, NBC NEWS (Feb. 26, 2019, 4:14 PM), https//:www.nbcnews.com/politics/congress/senate-testimony-pharma-executive-admits-drug-prices-hit-poor-hardest-n976346 [https//:perma.cc/BM8Q-E4U2].

3. Ashley Kirzinger et al., *KFF Health Tracking Poll — September 2019: Health Care Policy in Congress And On The Campaign Trail*, KAISER FAM. FOUND.: POLLING fig. 1 (Sept. 12, 2019), https//:www.kff.org/health-reform/poll-finding/kff-health-tracking-poll-september-2019/ [https//:perma.cc/UNE9-DXZU] (finding seventy percent of respondents found "[l]owering prescription drug prices" a "top priority").

4. *Report shows U.S. brand-name drug prices "highest in the world"*, EUR. PHARM. REV. (May 7, 2019), https//:www.europeanpharmaceuticalreview.com/news/87383/us-drug-prices-highest-world/ [https//:perma.cc/YTT5-BYV6].

5. Andis Robeznieks, *AMA to Congress: Patients pay painful price for high drug costs*, AM. MED. ASS'N (May 9, 2019), https//:www.ama-assn.org/delivering-care/public-health/ama-congress-patients-pay-painful-price-high-drug-costs [https//:perma.cc/Q66A-BSCR] ("I currently have a patient unable to afford the Enbrel or Humira that would alleviate his . . . painful psoriatic arthritis — the average wholesale prices for a year of these drugs, both out

over what and who is most to blame, it is clear many factors are responsible for the current predicament.[6]

This Note focuses on one factor contributing to high prices: anticompetitive collusive actions by pharmaceutical companies that improperly extend drug monopolies, allowing them to extract monopolistic or supracompetitive prices that deny U.S. patients the lower prices that come with competition.[7] More specifically, this Note will discuss reverse payments, also known as "pay-for-delay" agreements, that occur when a branded drug manufacturer pays a rival drug company to delay its launch of a drug that will compete with the brand.[8] These reverse payment agreements are executed in the context of settling patent infringement litigation in which the patent-holding brand company pays its rivals to agree not to compete for a period of time when the rival otherwise likely would have entered the market.[9] "Payment" takes a variety of forms[10]

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for more than 15 years — has quadrupled to around $80,000 per year, and his PPO copay is 40% until he reaches his deductible. . . . So, he stopped his treatment.").

6. For example, Congress has been allegedly wary of enacting pricing control in part due to the "quite powerful" PHRMA, a trade association that lobbies for the pharmaceutical companies. Sandy Hausman, *Why Are U.S. Prescription Drug Prices So High?: Podcast Transcript*, COMMONWEALTH FUND (Oct. 17, 2017), https//:www.commonwealthfund.org/sites/default/files/documents/___media_files_multimedia_podcasts_cmwf_podcast_transcript_rxdrugs.pdf [https//:perma.cc/7KBW-CTTS]. Former Congressman Henry Waxman notes that PHRMA increased their lobbying and advertising budget, reinforcing the narrative that pharmaceutical companies are good guys searching for cures. *Id.* Yet, those companies fail to advertise that much of the research leading to new medications is conducted through the National Institutes of Health, a federal agency funded by tax dollars. *Id.* Meanwhile, pharmaceutical companies can legally charge monopoly prices once they obtain a patent. The problematic behavior arises when companies game the system to ensure the patent lasts longer than the original length of the congressionally-sanctioned legal monopoly. Companies, in the meantime, are spending more than ever on lobbying efforts and sales and marketing of their drugs to consumers, doctors, and hospitals — costs that are then transferred onto consumers. *Id.*

7. *See, e.g.*, Murat C. Mungan, *Reverse Payments, Perverse Incentives*, 27 HARV. J.L. & TECH. 1, 4–6 (2013) (using game-theoretical model to prove that restricting reverse payments increases firms' incentives to invest and engage in research and development, and noting that reverse payments "allow [a branded drug manufacturer] to preserve its monopoly, which shrinks sales volume and increases deadweight loss[ ]").

8. *Id.* at 2–3. The author uses "the brand" or "the branded drug" to refer to the first "pioneer" drug — whether biologic or small molecule — on the market that is patent-protected.

9. *See id.* (discussing the context under which reverse payments arise).

10. *See* Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHICAGO-KENT J. OF INTELL. PROP. 249, 259 (2019). Profit-sharing between rivals can take many forms, including no-AG clauses and acceleration clauses. *Id.; see also* FED. TRADE CMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2016, https//:www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/

but is typically a share of the extra monopoly profits that the brand expects to secure from the delayed competition — an amount that may exceed the rival's expected profits from competing on the market.[11] These "pay-for-delay" agreements are known as "reverse payments" because of the inverted direction of compensation where a *plaintiff*, the brand-name patent holder who commenced the infringement suit, pays an amount to the *defendant*, the rival accused of allegedly infringing the brand's patents, to settle the suit it commenced.[12]

It was not until 2013 that the U.S. Supreme Court addressed the legality and antitrust consequences of these agreements in *FTC v. Actavis*.[13] The Court held that these pay-for-delay agreements could have anticompetitive effects and were not shielded by patent law from antitrust scrutiny or justified by public policy favoring settlements.[14] Furthermore, it held the judicial standard of review for reverse payment agreements under federal antitrust law was the rule of reason.[15] It rejected the Federal Trade Commission's (FTC) argument that these settlements should be presumptively illegal or per se illegal because the Court could not conclude that these agreements would almost always be

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mma_report_fy2016.pdf [https//:perma.cc/Q63P-J77M] (last visited Dec. 2, 2020) (noting the increased use of no-AG clauses in pharmaceutical settlements); Laura Karas et al., *Pharmaceutical "Pay-for-Delay" Reexamined: A Dwindling Practice or a Persistent Problem?*, 71 HASTINGS L.J. 959, 965 (2020) (noting the increased use of acceleration clauses in settlements that can "discourage[ ] other generic companies to enter [the market], leading one academic to describe them as having a 'poison pill' effect[ ]").

11. Feldman & Misra, *supra* note 10, at 249.

12. *Id.*

13. *See* FTC v. Actavis, Inc., 570 U.S. 136 (2013). Solvay sued its rival company Actavis for patent infringement upon Actavis's application for its generic version of Solvay's Androgel. After years of litigation, the FDA approved Actavis's generic Androgel drug, but rather than begin selling their market-ready generic, Actavis agreed with Solvay to delay the entry of its drug. *Id.* For more information on *Actavis*, see *infra* notes 102 to 111 and accompanying text.

14. 570 U.S. at 158 ("Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement."); *id.* at 159 (rejecting the scope of the patent defense that argued that patent law protected agreements to pay rivals not to compete as such an agreement would be within the "scope" of the patent's grant of power).

15. *Id.* at 159–60 (subjecting reverse payment agreements to a "rule-of-reason" analysis that requires a finding of market power and a balancing test of the procompetitive rationales with the anticompetitive effects).

anticompetitive, noting that some might be justified for procompetitive reasons.[16]

Since *Actavis*, the FTC has found the number of patent settlement agreements that on their face show pay-for-delay is decreasing, i.e., explicit cash settlement payments, but that the number of settlements with restrictions on generic entry that include other alleged forms of compensation have more than doubled from 2015 to 2016.[17] Moreover, the FTC reports do not include every type of pharmaceutical agreement, and suggest that the form of pay-for-delay has become more opaque and that any celebration of the demise of the pay-for-delay problem is premature.[18] The FTC only recently began requiring biologic companies to report their patent

16. *Id.* at 159 (holding that settlements in which a reverse payment is "large and unjustified" can "bring with it the risk of significant anticompetitive effects").

17. FED. TRADE CMM'N, *supra* note 10 (noting that in FY 2016, sixteen final settlements with restrictions on generic entry and compensation involving first filers were reported, compared with seven in FY 2015); Brad Albert et al., *MMA Reports: No tricks or treats — just facts*, FED. TRADE CMM'N: COMPETITION MATTERS BLOG (Oct. 27, 2020, 5:15 PM), https//:www.ftc.gov/news-events/blogs/competition-matters/2020/10/mma-reports-no-tricks-or-treats-just-facts [https//:perma.cc/NE8T-BM8Q] ("Over time, settlements included other ways for a brand company to provide a generic company significant value that did not involve cash payments. Most notably, some potentially anticompetitive payments took the form of exclusive licenses, exclusive supply deals, and explicit "no-AG" commitments[.]").

18. *See generally* Brad Albert et al., *supra* note 17 ("As early as FY 2008, MMA reports began to identify certain terms that did not explicitly compensate the generic company, but might operate as compensation. . . . Beginning in FY 2013, MMA reports started systematically tracking this and similar terms, categorizing them as 'possible compensation.' . . . [T]he 'possible compensation' category arose precisely because of the increasing complexity of some pharmaceutical settlement agreements and need for facts beyond the face of the agreements to assess their true nature and likely effects."); Feldman & Misra, *supra* note 10 (laying out the argument that pay-for-delay agreements are not actually declining); Karas et al., *supra* note 10, at 961 (arguing that pay-for-delay settlements have evolved to include other categories of value transfer less likely to attract antitrust scrutiny). *Compare* Zachary Brennan, *FTC Finds Dwindling Number of Anticompetitive Reverse Payment Deals*, REGUL. FOCUS (May 23, 2019), https//:www.raps.org/news-and-articles/news-articles/2019/5/ftc-finds-dwindling-number-of-anticompetitive-reve [https//:perma.cc/F6ZJ-MCGJ] ("The Association for Accessible Medicines [said] in a statement: 'Current 'pay-for-delay' legislation, however, would unfortunately overturn the *Actavis* decision and unwind the many procompetitive benefits that lower prescription drug costs for patients. We urge policymakers to revisit the need for legislation given this new report from the FTC.'"), *with* Brad Albert et al., *supra* note 17 ("[S]ince a California pharmaceutical patent settlement law took effect at the beginning of [2020], the most common patent settlements — those in which the generic agrees not to sell for some period but then gets a non-exclusive license to enter prior to patent expiration without compensation — have not disappeared. To the contrary, the MMA filings from the first nine months of 2020 indicate that such settlements appear to have increased slightly since the law took effect as compared to the same period in 2019.").

settlement agreements involving biologic drugs, and no FTC reports have yet been issued.[19]

Efforts to curb collusive pay-for-delay agreements are complicated by the different pharmaceutical manufacturing processes that enhance opportunities to game the system and by divergent regulatory and reporting regimes that can create undue confusion when interpreting and applying related case law. In large part, these differences are due to two different forms of pharmaceuticals — small and large molecule drugs — each with their own pathway to regulatory approval.[20]

Small molecule drugs are synthetic and have simpler, well-defined manufacturing processes.[21] Many of the drugs on the market, such as Aspirin, are small molecule drugs.[22] Large molecule drugs, also known as biologics, are generally produced using larger, complex molecules in living cells and are the fastest growing part of the drug market, often launched at eye-popping prices.[23] Not only do biologics offer some revolutionary advances in treating and curing previously incurable diseases, including some cancers,

19. Kathy L. Osborn, *Biologic and Biosimilar Settlement Agreements Now Must be Disclosed to DOJ and FTC*, FAEGRE DRINKER (Nov. 5, 2018), https//:www.faegredrinker.com/en/insights/publications/2018/11/biologic-and-biosimilar-settlement-agreements-now-must-be-disclosed-to-doj-and-ftc [https//:perma.cc/3EUJ-WAH5]; Brad Albert et al., *supra* note 17 ("Since 2018, the [Medicare Prescription Drug, Improvement, and Modernization Act of 2003] also requires pharmaceutical companies to file certain agreements involving biologics and biosimilars.").

20. *See* Jonathan J. Darrow, *Biosimilar Approvals And The BPCIA: Too Soon To Give Up*, HEALTH AFFS.: HEALTH AFFS. BLOG (July 29, 2019), https//:www.healthaffairs.org/do/10.1377/hblog20190718.722161/full/ [https//:perma.cc/8N3N-FZH4] ("[A]lthough a handful of follow-on biologics were approved prior to 2010 under the Hatch-Waxman Act's 505(b)(2) New Drug Application (NDA) pathway, the new BPCIA pathway was distinct from it. The 505(b)(2) pathway, for example, was primarily used for small-molecule drugs and permitted differences in characteristics such as strength, dosage form, or route of administration, whereas these differences were not permitted under the BPCIA's biosimilar framework, which applied only to biologics. Biosimilar approvals were also judged under a different statutory standard than 505(b)(2) approvals . . . [which] continued to exist after 2010 alongside the new BPCIA pathway. . . .").

21. *Small Molecule Versus Biological Drugs*, GENERICS & BIOSIMILARS INITIATIVE: BIOSIMILARS RSCH. (June 29, 2012), http//:www.gabionline.net/Biosimilars/Research/Small-molecule-versus-biological-drugs [https//:perma.cc/YCJ9-C6K9].

22. *Id.*

23. *Id.;* STEPHEN M. HAHN & JOSEPH J. SIMONS, JOINT STATEMENT OF THE FOOD & DRUG ADMINISTRATION AND THE FEDERAL TRADE COMMISSION REGARDING A COLLABORATION TO ADVANCE COMPETITION IN THE BIOLOGIC MARKETPLACE 1 (2020), https//:www.fda.gov/media/134864/download [https//:perma.cc/Y2JK-5PUE].

but also the biologics market is expected to increase from $239.2 billion in 2020 to $464.7 billion worldwide by 2023.[24]

Unlike small molecule drugs that can be replicated with relatively greater ease and confidence, large molecule biologics involve between dozens and hundreds of operating procedure controls to create the specific conditions that ensure an unexpected factor does not alter the resulting product.[25] Not only must a manufacturer know what components to use, it must also know the precise sequence to assemble those pieces.[26] This also means that any attempts to make a "copycat" or "generic" version of a biologic drug — i.e., biosimilars — are more expensive. On average, some estimate that the cost of developing a generic is roughly $2 million, while developing a biosimilar may require $200 million or more.[27]

Though biosimilars compete with biologics as generics compete with brands, biosimilars are subject to different regulations and state laws governing when and how they can be substituted or interchanged with the branded drug at the doctor and pharmacy level.[28] With small molecule drugs, the FDA determines whether the generic is a reliable copy or substitute for a brand drug (or an AB-rated generic); under many state laws, this FDA determination allows and often mandates a pharmacy to substitute a generic for

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24. *Global Biologics Market Report (2020 to 2030) — COVID-19 Impact and Recovery — ResearchAndMarkets.com*, BUS. WIRE (May 22, 2020, 11:45 AM), https//:www.businesswire.com/news/home/20200522005337/en/Global-Biologics-Market-Report-2020-to-2030---COVID-19-Impact-and-Recovery---ResearchAndMarkets.com [https//:perma.cc/WUA9-PZKR]; *How Are Biologic Drugs Different from "Normal" Drugs?*, MOTLEY FOOL (Sept. 10, 2018, 12:39 PM), https//:www.fool.com/knowledge-center/how-are-biologic-drugs-different-from-normal-drugs.aspx [https//:perma.cc/AW7V-GYNC].

25. MOTLEY FOOL, *supra* note 24; HAHN & SIMONS, *supra* note 23, at 8.

26. *Id.*

27. Michael Carrier & Carl Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 9 (2018).

28. Martha M. Rumore & F. Randy Vogenberg, *Biosimilars: Still Not Quite Ready for Prime Time*, 41 PHARMACY & THERAPEUTICS 366, 368–75 (2016), https//:www.ncbi.nlm.nih.gov/pmc/articles/PMC4894513/ [https//:perma.cc/F2D2-LEVT] ("Unlike generic drugs, *biosimilars cannot be assumed to be interchangeable* with the reference product, nor can two different biosimilars of the same reference product be considered equivalent. . . . Switching between reference biologic drug and biosimilar is currently regarded as a change in clinical management unless the two are deemed 'interchangeable.'" (emphasis added)); *see also Biosimilar and Interchangeable Products*, U.S. FOOD & DRUG ADMIN., https//:www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products [https//:perma.cc/64M6-QXJN] ("[A]n interchangeable product, in addition to being biosimilar, meets additional requirements based on further evaluation and testing of the product[ ] . . . to show that [it] is expected to produce the same clinical result as the reference product in any given patient. . . . As a result, a product approved as an interchangeable product means that FDA has concluded it may be substituted for the reference product *without consulting the prescriber*." (emphasis added)).

a prescribed brand drug.[29] As a result, generics have an almost automatic path to competition in many situations.

In contrast, the FDA only recently developed the regulations allowing it to determine that a biosimilar is "interchangeable" with a biologic.[30] As of September 2020, the FDA has yet to designate a single biosimilar or biologic drug in the U.S as "interchangeable."[31] Indeed, the FDA has been relatively slow to even approve biologic and biosimilar drugs for sale in the U.S., making biosimilar introduction relatively slow in the U.S compared to Europe.[32] While there are seventy-one biosimilar drugs approved in Europe as of January 2020, only twenty-six biosimilars had been approved in the U.S.[33]

But even when the FDA actually approves a biosimilar as an "interchangeable" drug, most states do not have laws that permit or mandate the substitution of the "interchangeable" drug with the biologic.[34] The pharmaceutical industry successfully lobbied for laws requiring naming conventions for biosimilar drugs that make it difficult for pharmacists to identify similar biologic drugs.[35]

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29. Carrier & Minniti, *supra* note 27, at 13–14 ("[S]tate drug product selection ('DPS') laws . . . in effect in all fifty states today, allow — *and in many cases require* — pharmacists to substitute generic versions for brand prescriptions. . . . The laws typically allow pharmacists to substitute a generic version if it is therapeutically equivalent to the brand, which means that it is bioequivalent and has the same active ingredient, form, dosage, strength, and safety and efficacy profile." (emphasis added)).

30. Daniel Tomaszewski, *Biosimilar Naming Conventions: Pharmacist Perceptions and Impact on Confidence in Dispensing Biologics*, 22 J. MANAGED CARE & SPECIALTY PHARMACY 919, 920 (2016) (noting that as of August 2016 the FDA had yet to provide guidance for the requirements of approval for interchangeable biosimilars and biologics, including inconsistent naming conventions, causing low pharmacist confidence in prescribing biosimilars); Amanda Murphy et al., *New FDA Guidance on Biosimilar Interchangeability*, LIFE SCI. LEADER (July 3, 2019), https//:www.lifescienceleader.com/doc/new-fda-guidance-on-biosimilar-interchangeability-0001 [https//:perma.cc/6MEK-6ZQM] (discussing the FDA's May 2019 "final guidance" entitled "Considerations in Demonstrating Interchangeability with a Reference Product"); *see also infra* Parts II.B–C.

31. *Purple Book Monthly Historical Data Changes Report — September 2020*, U.S. FOOD & DRUG ADMIN., https//:purplebooksearch.fda.gov/files/2020/purplebook-search-september-data-download.xlsx [https//:perma.cc/FVT7-4PPH] (last visited Oct. 11, 2020).

32. Henry Miller, *The Feds Act to Boost Competition in the Biosimilars Market*, 117 MO. MED., 196, 197 (2020), https//:www.ncbi.nlm.nih.gov/pmc/articles/PMC7302035/ [https//:perma.cc/TG4A-Y7YS].

33. *See* Rumore & Vogenberg, *supra* note 28, at 368–75; Miller, *supra* note 32.

34. *See* Carrier & Minniti, *supra* note 27, at 29-30 ("A biologic manufacturer also should experience less urgency to switch the market to a reformulated version because of the absence of state substitution laws, which could have shifted the emphasis from biosimilar marketing to price-conscious pharmacists." (citation omitted)).

35. *See* Ike Brannon, *The Biotech Lobby Fights to Undermine Less-Costly Biosimilar Drugs*, FORBES (Sept. 4, 2014, 9:25 AM), https//:www.forbes.com/sites/theapothecary/2014/09/04/the-biotech-lobby-fights-to-undermine-less-costly-biosimilar-drugs [https//:perma.cc/

States, for their part, have generally not updated their laws to provide more substitution of biosimilars or those drugs with interchangeability designations.

However, with the end of the "golden age" for small-molecule brand drugs in sight and $200 billion in brand sales subject to generic competition by 2025, companies increasingly see biologics and biosimilars as the future of the pharmaceutical market.[36] As explained *infra*, biologic drugs' large price tag derives, in part, from a lack of meaningful competition in the U.S. and few pricing constraints.[37] Some $67 billion of the biologic market is vulnerable to biosimilar competition as major patents are set to expire in 2020;[38] the use of patents and pay-for-delay agreements by biologics companies remains a potent threat to any real competition.

For instance, Humira has been the top-selling rheumatoid arthritis and immunology drug in the U.S. for more than six years, generating over $20 billion in sales for 2018 alone.[39] Popularity and high sales' volume alone do not explain the enormous

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F4QY-ZL4Q] ("[The producers of biologics] have strived mightily to limit the ability of biosimilars to enter the U.S. market and compete with biologics. . . . [A] few of the major pharmaceutical companies have embarked upon a campaign to convince the FDA to issue different International Nonproprietary Names (or INNs) for biosimilars and its functionally identical biologic twin. . . . Requiring functionally equivalent drugs to have different names introduces an entirely new level of complexity[.] . . . The end result would invariably be that doctors would be more prone to prescribe the original biologics and shy away from (or forget about) their functionally equivalent biosimilars[.]"); Tomaszewski, *supra* note 30, at 919 (finding from a study of pharmacists that 62.9% of participants reported "high levels of confidence" to dispense biosimilars instead of the reference biologic when the two shared the same nonproprietary name, but that 64.9% felt an "increased burden" if additional reporting was required to determine that two drugs with different nonproprietary names were indeed substitutable); Ned Pagliarulo, *FDA walks back plan to alter generic names of already approved biologics*, BIOPHARMA DIVE (Mar. 7, 2019), https//:www.biopharmadive.com/news/fda-walks-back-plan-to-alter-generic-names-of-already-approved-biologics/549991/ [https//:perma.cc/5X5W-F5L8] (describing the FDA's naming convention of adding a suffix to all biologics nonproprietary name as "a significant, artificial barrier to biosimilars").

36. Carrier & Minniti, *supra* note 27, at 8–9 ("[D]rug companies developing biologics[ ] plan[ ] to receive as much as 50% of their revenues from [biologics] in the near future. Such a development will be profitable, with an average daily cost of $45 for a biologic vastly exceeding that of a $2 daily cost for a small-molecule drug.").

37. *See infra* Part II.C (discussing the biologics market); Part III.A (discussing the harms stemming from lack of competition).

38. *US$67 billion worth of biosimilar patents expiring before 2020*, GENERICS AND BIOSIMILARS INITIATIVE (Jan. 20, 2014), http//:www.gabionline.net/Biosimilars/General/US-67-billion-worth-of-biosimilar-patents-expiring-before-2020 [https//:perma.cc/ZSH6-TYML]; MOTLEY FOOL, *supra* note 24; *see also* BUSINESS WIRE, *supra* note 24 (noting that the global biologics market declined from $269.2 billion in 2019 to $239.2 billion in 2020, blaming mainly the worldwide drug shortages resulting from supply and demand failures during the COVID-19 outbreak).

39. Complaint ¶ 2, *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811 (N.D. Ill. 2020) (No. 1:19-cv-01873) [hereinafter "*Humira* Complaint"].

revenues, which can be primarily attributed to its high price: in 2020, $72,000 per patient annually.[40] Yet, in 2018, AbbVie — Humira's manufacturer — cut Humira's price by 80% in Europe once biosimilar versions became available.[41] Meanwhile, Humira has entered a number of settlement agreements with biosimilar competitors, two of whom had already received FDA-approval in 2016 and 2017.[42] None of the biosimilar companies will enter the U.S. market until 2023, leaving U.S. consumers to pay up to 500% more than their European counterparts for the same drug.[43] In contrast, the same biosimilar companies received entry dates into European markets more than five years before entry in the U.S.[44] In total, eight companies with Humira biosimilars have settled with AbbVie, extending Humira's U.S. monopoly, and its supracompetitive prices in the U.S., seven years past its main ingredient's patent expiry date.[45]

A class action, *In re Humira (Adalimumab) Antitrust Litigation*,[46] alleges that AbbVie's multiple agreements are actually market allocating agreements and settlements qualifying as reverse payments. As of this writing, the *In re Humira* litigation is undergoing appeal after a district court ruled in favor of AbbVie, noting that while the behaviors seem unsavory, they were legal "exploited

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40. Christopher Rowland, *Why price of Humira keeps rising despite FDA approval of generic competition*, Wash. Post (Jan. 8, 2020, 7:00 AM), https//:www.washingtonpost.com/business/economy/why-humiras-price-keeps-rising-despite-fda-approval-of-generic-competition/2020/01/07/549ed0ce-2e3a-11ea-bcb3-ac6482c4a92f_story.html [https//:perma.cc/HX4P-YSKE] (noting that "Humira was among a handful of drugs with the highest [price] jumps" of more than seven percent in 2020, following total "price hikes of [nineteen] percent during 2017 and 2018").

41. Bob Herman, *AbbVie cuts Humira's price by 80% (in Europe)*, AXIOS (Nov. 1, 2018), https//:www.axios.com/abbvie-cuts-humira-price-europe-biosimilars-cc2d3d61-5782-4042-8c24-b322ea8285b4.html [https//:perma.cc/F9QB-2NRF].

42. *Humira* Complaint, *supra* note 39, ¶¶ 58–62 (noting that three adalimumab biosimilars have FDA approval and a fourth is expected to receive approval in 2019); Andrew Dunn, *With Boehringer settlement, AbbVie completes Humira sweep*, BIOPHARMA DIVE (May 14, 2019), https//:www.biopharmadive.com/news/abbvie-boehringer-ingelheim-settle-humira-patent-biosimilar/554729/ [https//:perma.cc/6Z4Y-6XVW]. As of the writing of this Note, five Humira biosimilars have been approved by the FDA. Rowland, *supra* note 40.

43. With EU prices cut 80%, that means U.S. consumers are now paying 500% more than their European peers. *See* Herman, *supra* note 41. As European patients benefit from cheaper prices, U.S. consumers continue to face consistent annual price hikes. *See* Rowland, *supra* note 40 and accompanying text.

44. *Humira* Complaint, *supra* note 39, ¶¶ 85–92.

45. Dunn, *supra* note 42; Monica Chin Kitts, *Biologic Patent Transparency Act Addresses High Biologic Prices*, ROTHWELL FIGG'S BIOSIMILAR L. BULL. (May 2, 2019), https//:www.biosimilarsip.com/2019/05/02/biologic-patent-transparency-act-addresses-high-biologic-prices/ [https//:perma.cc/KKJ2-QDS8].

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

advantages" derived from the current regulatory system.[47] The court went further astray, finding that the agreements were not anticompetitive, and in contradiction with *Actavis*'s rejection of the scope of the patent doctrine, did so by relying upon the alleged strength of AbbVie's Humira patents.[48] But neither the parties nor the Court in *In re Humira* questioned the basic application of *Actavis* to the agreements in this case. Though the *In re Humira* district court dismissed the case in favor of defendants,[49] this Note argues that the *In re Humira* district court was correct to engage in an *Actavis* analysis but did so incorrectly.

A constrictive reading of *Actavis* to not include biologics, despite similar economic incentives to game the system and collusively divide the markets, would undoubtedly result in the proliferation of collusive biologic settlement agreements that will increase the already staggering biologic prices. There is clear congressional intent that supports treating biologic and small molecule collusive agreements under the same standards.[50] Further, using the ongoing *In re Humira* litigation as a framing device, an opportunity for courts to explicitly determine whether and how to apply the *Actavis* framework to biologic drug settlements, this Note will demonstrate how the reasoning and analysis of *Actavis* applies to qualifying settlements in the biologic sphere and is consistent with precedent, congressional intent, and public policy.

While differences between biologics and small molecule pharmaceutical production warrant different FDA manufacturing

47. *Id.* at 819 ("The legal and regulatory backdrop for patented biologic drugs, together with a well-resourced litigation strategy, gave AbbVie the ability to maintain control over Humira. Plaintiffs say that AbbVie's plan to extend its power over Humira amounts to a scheme to violate federal and state antitrust laws. But what plaintiffs describe is not an antitrust violation. AbbVie has exploited advantages conferred on it through lawful practices and to the extent this has kept prices high for Humira, existing antitrust doctrine does not prohibit it.").

48. *Compare id.* at 844 ("The first problem with the litigation theory is that it only takes one valid, infringed patent to render all the rest — whether invalid, infringed, or not — irrelevant for purposes of cause-in-fact analysis."), *with* FTC v. Actavis, 570 U.S. 136, 151 (2013) ("[The Supreme Court's precedent] seek[s] to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition. Thus, contrary to the dissent's suggestion, there is nothing novel about our approach. What does appear novel are the dissent's suggestions that a patent holder may simply 'pa[y] a competitor to respect its patent' and quit its patent invalidity or noninfringement claim without any antitrust scrutiny whatever, and that 'such settlements . . . are a well-known feature of intellectual property litigation[.]'" (citations omitted) (final bracket in original)).

49. *Id.* at 847.

50. *See infra* Parts II.B–C (discussing the BPCIA and the Hatch-Waxman Act); *infra* Part IV.A.2 (discussing the relevant congressional intent).

procedures,[51] recent and ongoing legislative proposals addressing pay-for-delay agreements apply the same legal standards to adjudication of agreements for biologic and small molecule drug manufacturers.[52] Some commentators, however, have advocated a narrow interpretation of *Actavis* to apply only to small molecule drugs[53] because the Court only discusses the relevant regulatory framework for small molecule drugs in that case.[54] They argue that the *Actavis* result was founded and based on the language and intent of the Hatch-Waxman Act.[55] Just as the courts then spent years litigating whether *Actavis* only implicated cash-only "payments,"[56] savvy pharmaceutical attorneys are likely to argue that *Actavis* should apply only to drugs covered by the Hatch-Waxman Act.

Part II will first discuss various forms of antitrust abuses that arise in the pharmaceutical space and are often utilized as part of or together with reverse payment agreements. It goes on to explain the legal and regulatory backgrounds of small and large molecule drugs, focusing on how the biologic regulatory regime differs. Part III then discusses the consequences of lax antitrust scrutiny on pharmaceuticals, and finishes with the allegations, arguments, and findings currently on appeal in *In re Humira*. Lastly, Part IV proposes a two-fold solution to the problems posed by *Actavis*'s lack of legal clarity. First, there must be regulation or precedent that clearly indicates that for antitrust purposes, biologic settlement agreements should be subject to the same antitrust scrutiny as

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51. *See infra* Parts II.B–C (discussing the differences between biologic and small molecule drugs, and how those have facilitated different regulatory regimes).

52. *See infra* Part III.B (discussing new legislative bills).

53. *See* Marc G. Schildkraut, Actavis, *Authorized Generics, and the Future of Antitrust Law*, *in* HEALTHCARE ANTITRUST, SETTLEMENTS, AND THE FEDERAL TRADE COMMISSION 25, 48 (2018) ("An even more narrow reading of *Actavis* is that it only applies to Hatch-Waxman [small molecule] settlements: Congress created the potential for anticompetitive settlements under the Hatch-Waxman and some solution had to be found. . . .").

54. *See infra* Part II.A (noting that because reverse payments originally arose out of the Hatch-Waxman framework that covers small molecule generic approval, some presume *Actavis* must apply only to Hatch-Waxman settlements).

55. *See* Schildkraut, *supra* note 53; *infra* Parts II.A–B (discussing the Hatch-Waxman Act that arose to spur generic competition among small molecule pharmaceuticals).

56. Robin A. Van der Meulen & Rudi Julius, *Cash or No Cash — That is No Longer the Question!*, ANTITRUST HEALTH CARE CHRON. 12, 14–21 (2016), https//:info.labaton.com/hubfs/Chronicle-Article.pdf [https//:perma.cc/MC5Y-K4F9] (discussing the case law that eventually led to the explicit inclusion of non-cash payments under the *Actavis* framework); Michael Carrier, *The Rule of Reason in a Post-*Actavis *World*, 2018 COLUM. BUS. L. REV. 25, 41 ("The primary issue that has been litigated since *Actavis* is whether payment is limited to cash or extends to noncash conveyances.").

those concerning small molecule drugs. *In re Humira* provides the perfect opportunity; and as the Part IV analysis will show, applying *Actavis* to biologics is in the spirit of the law, aligns with public policy, and follows precedent — despite the *In re Humira* district court ruling in favor of the defendants. Second, this Note suggests a need for a corresponding legislative solution. This Note's purpose is to demonstrate that the way a drug is manufactured, approved, or allowed to compete does not alter the application of antitrust law seeking to rid the market of collusive agreements between rivals.

II. HOW BIG PHARMA GOES BAD: LEGAL AND REGULATORY BACKGROUNDS

The biologic drug market presents ample opportunity and incentive to collude in pay-for-delay agreements, particularly given the secrecy of the pharmaceutical companies' agreements, the amorphous rule of reason standard governing their adjudication under antitrust law, and the industry's use of patent protections.[57] While biologic competitors may profit from their collusive market allocation schemes, consumers and health insurance companies suffer the consequence of paying higher drug prices.[58] In a 2010 study, the FTC estimated that reverse payment agreements cost American consumers $35 billion between 2010 and 2020.[59] This number likely understates the true consumer damage caused by these agreements.[60] While there is no recent study on the potential

57. *See* Feldman & Misra, *supra* note 10, at 273 ("The challenges to biosimilars and the disincentives in the Biologics Act are real. . . . [T]he dollars at stake in the biologics market create incentives to develop strategic behavior to limit or delay competition. . . . [E]xamples . . . suggest that pay-for-delay is, indeed, making its way into the biologics market."). Though the *In re Humira* allegations are deeply intertwined with potential patent law abuses other than pay-for-delay agreements, they are outside the scope of this Note.

58. *Id.* at 256 (noting that reverse payments "result in lower consumer welfare compared to lawsuits that are litigated to completion" and that "privately optimal agreements" impose "large negative effects" on average consumers).

59. FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010), https//:www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf [https//:perma.cc/8MT3-ZBQX].

60. *See also* Feldman & Misra, *supra* note 10, at 256 ("Hemphill's study of 21 drug settlements involving monetary payment revealed that a one-year delay in generic entry represented a transfer of $12 billion from consumers to producers, by a conservative estimate."); *id.* at 282 (showing that although the number of pay-for-delay agreements with explicit payments has gone down, the total number of agreements with "possible payment" increased, demonstrating an increased use of these agreements even after *Actavis*).

consumer cost of biologic pay-for-delay agreements, it is clear a single agreement can have a multi-billion dollar impact. This compounds an already-existing national health-care crisis, where the U.S. pays the world's highest drug prices, arguably subsidizing the rest of the world's drug research.[61]

Part II.A discusses the types of anticompetitive abuse that arise in the pharmaceutical sphere. Part II.B continues by focusing on the legal and regulatory background for small molecule drugs and the Hatch-Waxman Act. It looks into the recent treatment of reverse payments, how the landmark case *FTC v. Actavis* has affected these agreements' legal treatment, and how the case has since been applied. Part II.C then delves into the regulatory background of biologic drugs and their markets to explain the existing incentives and opportunities for competition and market abuse. While differences in scientific complexity warrant different approval mechanisms, these differences do not impact how companies strategically — sometimes, illegally — game the regulatory and legal systems to extend their drug's "lifecycles."

A. ANTICOMPETITIVE ABUSE

While this Note focuses on reverse payments, companies use a variety of anticompetitive behaviors to artificially extend their patent monopolies. These include product hops, where a company introduces a slightly reformulated product — with its own, new patent — to replace its current branded drug in the market, thereby thwarting an impending generic entry via state substitution laws.[62] Companies often tout these monopoly-extension

61. Sarah Kliff, *The true story of America's sky-high prescription drug prices*, VOX (May 10, 2018, 9:19 AM), https//:www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained [https//:perma.cc/5CWC-TJ8L] (arguing that as companies are unable to charge U.S.-level prices in countries with more stringent drug pricing regimes, "the United States' exceptionally high drug prices help subsidize the rest of the world's drug research").

62. *See* Brief for the Fed. Trade Comm'n at 7–10, Impax Lab'y's, Inc. v. Fed. Trade Comm'n, No. 19-60394 (5th Cir. 2019), https//:www.ftc.gov/system/files/documents/cases/impax_ca5_ftc_brief_public_2019-1209.pdf [https//:perma.cc/SG3C-8LXD] (discussing Endo's efforts to thwart Impax's generic via a product hop, even paying a $102 million cash-insurance policy because the expected monopoly profits were so lucrative). State substitution laws refer to mandatory generic substitution laws as adopted by the state, which require "pharmacists to substitute a generic for a brand-name medication if the prescriber did not specify that the latter drug should be dispensed." William Shrank et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 HEALTH AFFS. 1383, 1384 (2010), https//:www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2009.0424 [https//:perma.cc/

strategies, i.e., regulatory and legal arbitrage, as "life cycle management."[63] As seen in *Impax Laboratories v. FTC*,[64] companies often combine strategies to defeat competition that limits their ability to charge monopolistic prices.[65]

Due to the opaque documentation of patent settlement agreements and the creative ways that compensation can be crafted and transferred to minimize detection, it is often very difficult to identify reverse payments.[66] However, when competitors agree in a reverse payment to stagger market entry dates such that a competitor is allowed earlier entry into one market and another, generally later, entry into the U.S. market, the agreement has the markers of a market allocation scheme.[67] Though the claim was not made in the Lantus (Insulin) litigation discussed *infra*, academics and investigative reporters have since described the reverse payments at issue as effective market allocation agreements between U.S. and non-U.S. markets.[68]

In the Lantus litigation, rival drug manufacturers Eli Lilly and Sanofi (manufacturer of Lantus) entered into an agreement in which Eli Lilly agreed to refrain from entering the U.S. market for fifteen months with its Insulin biosimilar, while simultaneously being allowed to market the drug outside the U.S., giving Sanofi

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9JTP-CPT4]; *see also supra* notes 28–29 (discussing state substation laws, also known as DPS laws).

63. *See* Arti K. Rai & Barak D. Richman, *A Preferable Path for Thwarting Pharmaceutical Product Hopping*, HEALTH AFFS.: HEALTH AFFS BLOG (May 22, 2018), https//:www.healthaffairs.org/do/10.1377/hblog20180522.408497/full/ [https//:perma.cc/X28X-KFQ8].

64. Impax Lab'y's, Inc. v. Fed. Trade Comm'n, No. 19-60394 (5th Cir. 2019), https//:www.ftc.gov/system/files/documents/cases/impax_ca5_ftc_brief_public_2019-1209.pdf [https//:perma.cc/SG3C-8LXD].

65. *See infra* notes 115–118 and accompanying text (showing that Endo's reverse payment was fueled by a desire to extend its monopoly and attempt to implement a successful product hop).

66. *See supra* notes 17–18 (discussing the various forms that a reverse payment can take and how the FTC has accordingly changed its reporting methods).

67. *See supra* text accompanying notes 39–45 (introducing Humira and the settlement agreements at issue); *infra* Part III.C (discussing in detail the Humira allegations). Market allocation agreements are "agreements in which competitors divide markets among themselves." U.S. DEP'T JUST., PRICE FIXING, BID RIGGING AND MARKET ALLOCATION SCHEMES: WHAT THEY ARE AND WHAT TO LOOK FOR 3 (2015), https//:www.justice.gov/atr/price-fixing-bid-rigging-and-market-allocation-schemes [https//:perma.cc/S8FF-YPF5]. *Cf.* Verizon Commc'ns, Inc. v. L. Offs. of Curtis V. Trinko, LLP, 540 U.S. 398, 408 (2004) ("[C]ollusion" is "the supreme evil of antitrust.").

68. Feldman & Misra, *supra* note 10, at 276 ("One has to wonder whether the worldwide . . . Insulin market[ ] is being quietly carved up by large players, just when it should be going off patents.").

over a year's worth of supracompetitive U.S. profits.[69] This settlement, if it were classified as a market allocation agreement,[70] would normally be subject to per se liability.[71] But *Actavis* subjects reverse payment agreements to a rule of reason analysis, resulting in a classification issue where normally per se behavior is being treated under the more lax rule of reason standards.[72] The notion that reverse payment agreements can be horizontal market allocations is by no means novel.[73] Behavior traditionally considered illegal and abhorrent is now treated more leniently under the rule of reason because the conduct is done under the cloak of patent rights. This may be due in part to the complex nature of intellectual property agreements and courts' reluctance to classify reverse payments as per se illegal given the confusing interplay of patent rights in the settlements.[74]

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69. *Id.*

70. JULIAN O. VON KALINOWSKI ET AL., 1 ANTITRUST LAWS AND TRADE REGULATION: DESK EDITION § 2.03(3)(a) (2020) (defining horizontal market allocations as "when competitors agree to divide territories, customers, or product markets" and are generally treated as per se offenses).

71. *See id.* ("The rationale for the use of the per se rule, where horizontal price fixing is alleged, is the fundamental belief that the marketplace must determine whether prices are 'reasonable' and *any agreement that undermines the market is inherently unreasonable*." (emphasis added)). If per se liability was enforced, it would mean that the agreement is illegal — no matter the procompetitive justifications.

72. In addition, the *In re Humira* district court held that the market allocating effects of the reverse payment settlement agreement were the kind of territorial restrictions afforded to a patent holder. *See In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 834 (N.D. Ill. 2020) ("Some of AbbVie's conduct was not immunized by the *Noerr-Pennington* doctrine — including what plaintiffs allege to be the heart of their monopolization claim — but much of what preceded and followed that conduct was immunized, which makes the entirety of alleged monopolization scheme immune, because plaintiffs' theory depends on all the components of AbbVie's conduct as the means to suppress competition."). The Author suspects that this issue will be further addressed during *Humira*'s appeal. *See* Notice of Appeal, *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811 (N.D. Ill. 2020) (No. 19-CV-1873); *cf.* PHILLIP AREEDA ET AL., ANTITRUST ANALYSIS 158 n.19 (7th ed. 2013) ("*Topco* is not cited in *BMI* except for the proposition that the application of per se rules requires experience with the practice before the court. Judge Bork argued that 'In *BMI*, *NCAA*, and *Pacific Stationery*, the Supreme Court returned the law to the formulation of *Addyston Pipe* and thus effectively overruled *Topco* and *Sealy* as to the per se illegality of all horizontal restraints.'" (citation omitted)).

73. *See, e.g.*, *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003) (striking down a settlement agreement where a generic competitor was paid $10 million to withhold its generic for 180 days for being a *per se unlawful horizontal market allocation agreement*); Andrx Pharms. v. Biovail Corp. Int'l, 256 F.3d 799, 819 (D.C. Cir. 2001) (holding that the settlement agreement was tantamount to a market allocation agreement).

74. *See supra* note 72 (discussing how courts have increasingly not treated horizontal market allocations as per se violations).

Some courts used a "quick look" standard as a middle ground pre-*Actavis*.[75] The "quick look" rule of reason represents a compromise between rule of reason and per se violations. *In re Blue Cross Blue Shield Antitrust Litigation*[76] noted that the quick look "test is useful when the anticompetitive nature of an agreement is so blatant that a detailed review of the surrounding marketplace would be unnecessary."[77] This test is limited to cases that blur "the line between per se and rule of reason" where an agreement seems anticompetitive on its face but may have a procompetitive justification.[78] This fosters a threat to enforcement against traditionally per se antitrust behavior as a company is undoubtedly likely to find or devise allegedly procompetitive justifications for a behavior at issue to reduce the level of judicial scrutiny.[79]

Because patent settlements at issue in antitrust cases may be justified by considerations of the strength of the underlying patents, the *Actavis* Court could neither completely ban nor completely permit all such agreements. Nonetheless, the logic of a per se classification is that the behavior is so inherently contradictory to the spirit of the law, justifications do not matter. Thus, when signs of traditionally per se illegal behavior are present, it is necessary to either uphold and follow legal precedent or have Congress implement new legislation.

B. SMALL MOLECULE REGULATORY BACKGROUND AND THE *ACTAVIS* IMPACT

In 1984, the Hatch-Waxman Act,[80] also known as the Drug Price Competition and Patent Term Restoration Act, was enacted to incentivize generic competition and increase consumer access to

75. *See id.*

76. 26 F. Supp. 3d 1172 (N.D. Ala. 2014).

77. *Id.* at 1186 (citing Cal. Dental Ass'n v. FTC, 526 U.S. 756, 769–70 (1999)).

78. *Id.* at 1185 (citing *In re* Se. Milk Antitrust Litig., 739 F.3d 262, 274–75 (6th Cir. 2014)).

79. Or perhaps, it is the reality that modern business is too complicated for bright-line rules. This finding would likely undo years of antitrust experience and congressional intent behind certain causes of actions and the Sherman Act. *Cf.* United States v. Microsoft Corp., 253 F.3d 34, 49 (D.C. Cir. 2001) (per curiam) ("As the record in this case indicates, six years seems like an eternity in the computer industry. By the time a court can assess liability, firms, products, and the marketplace are likely to have changed dramatically. This, in turn, threatens enormous practical difficulties for courts[.]").

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

low-cost drugs by streamlining the FDA-approval process.[81] The gravamen of the Act was Congress' recognition that patents of dubious validity and value were being used by brand companies to thwart the entry of generic competition.[82] The hope was that generic companies most adept at recognizing those patents that wrongfully impeded competition could mount a challenge, and that consumers would benefit from the lower prices derived from a competitive market resulting from the patent challenges.[83] The Act provides a set of valuable incentives to generic drug companies, including streamlined testing requirements during the application period[84] and an immensely valuable 180-day period of market exclusivity for the generic that first makes it to the market or the first to successfully challenge the patents preventing the launch of an FDA-approved generic.[85] The Act protects brand-name drug manufacturers by providing opportunities to challenge generic applicants whose proposed generic is believed to infringe on their patent.[86] Reverse payments arose as a form of regulatory arbitrage from the Hatch-Waxman Act.[87]

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81. Feldman & Misra, *supra* note 10, at 249; Erika Lietzan, *The History and Political Economy of the Hatch-Waxman Amendments*, 49 SETON HALL L. REV. 53, 56–57 (2018) ("Conventional wisdom holds that the legislation represented a compromise between the competing interests of the generic drug companies and the innovating drug companies. . . . Courts, too, accept this conventional wisdom.").

82. Indeed, Congress specifically enacted Amendments to the Act in 2003 to address the increased abuse of patent infringement settlement agreements. *See* Brief of Amicus Curiae Representative Henry A. Waxman for Petitioner at 25, FTC v. Watson Pharms., Inc., 568 U.S. 1066 (2012) (No. 12-416) ("The Eleventh Circuit's permissive approach to the [reverse payment] agreement in [*Actavis*], and its erroneous notion that settlement agreements involving payments to generics to keep their products off the market are a natural consequence of Hatch-Waxman, threatens to render the mechanism Congress created to police anticompetitive agreements toothless. . . . [T]he decision below stands as a significant obstacle to the accomplishment of Congress's intent, in the 2003 legislation, to correct the abuses that had arisen under the Hatch-Waxman Amendments and to shore up the Amendments' principal purpose of increasing competition in the prescription drug market for the benefit of consumers."), *sub nom.* FTC v. Actavis, Inc., 570 U.S. 136 (2013).

83. Hausman, *supra* note 6.

84. H.R. REP. NO. 98-857, pt. 2, at 4–5 (1984) ("The FDA rules on generic drug approval for drugs . . . have had serious anti-competitive effects. The net result of these rules has been the practical extension of the monopoly position of the patent holder beyond the expiration of the patent. This is so because of the inability of generics to obtain approval for these post-1962 drugs without enormous expenditures of money for duplicative tests.").

85. Thomas Sullivan, *FTC Report Finds Fewer Anticompetitive Reverse Payment Deals in Hatch-Waxman Settlements*, POL'Y & MED. (Jul. 14, 2019), https//:www.policymed.com/2019/08/ftc-report-finds-fewer-anticompetitive-reverse-payment-deals-in-hatch-waxman-settlements.html [https//:perma.cc/889B-ASBQ].

86. *Id.*

87. Feldman & Misra, *supra* note 10, at 254.

A generic manufacturer seeking FDA approval must file an abbreviated new drug application (ANDA) which allows the generic to rely on the safety and efficacy testing of the brand,[88] and grants the first generic filer (first-filer or first-to-file) exclusivity before other generics are allowed onto the market.[89] While trying to create workable rules, the Hatch-Waxman Act seeks to balance interests of incentivizing generics to challenge those brand patents that were of doubtful validity or scope while not disregarding patent rights; thus providing,

> [A] company hoping to launch a generic drug must certify that all patents listed by the brand company as related to the drug (1) have not been filed, (2) have expired already, (3) will have expired by the time the generic enters, or (4) are invalid or that the generic will not infringe[.][90]

If a "Paragraph IV" challenge[91] is initiated — a challenge by a brand company in response to a generic manufacturer filing a Paragraph IV certification that their product will not infringe a valid patent of the brand — the FDA's approval of the generic's ANDA is automatically subject to a thirty-month stay for the litigation to proceed.[92] This scheme incented challenges by rendering the very act of filing an ANDA with a "paragraph IV certification . . . an act of infringement" since the generic manufacturer is applying while an otherwise-valid patent exists, thus allowing brand-name companies to sue the generic applicant for infringement despite not

88. *See id.* at 255; Philip S. Johnson, *Hatch Amendment Would Preserve Balanced Incentives for Pharmaceutical Innovation and Drug Affordability*, HEALTH AFFS.: HEALTH AFFS. BLOG (Nov. 9, 2018), https//:www.healthaffairs.org/do/10.1377/hblog20181106.217086/full/ [https//:perma.cc/62H9-ENE3] ("The principal purpose of the Hatch-Waxman Act was to establish an appropriate balance between the need to maintain incentives for pharmaceutical innovation and *the need to make generic versions of previously approved drugs immediately available upon the expiration of the patents* covering those drugs." (emphasis added)).

89. *See* Feldman & Misra, *supra* note 10, at 255.

90. *Id.* (citing 21 U.S.C. §§ 355(j)(2)(A)(viii)(I)–(IV) (2018)) (describing how this provision has led to "a certification that operates as an artificial act of infringement and opens the door for the brand-name company to sue").

91. These are called "Paragraph IV" challenges because of the statutory provision that provides for these options: 21 U.S.C. § 355(b)(2)(A)(iv).

92. 21 U.S.C. § 355(c)(3)(C). Brand-name drug manufacturers can take advantage of the thirty-month stay for Paragraph IV challenges to delay a generic's entry without regard to the merits or scope of the underlying patents. The automatic stay provides yet another opportunity to game the system, extending the process for generic entry by more than two years.

having yet produced or marketed its drug.[93] If infringement litigation were delayed, as it was before the Act, until a rival actually sold a competing version of the brand drug, then the rival's exposure to possible infringement damages and the delay and uncertainty of patent litigation would remain a huge deterrent to any generic competition.

Unfortunately, the Hatch-Waxman litigation scheme failed to break the strong economic incentives to enter reverse payment settlements that divided markets between litigating drug companies. While generally generic and brand-name manufacturers should be incented to compete vigorously against one another, the enormous profits that can be gained by extending the brand monopoly and delaying generic competition create an opportunity for the brand company to pay the generic not to compete, using some share of the additional monopoly profits the brand realizes. Indeed, many generics make more money by accepting payment under these agreements than they would make had they actually competed.[94] While brand-name manufacturers get to maintain or extend their period of monopoly pricing (and thus profits), first-filers get a share of the monopoly profits through the reverse payment and can still secure an 180-day period of exclusivity so long as the settlement does not make a determination of blame or patent validity.[95]

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93. Feldman & Misra, *supra* note 10, at 254. This is an equally important mechanism to ensure that holders of valid patents can protect their intellectual property from generic manufacturers that attempt to game the system. *See* Andrew Berks, *The Hatch-Waxman Act (Simply Explained)*, BERKS IP LAW: BLOG (June 10, 2019), https//:berksiplaw.com/2019/06/the-hatch-waxman-act-simply-explained/ [https//:perma.cc/T5A9-CM6G] ("The Hatch-Waxman Act was created in response to a court case called *Roche Products, Inc. v. Bolar Pharmaceutical Co.* . . . Roche owned flurazepam, and Bolar was seeking to sell a copy after Roche's patents expired. Bolar was hoping to time the approval with the expiration of the patents and began work on drug development activities while Roche's patents were still in force. The problem for Bolar was that by doing so, it was legally infringing. Roche sued them for infringement and ultimately won. From a public policy perspective, this in effect extended the term of the patent. That is, if another manufacturer cannot work on a drug while the patent is still in force, that means it could only work on it after the patent expired — and the approval process for a drug is two to three years, so this would have the effect of extending the life of the patent.").

94. *See* Herbert Hovenkamp, *The Rule of Reason and the Scope of the Patent*, 52 SAN DIEGO L. REV. 515, 522 (2015) ("The parties are in a position to share the full returns available on a patent that has now been placed beyond challenge by potential infringers.").

95. Feldman & Misra, *supra* note 10, at 255–56 ("The icing on the cake is that the generic company usually does not care about its drug's market entry date, so long as its sales are unlikely to drop before the branded drug's patent expires and it secures the whole six months of marketing exclusivity alongside the branded drug. . . . From the first-filer generic company's perspective, it has 180-day exclusivity in its pocket *and a cash payment dangling in front of it*." (emphasis added)).

Prior to the landmark *Actavis* decision, the circuits were split on the standard of review for reverse payment analysis under antitrust law, and even whether the agreements could be subjected to antitrust review at all.[96] Debates flourished on whether these pay-for-delay agreements were legal exercises of patent holder rights or flagrant illegal market allocations.[97] While some courts held them to be almost presumptively unlawful, an increasing number of circuits adopted a variant of the "scope of the patent" test[98] that virtually immunized the agreements from any antitrust scrutiny if *any* patents were asserted, regardless of the validity or scope of the patents.[99] In 2013, the *Actavis* Supreme Court explicitly rejected this test and held that in certain circumstances, reverse payment settlements can be legal exercises of a patentee's rights, but can nonetheless be abused, triggering antitrust scrutiny and potential liability.[100]

Actavis involved drug manufacturers Solvay (an AbbVie predecessor), the manufacturer of AndroGel,[101] which sued Actavis for

96. *Compare In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008) (holding the essential inquiry was "whether the agreements restricted competition beyond the exclusionary zone of the patent"), *with In re* K-Dur Antitrust Litig., 686 F.3d 197, 214 (3d Cir. 2012) (rejecting the "scope of the patent test" as it improperly shields reverse payments from antitrust scrutiny), *and In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003) (holding that the reverse payment was a per se unlawful horizontal market allocation agreement).

97. *See "Pay-for-Delay" Settlements: Antitrust Violation or Proper Exercise of Pharmaceutical Patent Rights?*, A.B.A.: BUS. L. TODAY (Jan. 31, 2011), https//:www.americanbar.org/groups/business_law/publications/blt/2011/01/02_hanks/ [https//:perma.cc/BQ5V-XLEB] (discussing prior to *Actavis*, that the FTC found reverse payments as per se illegal for their "inherently anticompetitive nature . . . and the enormous harm [they] cause[ ]," a view adopted by the Sixth Circuit who found the agreements to be illegal horizontal agreements; however, the Eleventh Circuit found that the "grant of patent rights necessarily encompasse[d] the right to exclude generics from the market" and that "a threshold analysis of the exclusionary scope of the patent must precede any specific antitrust inquiry."); Robin A. Van der Meulen & Rudi Julius, *supra* note 56, at 14 ("[O]ne key question that has arisen since *Actavis* is whether a reverse payment must be in the form of cash in order to be subject to antitrust scrutiny[.]").

98. *See* Hovenkamp, *supra* note 94, at 525, 527 (describing how the "scope of the patent" test has been used both as a "limiting device to restrict activities thought to reach beyond the statutory authorization granted to the patentee" as well as a "walled garden whose contents are free from antitrust scrutiny, provided that the challenged conduct stays inside the wall").

99. *See, e.g.*, *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1323 (discussing the necessity of determining the scope of the patent).

100. FTC v. Actavis, Inc., 570 U.S. 136, 158–60 (2013) ("These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.").

101. AndroGel is a testosterone gel used for "adult males who have low or no testosterone[.]" *Use and Safety Information*, ANDROGEL, https//:www.androgel.com/ [https//:perma.cc/E7MF-435E].

patent infringement for its submission of an application for FDA approval of its generic version of AndroGel.[102] To settle the case, Solvay, the patent holder, paid Actavis, the alleged infringer, between $19 and $30 million annually for each year it delayed entry of its generic AndroGel, resulting in delayed entry of any generic competition for nine years, from 2006 until 2015.[103] Additionally, Solvay gave consideration valued at $72 million to two other potential generic competitors to delay their launch of a generic version of AndroGel.[104]

In arriving at its conclusion that pay-for-delay settlement agreements are subject to antitrust scrutiny, the Court reflected on five considerations why the "general legal policy favoring the settlement of disputes" did not preclude antitrust scrutiny[105]:

> (1) Reverse settlements specifically have the ability to inflict anticompetitive harm — e.g., forcing consumers to pay monopoly prices.[106]
>
> (2) A reverse payment may reflect the transfer of traditional settlement considerations — e.g., avoided litigation costs.[107]
>
> (3) The paying party needs substantial market power to have the capacity to cause anticompetitive harm — e.g., the power to set supracompetitive prices.[108]
>
> (4) The size of a reverse payment acts as a "workable surrogate" for a perceived patent's validity, negating the need for courts to adjudicate patent validity.[109]
>
> (5) Subjecting the agreement to antitrust liability would not foreclose legitimate settlement options.[110]

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102. Feldman & Misra, *supra* note 10, at 257.
103. *Id.* at 257–58.
104. *Actavis*, 570 U.S. at 145 ("The companies described these payments as compensation for other services the generics promised to perform, but the FTC contends the other services had little value.").
105. *Id.* at 153.
106. *Id.* at 154.
107. *Id.* at 156.
108. *Id.* at 157.
109. *Id.*
110. *Id.* at 158.

In particular, the Court noted that a "large and unjustified" reverse payment indicates a higher risk of anticompetitive effects.[111] This is because such a payment only makes economic sense if the challenged patent was likely invalid or noninfringed, thus revealing a transfer of valuable consideration most likely representing expected revenues forgone from competition and captured by a monopolistic market.[112]

Post-*Actavis*, many circuits struggled with the meaning of *Actavis*'s use of "payment." Because the *Actavis* Court did not explicitly address what type of payments were implicated by its holding nor leave a specific test for the lower courts,[113] drug companies seeking to minimize *Actavis*'s effect argued that *Actavis* only applied to literal cash payments and did not reach settlements with alternative forms of consideration. The greater weight of authority eventually recognized that non-cash transfers of value to the alleged infringer had the same anticompetitive effect as cash payments and should be included in the *Actavis* framework.[114]

In the first chance to apply *Actavis* in its administrative courts, the FTC found that a patent settlement agreement between Endo and Impax violated antitrust laws.[115] Endo agreed to refrain from

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111. *Id.* at 158–59.

112. *See* Brief for Fed. Trade Cmm'n at 6, Impax Lab'y's, Inc. v. FTC, No. 19-60394 (5th Cir. Dec. 10, 2019), https//:www.ftc.gov/system/files/documents/cases/impax_ca5_ftc_brief_public_2019-1209.pdf [https//:perma.cc/G2KT-HXGX] ("[T]he Supreme Court found [reverse payment] settlements to be 'unusual,' since the generic, 'a party with no claim for damages[,] walks away with money simply so it will stay away from the patentee's market.'" (quoting *Actavis*, 570 U.S. at 147, 152)).

113. *Actavis*, 570 U.S. at 159–60 ("We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation.").

114. *See In re* Loestrin 24 FE Antitrust Litig., 45 F. Supp. 3d 180, 192 (D.R.I. 2014) ("These considerations militate in favor of a cautious approach by the district courts, and against a cavalier extension of the *Actavis* holding to virtually any non-cash settlement package that has presumably substantial value. . . . Actavis *should be read to apply solely to the cash settlements that it describes, and to exclude non-cash settlements, preserving for litigants a viable path to resolve their disputes*." (emphasis added)), *rev'd*, 814 F.3d 538, 552 (1st Cir. 2016) ("[R]ather than rejecting wholesale *Actavis's* applicability to non-cash payments, [we] require[ ] that the plaintiffs plead information sufficient "to estimate the value of the term, at least to the extent of determining whether it is 'large' and 'unjustified.'"); *see also* Carrier, *supra* note 56, at 41 ("Nearly every court that has examined the issue has adopted the broader approach — extending the payment to noncash conveyances — and the two district courts that did not were overturned on appeal.").

115. *In re Impax Lab'y's Inc.*, 2019 WL 1552939, at *42 (F.T.C. Mar. 28, 2019). In 2007, Endo sued Impax soon after Impax filed its Paragraph IV certification asserting that three of Endo's patents were invalid or not infringed by Impax's product, indicating its plan to launch a generic version of Endo's drug Opana (a type of opioid). Brief for Fed. Trade Cmm'n at 6, *Impax*, No. 19-60394, at 7–10. After being sued, Impax offered to settle with Endo by agreeing to an initial proposed entry date in 2011 which Endo rejected. *Id.* Impax was

selling its own generic during Impax's 180-day exclusivity period; paid Impax to delay market entry of its generic version of Endo's Opana drug by two-and-a-half years; gave Impax a cash insurance policy whereby Endo would pay — and eventually did pay — $102 million if Endo initiated a product hop prior to Impax's launch; and gave Impax a license to its current patents.[116] Impax's expert explained that "a generic manufacturer will reject a settlement when its expected 'generic entry date under continued litigation' is earlier than the 'generic entry date in that settlement.'"[117] Likewise, a branded manufacturer normally doesn't have an incentive to pay a would-be-generic competitor that it sues unless the branded manufacturer fears that their patents will likely be found invalid or not infringed, and that successful generic entry is imminent, threatening the majority of its sales.[118]

Actavis attempted to balance two important public policy goals: encouraging dispute settlement and facilitating competition to ensure high quality drugs at the lowest possible price.[119] The Court recognized that reverse payments can represent collusion between generic and branded drug manufacturers contradicting the Hatch-Waxman Act's spirit.[120] It noted that some settlements might be justified by traditional settlement concerns, unlike those involving a "large and unjustified" payment — with little to no discussion on what constitutes a payment nor what constitutes "large and unjustified."[121]

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ready to launch between June 2010 and July 2011, had also obtained DEA approval, manufactured more than $1 million worth of product (which it destroyed after the settlement), and secured purchasers. *Id.* Endo knew that Impax's entry could result in a loss of 85% of Endo's sales within three months of entry. *Id.* Endo also wanted to introduce a reformulated Opana ER as a product hop to eliminate the market for Impax's generic but could not launch it before Impax's projected entry dates. *Id.* Endo only resumed negotiations once the FDA indicated Impax's drug would be approved in June 2010. *Id.*

116. Brief for Fed. Trade Cmm'n at 6, *Impax Lab'y's*, No. 19-60394.

117. *Id.* at 28.

118. *See id.* at 17 ("Had Impax posed no threat to Endo's monopoly, the reverse payment would have been an 'irrational act.'").

119. FTC v. Actavis, Inc., 570 U.S. 136, 152, 154 (balancing legislative intent with the public's "strong interest in settlement").

120. *Id.* at 154 ("It was and is very clear that the [Hatch-Waxman Act] was not designed to allow deals between brand and generic companies to delay competition." (quoting 148 CONG. REC. 14,437 (2002) (statement of Sen. Hatch)); *id.* ("[I]ntroducing bill to deter companies from 'strik[ing] collusive agreements to trade multimillion dollar payoffs by the brand company for delays in the introduction of lower cost, generic alternatives'" (quoting 146 CONG. REC. 18,774 (2000) (statement of Rep. Waxman))).

121. *Id.* at 158–59.

While some courts have expressed a desire to read *Actavis* as narrowly as possible,[122] others are quick to condemn narrow constructions of *Actavis* for failing to reflect modern, complex business realities.[123] This new business reality is evident in pre- and post-*Actavis* FTC reports that show the number of final settlements with explicit compensation have decreased in frequency since 2010, while those with "possible" or "implicit" payments have become increasingly frequent.[124]

C. BIOLOGICS LEGAL AND REGULATORY BACKGROUND

Biologics are currently regulated by the Biologics Price Competition and Innovation Act (BPCIA), passed as part of the 2010 Affordable Care Act.[125] With similar motivations as those behind the Hatch-Waxman Act for small molecule drugs,[126] the BPCIA is aimed at regulating biologics, addressing the expiration of first-generation drugs, and promoting biosimilar competition.[127]

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122. *See* Feldman & Misra, *supra* note 10.

123. Feldman & Misra, *supra* note 10, at 273 ("The modern era of pay-for-delay agreements bear little resemblance to its earlier predecessors. The agreements may be more cleverly disguised, and they often incorporate complex side-deals that are difficult for courts and antitrust authorities to unravel."); *see In re* Effexor XR Antitrust Litig., No. 11-5479, 2014 WL 4988410, at *20 (D.N.J. Oct. 6, 2014) ("Although *Actavis* addressed cash payments, reading the opinion as a whole, it is clear that the Supreme Court focuses on the antitrust intent of the settling parties rather than the manner of payment."), *rev'd sub nom. In re* Lipitor Antitrust Litig., 868 F.3d 231 (3d Cir. 2017); *In re* Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 392 (D. Mass. 2013) ("Nowhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction.").

124. FED. TRADE CMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2010, at 1, https//:www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/1105mmaagreements.pdf [http//:perma.cc/5EQB-6ZAY] (last visited Dec. 3, 2020) (In 2010, thirty-one final settlements contained compensation to a generic — covering products representing a combined annual sales of $9.3 billion — on top of a restriction, and only three others that "may provide implicit compensation to the generic in order to agree to a restriction on entry."); FED. TRADE CMM'N, *supra* note 10, at 1 (In 2016, thirty final settlements contained "explicit" compensation to and a restriction on a generic, while fourteen other final settlements are categorized as containing "one or more forms of 'possible compensation' because it is not clear from the fact of each agreement whether certain provisions act as compensation."); *see also supra* notes 17–18 (noting, for example, that payments have been seen in the form of exclusive licenses, exclusive supply deals, and explicit "no-AG" commitments).

125. Carrier & Minniti, *supra* note 27, at 14.

126. *See Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Cts. and Competition Pol'y of the H. Comm. on the Judiciary*, 111th Cong. (2009); *see also* 21 U.S.C. § 355(j)(2)(A) (2018).

127. *See Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Cts. and Competition Pol'y of the H. Comm. on the Judiciary*, *supra* note

The BPCIA seeks to incentivize the development of biologics while also ensuring that biosimilars can follow onto the market, helping eventually curb prices for consumers. To encourage biologics production, the BPCIA provides market exclusivity periods for the first biologic to market.[128] The first biosimilar cannot file an application for market entry until four years after the reference biologic (RB) has been approved, nor can it be approved until twelve years after the RB's approval if it relied on the RB's data.[129] The twelve-year total exclusivity period and four-year initial freeze on biosimilar applications incentivize and reward companies that spend the approximate $2 billion in capital costs to develop a biologic.[130]

Though the initial four-year freeze prohibits the FDA from accepting *any* biosimilar applications, biosimilars can apply for approval during the RB's following eight-year exclusivity period, and go through a process to show that the drug is "*highly similar to* and has *no clinically meaningful differences from* the referenced product."[131] This fact-intensive inquiry uses a totality of the evidence standard and the first-to-file biosimilar does not receive any period of exclusivity.[132] Instead, the first biosimilar that applies for an "interchangeability" designation and is found by the FDA to be "interchangeable" with the reference biologic will be granted a one-year period of exclusivity.[133] Since the first biosimilar approval in 2015, no biosimilar has been deemed "interchangeable" by the FDA.[134]

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126 at 1–2 (statement of Rep. Johnson) (noting that the BPCIA intended to boost competition from biosimilars while preserving incentives for biologic innovation); 21 U.S.C. § 355(j)(2)(A).

128. Jason Premus, *Biosimilars After Actavis: Similar Considerations, Similar Results*, 14 RUTGERS J.L. & PUB. POL'Y 255, 263 (2017) (noting that the BPCIA granted a period of data exclusivity as well as market exclusivity). The data exclusivity grant is no longer quite as serious of an issue as the FDA has published a public and searchable database, the Purple Book, to which biologic manufacturers are *supposed* to submit their patents. *See FDA Launches Searchable Database Intended to Replace Static Purple Book Lists*, CTR. FOR BIOSIMILARS (Feb. 24, 2020), https//:www.centerforbiosimilars.com/news/fda-launches-searchable-database-intended-to-replace-static-purple-book-lists [http//:perma.cc/527W-V8V5].

129. Daryl Lim, *Biologics as the New Antitrust Frontier: Reflections, Riposte, and Recommendations*, 2018 U. ILL. L. REV. ONLINE 209, 211.

130. *Id.* at 210.

131. Carrier & Minniti, *supra* note 27, at 15 (emphasis in original).

132. *Id.*

133. *Id.* at 16. For a definition of "interchangeability," see Rumore & Vogenberg, *supra* note 28, at 368.

134. U.S. FOOD & DRUG ADMIN., *supra* note 31.

While the exclusivity periods for biologics generally follow a pattern similar to those provided in the Hatch-Waxman Act for small molecule drugs, there are several differences. Those differences exacerbate existing abusive behavior with small molecule drugs, particularly reverse payments and regulatory abuse. For example, the lack of patent notice in the BPCIA was a fundamental distinction with the Hatch-Waxman Act, which allows the FDA to publish the Orange Book, an annual list of approved drugs and associated patents, *and* forces drug sponsors to list patents it could reasonably assert against generics.[135] Only in February 2020 did the FDA approve a public searchable biologic version of the Orange Book, known as the Purple Book.[136]

The Orange Book allows a generic to immediately enter the market if it establishes noninfringement — which it can demonstrate by using the patent information listed in the Orange Book — providing regulatory and legal predictability for generic developers.[137] In contrast, the BPCIA by not requiring the disclosure of patents alleged to cover biologic drugs for the past ten years, created a patent-exchange framework that depends on private negotiations.[138] A justification for patent non-disclosure under the BPCIA relates to a concern that biosimilar manufacturers would improperly gain access to proprietary information on the manufacturing process, information central to biologic and biosimilar development.

The original BPCIA patent-exchange framework for biologic drugs, which involves biosimilar manufacturers identifying potential patents that *could be* litigated, uses a six-step process that attempts to limit abuses by requiring good faith negotiations and limiting the number of patents a biologic manufacturer can list for litigation to no more than the amount listed by the biosimilar applicant.[139] However, the inherently complex nature of biologics

135. Carrier & Minniti, *supra* note 27, at 16.

136. CTR. FOR BIOSIMILARS, *supra* note 128.

137. Carrier & Minniti, *supra* note 27, at 16.

138. *Id.* at 17 (explaining that private negotiations would "ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large" (quoting *Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Cts. & Competition Pol'y of the H. Comm. on the Judiciary*, 111th Cong. 9 (2009) (statement of Rep. Eshoo))).

139. *Id.* at 17–18. This lengthy six-step process is more popularly known as the "patent dance" as each party, a reference biologic and biosimilar applicant, go back and forth to

means a manufacturer can litigate any of the patents on the list during the six-step process or even years later.[140] Even with the new Purple Book, there is no certain path to identifying and resolving all potential patent disputes. Furthermore, unlike the Hatch-Waxman Act, patent settlements under the BPCIA were not reportable to the FTC or DOJ until late 2018.[141]

At the moment, solely from an antitrust perspective, the path to competition and enforcement of patents alleged to cover biologic drugs is less regulated than their small molecule counterparts. Though the Purple Book attempts to fill a regulatory gap in the biologics sphere, it is not obligatory and thus falls short. Consequently, the biologics market is prime for abuse without consequence, particularly if *Actavis* is read so narrowly as to only apply to Hatch-Waxman Paragraph IV settlements.

III. CONSEQUENCES OF UNCLEAR STANDARDS AS SEEN THROUGH THE BEST-SELLING U.S. DRUG

This Part reviews the consequences of having different regulatory regimes and unclear legal standards. It begins with a discussion on how unclear standards and lax antitrust enforcement have led to high U.S. drug prices, disproportionally burdening American consumers. Part III.B then discusses proposed and enacted legislative treatment of biologics from an antitrust perspective. Part III.C continues with the arguments and allegations in the *In re Humira* litigation, as well as the district court's findings.

A. UNIQUELY AMERICAN CONSEQUENCES: CONSUMER HARM & SKYROCKETING PROFITS

It is clear that pharmaceutical companies are taking advantage of the lenient U.S. antitrust regulatory regime. U.S. enforcers, patients, and health insurance providers lose when pharmaceutical

identify any patents that need to be litigated and negotiate or, if need be, commence litigation. *Id.*

140. *Id.*

141. Lim, *supra* note 129, at 216; Osborn, *supra* note 19. The Patient Right to Know Drug Prices Act became law on October 10, 2018, amending the Medicare Prescription Drug, Improvement and Modernization Act of 2003, to require the reporting of any executed settlement agreements addressing biologic or biosimilar drugs within ten days of their execution to the FTC and the Assistant Attorney General. *See* Patient Right to Know Drug Prices Act, Pub. L. No. 115-263, 132 Stat. 3672, 3673–74 (2018) (codified in relevant part at 21 U.S.C. § 355 (2018)).

companies are allowed to game the differing EU and U.S. patent systems. The negative consequences of reverse payment settlements are particularly apparent in the U.S.: the cost of the four most popular types of Insulin has tripled over the past decade.[142] The effects of the price increase has led to one in four diabetes patients skimping on or skipping potentially-lifesaving doses.[143] The results of the different regulatory and legal approaches to pharmaceutical competition are evidenced by the much more robust biosimilar market in Europe, in which more than fifty biosimilar equivalents for biologics exist, compared to the mere fifteen biosimilars available in the U.S. market.[144]

The problem is further exacerbated by the more lenient antitrust enforcement in the U.S. that does not recognize excessive pricing as an independent antitrust violation.[145] In Europe, excessive pricing is an explicitly recognized base for an abuse of dominance case under Article 102 of the Treaty on the Functioning of the European Union (TFEU).[146] The U.S. perspective could not be more different, with Justice Scalia stating in *Verizon v. Trinko*[147]: "The opportunity to charge monopoly prices — at least for a short

142. Julia Belluz, *The absurdly high cost of insulin, explained*, VOX (Nov. 7, 2019, 6:00 AM), https//:www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive [http//:perma.cc/9AS2-XMAH]. While the increase of price cannot be explained solely as a reverse payment side effect, these agreements continue to exacerbate the problem. *See also* S. Vincent Rajkumar, *The High Cost of Insulin in the United States: An Urgent Call to Action*, 95 MAYO CLINIC PROCS. 22, 22 (2020) (noting that the price of insulin has risen "inexplicably over the past 20 years at a rate far higher than the rate of inflation[,]" increasing more than 1000% from 1999 to 2019).

143. Belluz, *supra* note 142.

144. *See* Sarah Tribble, *Why the U.S. Remains the Most Expensive Market for "Biologic" Drugs in the World*, NPR (Dec. 19, 2018, 1:02 PM), https//:www.npr.org/sections/health-shots/2018/12/19/676401634/why-the-u-s-remains-the-most-expensive-market-for-biologic-drugs-in-the-world [https//:perma.cc/X6K2-MWHX]; Bryant Furlow, *The State of Biosimilars in 2019*, MANAGED HEALTHCARE EXEC., Feb. 2019, at 31.

145. *See generally Excessive Pricing in Pharmaceutical Markets — Note by the United States* (Org. for Econ. Coop. & Dev., Working Paper No. DAF/COMP/WD(2018)111, 2018, https//:www.ftc.gov/system/files/attachments/us-submissions-oecd-2010-present-other-international-competition-fora/excessive_prices_in_pharmaceuticals_united_states.pdf [https//:perma.cc/US8D-DJE2] (FTC and DOJ explaining why excessive pricing in pharmaceuticals "by itself" does not violate U.S. antitrust law, "although high prices may be indicative of anticompetitive conduct").

146. *See* Treaty on the Functioning of the European Union, art. 102, May 9, 2008, 2008 O.J. (C 115) 47 ("Such abuse may, in particular, consist in: (a) directly or indirectly *imposing unfair purchase or selling prices*. . . ." (emphasis added)). Excessive pricing is not the only reason for lower European drug prices, but its existence as a cause of action demonstrates a difference in public policy priorities. The other factors for Europe's lower prices are outside the scope of this Note.

147. 540 U.S. 398 (2004).

period — is what attracts 'business acumen' in the first place; it induces risk taking that produces innovation and economic growth."[148] Thus, it is unlikely that the current U.S. antitrust laws alone can be an effective means to curb out-of-control drug prices. Nonetheless, the necessary U.S. antitrust laws do exist to address this anticompetitive conduct; and, if actually enforced, could target companies that improperly extend monopolies that result in increased consumer prices.

B. CONGRESSIONAL ATTEMPTS TO ADDRESS THE ISSUE IN VAIN

There is congressional appetite to mitigate the harmful effects of these agreements and anticompetitive behaviors. Within the past year, one state bill has passed and bipartisan groups have introduced two acts aimed at pharmaceutical industry use and misuse of patents: the Biologic Patent Transparency Act (BPTA) and the Affordable Prescriptions for Patients Act (APPA).[149] The BPTA aims to increase transparency by forcing companies to "publicly disclose the web of patents that protect their biologics" to make it easier for competitors to evaluate and plan for their biosimilar production and creating a searchable database.[150] By streamlining the BPCIA's disclosure process, a patent holder would only have thirty days to submit a list of patents they believe a biosimilar is infringing upon.[151] Failure to do so would result in the barring of any infringement assertions.[152] However, there are concerns that this measure would backfire, resulting in decreased efficiency as patent holders assert infringement on any "mildly relevant"

148. *Id.* at 407; *see* Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 UC IRVINE L. REV. 281, 290 (2016) ("Likewise, the Seventh Circuit in *Blue Cross v. Marshfield*: '[a] natural monopolist . . . without excluding competitors by improper means is not guilty of 'monopolizing' in violation of the Sherman Act . . . and can therefore charge any price that it wants . . . for the *antitrust laws are not a price-control statute or a public-utility*. . . .'" (citation omitted) (emphasis added)).

149. *See, e.g.*, Paul A. Ainsworth & Lauren A. Watt, *Proposed BPCIA reforms: More music, same dance*, IP STARS (May 16, 2019), https//:www.ipstars.com/NewsAndAnalysis/Proposed-BPCIA-reforms-More-music-same-dance/Index/4001 [https//:perma.cc/DR9A-36ME]; Steve Brachmann, *Affordable Prescriptions for Patients Act Would Allow FTC to Prosecute Pharma Patent Thickets, Product Hopping*, IP WATCHDOG (May 20, 2019), https//:www.ipwatchdog.com/2019/05/20/affordable-prescriptions-patients-act-allow-ftc-prosecute-pharmaceutical-patent-thickets-product-hopping/ [https//:perma.cc/QRD3-VMLX].

150. Ainsworth & Watt, *supra* note 149. This requirement would have the same effect as making listing biologic patents in the Purple Book mandatory.

151. *Id.*

152. *Id.*

patents.[153] Likewise, biologic companies might be hesitant to disclose their patent information so early, giving away any hint of trade secrets and giving biosimilar manufacturers a competitive advantage.[154]

The APPA's current draft would define patent thickets — the accumulation of large numbers of often overlapping patents — and product hopping as anticompetitive behavior, codifying it in the FTC Act.[155] This would allow the FTC to take enforcement actions against companies engaging in these behaviors unless the patent owner can demonstrate that the anticompetitive effects of the conduct do not outweigh its procompetitive effects, or that the conduct otherwise "achieves some clinically meaningful improvement in safety or therapeutic benefits."[156] However, the bill does not define how many patents would constitute a thicket, leaving that determination to the FTC.[157] Though there is bipartisan support for both bills, it seems unlikely that either the BPTA or APPA will be voted into law given the current climate.[158]

The most comprehensive, and only successfully-passed, legislative approach comes from California in 2020 as the Preserving Access to Affordable Drugs, AB 824.[159] AB 824 codifies "a presumption that any transfer of value from a branded to a generic pharmaceutical company settling patent infringement litigation, combined with a delay of the generic drug's entry into the market, has an anticompetitive effect."[160] It then creates a burden shifting scheme where settling parties must affirmatively demonstrate that either the payment is fair and reasonable consideration solely

153. *Id.*
154. *Id.*
155. Brachmann, *supra* note 148.
156. *Id.*
157. *Id.*
158. Katherine Fung, *Mitch McConnell's 'Legislative Graveyard' Helping Current Congress to Be the Least Productive in History, Report Says*, NEWSWEEK (Sept. 16, 2020, 3:48 PM), https//:www.newsweek.com/mitch-mcconnells-legislative-graveyard-helping-current-congress-least-productive-history-1532424 [https//:perma.cc/UL8B-PXA9].
159. Mark Ford et al., *Unprecedented State Law on Pharmaceutical "Reverse Payments" Goes into Effect*, JD SUPRA (Jan. 9, 2020), https//:www.jdsupra.com/legalnews/unprecedented-state-law-on-85464/ [https//:perma.cc/D7LD-XPBB]; *see also* Ass'n for Accessible Meds. v. Becerra, No. 2:19-cv-02281, 2019 WL 7370421 (E.D. Cal. Dec. 31, 2019) (denying a preliminary injunction motion seeking to bar Act's enforcement), *aff'd*, 822 F. App'x 532 (9th Cir. 2020) (holding the plaintiff lacked standing and ordering dismissal). After dismissal, the generic pharmaceutical industry trade organization filed a second suit, Ass'n for Accessible Meds. v. Becerra, No. 2:20-cv-01708-TLN-DB (E.D. Cal. Sept. 14, 2020), and filed a new motion for preliminary injunction, which is pending as of this writing.
160. Ford et al., *supra* note 159.

for goods or services provided by the generic company, or that the procompetitive benefits outweigh any anticompetitive effects.[161] The bill defines a payment as "anything of value," and explicitly covers agreements under the BPCIA and the Hatch-Waxman Act.[162] However, the Act has six exceptions to its definition of "anything of value" that would exempt settlements covering (1) certain non paid licenses, (2) covenants not to sue, (3) saved litigation costs (to be limited and documented prior to the settlement), (4) an acceleration clause triggered by product hopping conduct, (5) non-interference with a generic's regulatory approval, and (6) forgiveness of damages for an at-risk launch of the subject drug.[163]

Evidenced by the numerous legislative attempts, discussed *supra*, to fix gaps in or address misuses of the Hatch-Waxman Act and the BPCIA, it seems politically popular to attempt to curb anticompetitive pharmaceutical behavior despite failures to enact any express prohibitions into law — except for AB 824. While Congress fails to adopt stronger prohibitions on the drug industries' anticompetitive conduct and agreements, it is U.S. consumers, facing dire medical conditions, who are being forced to disproportionally subsidize pharmaceutical R&D and pay the world's highest drug prices.

C. HUMIRA ALLEGATIONS: OLD TRICKS APPEAR IN A NEW WORLD

In re Humira presents a particularly high-profile opportunity for the courts to determine whether *Actavis* will apply to the biologic sphere. Though the district court has dismissed the case in favor of the defendants, the case has already been appealed, with the FTC, many state enforcers, and academics filing amicus briefs decrying the court's failure to properly apply the precedent of *FTC v. Actavis*.[164] The *In re Humira* complaint does not expressly rely

161. *Id.*

162. *Id.*

163. Brief for Michael A. Carrier as Amicus Curiae Supporting Defendant's Opposition to Plaintiff's Motion for Preliminary Injunction at 6, *Ass'n for Accessible Meds.*, 2019 WL 7370421 (E.D. Cal. Dec. 9, 2019) (No. 2:19-cv-02281), 2019 WL 7631472 [hereinafter "Carrier Brief"]; CAL. HEALTH & SAFETY CODE §§ 134002(a)(2)(A)–(F) (2020).

164. *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 847 (N.D. Ill. 2020) (No. 19-CV-1873) (dismissing case), *appeal docketed sub nom.* UFCW Local 1550 Welfare Fund v. Abbvie Inc., No. 20-2402 (7th Cir. July 30, 2020); Brief of Amicus Curiae the Fed. Trade Comm'n Supporting No Party at 2, UFCW Local 1550 Welfare Fund v. AbbVie Inc., No. 1:19-cv-01873 (7th Cir. Oct. 13, 2020) ("[T]he district court's analysis is inconsistent with *Actavis* in two critical ways that could impede enforcement of the antitrust law if left

on *Actavis*, only arguing it in the alternative to other antitrust claims more grounded in patent thicket and sham litigation, and does not use the term "reverse payment" or "pay-for-delay."[165] Notably, the *In re Humira* district court readily purported to apply *Actavis* to the allegations, never once suggesting or considering that the biologic nature of the molecule precluded its application.[166]

The court found that *Actavis* rather than condemning, actually blessed the settlement agreements in which Humira rivals agreed to stay out of U.S. markets for more than five years while being provided instant entry to non-U.S. countries.[167] It also rejected the market allocation arguments and found much of the patent dance and patent thicket behavior to be legally immunized from scrutiny.[168] As it is likely that the outcome of this case on appeal will set the precedent for future analysis of patent settlements in the biologic sphere, this Note utilizes it as a vehicle to demonstrate that regulatory pathways to approval are not dispositive enough to warrant disparate antitrust treatment. The author bases her analysis on the allegations as pled, treating them as true, as a district court must do when making a determination on a motion to dismiss.[169] Furthermore, this Note argues, *infra*, that the district court correctly engaged in an *Actavis* analysis, but that the district court misapplied the case law in doing so.[170]

First approved in 2002 in the U.S. and 2003 in the EU, Humira is the world's best-selling pharmaceutical with approximately $20 billion in sales for 2018 alone.[171] Humira is a biologic drug that accounts for 70% of AbbVie's total revenue.[172] As AbbVie's most

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uncorrected."); Brief of Amici Curiae of 66 Law, Economics, Business, and Medical Professors Supporting Plaintiffs-Appellants at 13, UFCW Local 1550 Welfare Fund v. Abbvie Inc., No. 1:19-cv-01873 (7th Cir. Oct. 09, 2020) (noting the *Humira* District Court applied "the very scope-of-the-patent test rejected in *Actavis*").

165. The complaint only mentions *Actavis* twice. *See Humira* Complaint, *supra* note 39, ¶¶ 128, 210.

166. *In re* Humira, 465 F. Supp. 3d at 827, 836–42.

167. *Id.* at 842.

168. *Id.* at 839–42. The patent thicket allegations and the court's subsequent *Noerr-Pennington* treatment are beyond the scope of this Note, though the Author questions the court's interpretation of the doctrine and cause of action.

169. Ashcroft v. Iqbal, 556 U.S. 662, 680–82 (2009).

170. *See infra* Part IV.A (applying an *Actavis* analysis of the allegations related to Humira); *see also supra* note 164.

171. Ellen Hoen, *Humiragate: AbbVie's desperate attempts to keep its monopoly*, MEDS. L. & POL'Y BLOG (Mar. 27, 2019), https//:medicineslawandpolicy.org/2019/03/humiragate-abbvies-desperate-attempts-to-keep-its-monopoly/ [https//:perma.cc/8QD2-M9DR].

172. Tribble, *supra* note 144.

important drug, Humira has been protected by a web growing up to 247 patent applications, of which only 132 are approved.[173] With Humira's original patent approved in December 2002, AbbVie's exclusivity period originally was due to expire in December 2016.[174] The bulk of the Humira's 132 patents were granted after 2013 as an express attempt to build a "absolute minefield of IP" to deter potential competitors.[175]

This is problematic as the vast majority of these patents are alleged to be invalid because they were not filed within the first year of the original FDA-approved launch.[176] Undoubtedly, AbbVie was aware of this, but is alleged to have chosen to pursue patent protection via litigation against all would-be competitors regardless of merit.[177] Examples of such behavior include infringement claims brought by AbbVie against Sandoz's biosimilar for formulations that were neither present in Humira nor the Sandoz biosimilar;[178] abandoning a patent to avoid an adverse judicial decision by the U.K. High Court of Justice that would reveal its invalidity and end its ability to enforce these patents elsewhere in Europe;[179] and then submitting an additional patent application for

173. Hoen, *supra* note 171. If AbbVie was pursuing legitimate patent applications, the 53% approval rate would be highly concerning for the company. The patents should represent 247 novel innovations. However, the low approval rate indicates that many of the patents sought have underlying issues and raises a genuine concern that the sheer number of patents being sought is more likely business strategy, rather than a reflection of actual innovation.

174. *Humira* Complaint, *supra* note 39, ¶¶ 54, 64.

175. Amended Complaint & Demand for Jury Trial, Mayor & City Council of Baltimore v. AbbVie Inc., 465 F. Supp. 3d 811 (N.D. Ill. 2020), *sub nom. In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811 (N.D. Ill. 2020) (No. 1:19-cv-01873), ¶¶ 90, 91 [hereinafter "Amended *Humira* Complaint"]. As presented by AbbVie's CEO Richard Gonzalez, the patent minefield was part of a concerted corporate long-term strategy in an effort to preserve AbbVie's Humira profits. *See* Richard Gonzalez, *AbbVie Long-Term Strategy* (Oct. 30, 2015), http//:www.biotechduediligence.com/uploads/6/3/6/7/6367956/abbvie_strategy_presentation__1_.pdf [https//:perma.cc/JQ2N-T3WL].

176. Amended *Humira* Complaint, *supra* note 175, ¶¶ 126–29 ("[A]ny manufacturing or process patents resulting from patent applications filed more than one year after Humira's launch either describe a method used to manufacture Humira at launch or not. *Either way, such post-one-year patents cannot be used to prevent biosimilar entry.* The logic is this: If a formulation was used to make Humira at its launch, a patent application filed on that formulation more than a year after Humira's launch fails the novelty requirement of 35 U.S.C. § 102. It falls outside of the one-year grace period granted to the inventor and the invention is therefore not patentable. . . . If a patented formulation does not describe Humira as approved by the FDA and made at its launch, the patented formulation is not Humira but instead some modification of it . . . [and] *thus cannot be used to block biosimilar versions of Humira*." (emphasis added)).

177. *Id.* ¶¶ 167, 195.

178. *Id.* ¶¶ 167, 168.

179. *Humira* Complaint, *supra* note 39, ¶¶ 80–81.

the same subject matter as the abandoned patent just prior to its abandonment to escape adverse litigation results but continue to use the same patents to exert claims against competitors elsewhere.[180]

Despite what appears to be AbbVie's anticompetitive motive and intent, all competitors' agreed to the de facto market allocations agreements.[181] All seven potential competitors to AbbVie's Humira entered into agreements with AbbVie not to launch their biosimilars in the U.S. until 2023, despite the fact they could instantly enter into all non U.S. markets beginning in 2018 and that four had already received FDA approval.[182] AbbVie began by settling with the first-to-file competitor — Amgen — granting the biosimilar creator an agreed U.S. entry date of January 31, 2023.[183] Even though Amgen was "the defendant in the litigation and had no claims to damages or other monetary relief," AbbVie effectively agreed to give Amgen a de facto five-month exclusivity period worth almost a billion USD.[184] All the subsequent settlements resulted in staggered U.S. entry dates after June 30, 2023, thus providing Amgen the exclusivity.[185] In exchange for delayed U.S. entry, AbbVie also agreed to grant the remaining competitors access to the lucrative EU market.[186]

Because of the significantly lower prices for Humira in Europe, competition in Europe poses a smaller threat to AbbVie's overall profits, thus incentivizing AbbVie to "give up" its hold on the European market in exchange for the benefit of maintaining a monopoly over the U.S. market.[187] Allowing competitors entry into certain markets but not others unlawfully allocates the markets

180. *Id.* ¶ 81.

181. Amended *Humira* Complaint, *supra* note 175, ¶ 206.

182. *Id.* ¶¶ 211, 212. Amgen received FDA approval for its biosimilar in September 2016, while Boehringer received approval in August 2017, Sandoz received approval in October 2018, and Bioepis received its approval in July 2019. *Humira* Complaint, *supra* note 39, ¶¶ 59–62; *FDA Approves Adalimumab Biosimilar, Samsung Bioepis' Hadlima*, CTR. FOR BIOSIMILARS (July 23, 2019), https//:www.centerforbiosimilars.com/news/fda-approves-adalimumab-biosimilar-samsung-bioepis-hadlima [https//:perma.cc/743J-HFTJ].

183. *Humira* Complaint, *supra* note 39, ¶ 211.

184. Amended *Humira* Complaint, *supra* note 175, ¶ 151; *see id.* ¶ 154 ("Even if biosimilars captured only 20% of the market with price reductions of 20% (both conservative figures used here for emphasis only), biosimilar revenues would have been $2.2 billion in 2018 or $913 million for five months.").

185. *Id.* ¶ 211. The earliest U.S. entry date was granted for January 31, 2023. The following six entry dates are spread out between June 30, 2023 and November 20, 2023. *Id.*

186. *Humira* Complaint, *supra* note 39, ¶¶ 94, 95.

187. *Id.* ¶ 96.

between horizontal competitors.[188] Already, and despite the already-lower prices of Humira in Europe, once the biosimilar competition entered the market, Humira's price dropped eighty percent.[189] Meanwhile, U.S. consumers are denied the ability to buy cheaper Humira biosimilars.

Unfortunately, Judge Shah, the district court judge ruling in *In re Humira*, treated the early entry into the European market as somehow justifying the extended monopolization of the U.S. market and the agreements by Humira rivals to delay entry into the U.S. market. Specifically, though on its face a market allocation arrangement, Judge Shah found that because the entry into the EU market occurred *prior* to U.S. patent expiry, it did not run afoul of *Actavis* pay-for-delay principles.[190] His ruling interprets *Actavis* to immunize pay-for-delay in the U.S. so long as competitors can enter another market prior to a patent expiration date[191] — no matter that these same competitors with FDA-approved biosimilars agreed not to bring their undoubtedly profitable products to the U.S. market during the same period, despite already having overcome the regulatory barriers. Of course, this interpretation of *Actavis* as blessing any agreement allowing entry before patent expiry represents a rejection of the basic precept of *Actavis* that rejected the scope-of-the-patent test.[192]

This runs counter to conducting antitrust analysis within a relevant market. The relevant geographic market for *Humira* is the United States[193] and the drastically different pharmaceutical regulatory regimes in the U.S. and Europe prevent AbbVie or a rival from selling Europe-marketed biologics to U.S. consumers.[194] As

188. The temporary nature of the market allocation can be considered valid if considered ancillary to the main business purpose of a lawful contract and "necessary to protect covenantee's legitimate property interest" as in certain non-compete agreements. *Compare* Palmer v. BRG of Georgia, Inc., 498 U.S. 46, 50 (1990) (holding an agreement not to compete in the other's territory to be per se unlawful), *with* Lektro-Vend Corp. v. Vendo Co., 660 F.2d 255, 265 (7th Cir. 1981) ("[C]ovenants not to compete are valid if (1) ancillary to the main business purpose of a lawful contract, and (2) necessary to protect the covenantee's legitimate property interests, which require that the covenants be as limited as is reasonable to protect the covenantee's interests." (citing United States v. Addyston Pipe & Steel Co., 85 F. 271, 281–82, *aff'd as modified*, 175 U.S. 211 (1899))).

189. *Humira* Complaint, *supra* note 39, ¶ 96.

190. *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 839 (N.D. Ill. 2020).

191. *Id.*

192. Brief of Amicus Curiae the Fed. Trade Comm'n Supporting No Party at 6–7, *supra* note 164.

193. *In re* Humira, 465 F. Supp. at 826.

194. *Id.* at 821–22 (explaining biologics' approval process by the FDA).

such, the early entry dates for the European markets could not have conferred benefits onto U.S. consumers unless those consumers took flights to Europe to take advantage of cheaper European drug prices. Evidence of the lack of procompetitive benefits for U.S. consumers can be seen in the 7.4% increase in the U.S. price for Humira in 2020, following a 6.2% increase in 2019, as well as in AbbVie's increasing revenue from the drug.[195] While U.S. sales of Humira continue to account for an increasing overall proportion of AbbVie's Humira revenue,[196] AbbVie's international Humira revenue is declining due to "direct biosimilar competition in certain international markets."[197] Thus, while U.S. prices continue to grow to supracompetitive levels and fill AbbVie's coffers thanks to the lack of competition, European and other international markets benefit from lower prices derived in part — as seen in AbbVie's own words above — from direct biosimilar competition.

The district court's handling of the market allocative effects of AbbVie's reverse payments was flawed in another fundamental way: it improperly created a presumption that market entry prior to patent expiry immunizes a reverse payment from antitrust scrutiny. This directly rejects the basic holding of *Actavis* that patent settlements do not receive a presumption of legality or immunity from antitrust scrutiny.[198] The behavior at issue in *Actavis* included settlement terms that allowed market entry five years prior to the challenged patent expiry, but still were considered to have

195. Noam N. Levey, *Vaccine Maker Got $1 Billion from Taxpayers. Now It's Boosting Drug Prices*, L.A. TIMES (Sept. 14, 2020), https//:www.latimes.com/politics/story/2020-09-14/drug-maker-got-1-billion-from-taxpayers-boosting-prices [https//:perma.cc/VW93-KQGJ].

196. Prior to the settlement agreements at issue, Humira sold in the U.S. brought AbbVie $12.4 billion in revenue in 2017 — accounting for 67% of its *total Humira revenue*. Brief for States of Washington and California et al. as Amici Curiae Supporting Plaintiffs-Appellants at 18, UFCW Local 1500 Welfare Fund v. AbbVie, Inc., No. 20-2402 (7th Cir. Oct. 13, 2020) [hereinafter "Brief for State Amici"] (citing AbbVie Inc., Annual Report (Form 10-K) at 31 (Feb. 21, 2020), https//:investors.abbvie.com/static-files/71f9318f-9a32-42ee-92ee-a34975edcd19 [https//:perma.cc/EZW9-RDG5] [hereinafter "AbbVie 2019 Annual Report"]). As of February 2020, AbbVie's U.S. revenues have grown an addition $1.2 billion (total of $14.9 billion) and U.S. sales now account for over 77% of its total Humira revenue. *Id.*

197. AbbVie 2019 Annual Report, *supra* note 196, at 32.

198. Brief for State Amici, *supra* note 196, at 3 (arguing that by creating such a presumption, the court resurrects the "scope of the patent" test explicitly discredited in *Actavis*); Brief of Amicus Curiae the Fed. Trade Comm'n Supporting No Party at 6, *supra* note 164 ("[T]he Court rejected the 'scope-of-the-patent' test applied by the court of appeals and its resulting immunity for settlement agreements that allow entry before patent expiration.").

"potential for genuine adverse effects on competition."[199] Yet, the *In re Humira* district court erroneously claimed that *Actavis* both "approved" such agreements and that entry before patent expiration removes them from antitrust review regardless of the agreement's purpose or effect.[200]

This interpretation conflicts with the Supreme Court's analysis and subsequent *Actavis* holding.[201] The misinterpretation is even more glaring upon close observation of the court's language. The *In re Humira* district court noted that the claims reliant on *Actavis* calling for antitrust scrutiny "bump against a sentence in *Actavis* that approved settlements where the only reverse payment is an agreement permitting the alleged infringer to 'enter the patentee's market prior to the patent's expiration.'"[202] But that language is raised in the context of alternative settlement options lacking any payments and ignores the fact that the illegal *Actavis* agreements at issue included an early entry-date.[203] Subsequent court treatment supports the notion that this example did not create a presumption of legality for agreements where one feature is early market entry, no matter if that early market entry was given in exchange for delayed U.S. market entry.[204]

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199. Brief for State Amici, *supra* note 196, at 5–6; FTC v. Actavis, Inc., 570 U.S. 136, 145, 153 (2013).

200. *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 819, 827 (N.D. Ill. 2020) (No. 19-CV-1873).

201. As noted by State Attorneys Generals amicus curiae for plaintiffs, *Actavis* overruled "a near-immunity rule by applying a functional analysis of the potential anticompetitive effects of settlements agreements." Brief for State Amici, *supra* note 196, at 6 (citing *Actavis*, 570 U.S. at 154) ("[P]ayment in return for staying out of the market . . . keeps prices at patentee-set levels, potentially producing the full patent-related . . . monopoly return while dividing that return between the challenged patentee and the patent challenger."). Furthermore, in a recent FTC matter, the agency notes that *Actavis* did not "state a general rule that removes settlement agreements from antitrust scrutiny" unless they featured unusual provisions like a reverse payment. *Id.* (citing 1-800 Contacts, Inc., 166 F.T.C. 274, 287 (2018) ("[T]he form of a settlement alone is not what subjects an agreement to antitrust scrutiny.")).

202. *In re* Humira, 465 F. Supp. 3d at 827 (quoting *Actavis*, 570 U.S. at 158).

203. *Actavis*, 570 U.S. at 158 ("They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.); *supra* note 199 and accompanying text.

204. Staley v. Gilead Scis., Inc., 446 F. Supp. 3d 578, 610 (N.D. Cal. 2020) ("[It] does not hold that an early entry date (relative to the patent expiration date) is *automatically* procompetitive." (emphasis in original)). To determine whether an agreement is anticompetitive, courts must examine the "cumulative effect of the factual allegations[.]" Picone v. Shire PLC, No. 16-CV-12396, 2017 WL 4873506, at *12 (D. Mass Oct. 20, 2017) (quoting Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 14 (1st Cir. 2011)); *see* Sergeants Benevolent Ass'n Health & Welfare Fund v. Acta Vis, PLC, No. 15-CV-6549, 2016 WL 4992690, at *13

The *Actavis* language used by the *Humira* district court was one example of a type of agreement that could be procompetitive and using it to create a new presumption of legality is a misapplication of the case law. *Actavis* gave a set of five considerations as guidance for a holistic determination of whether a settlement agreement is anticompetitive,[205] yet the *Humira* court viewed the fifth factor — the opportunity to settle on other terms — as "an important exception" to antitrust scrutiny.[206] By viewing one provision as conferring automatic presumptive legality, the court's reasoning runs counter to the *Actavis* holding that such agreements are not presumptively legal and must be evaluated *on the whole*.

IV. PROPOSED SOLUTIONS: SUGGESTIONS FOR CLOSING REGULATORY LOOPHOLES AND CLARIFYING LEGAL TREATMENT

One new law or clarified legal treatment on its own is unlikely to solve the U.S. drug pricing problem. Updating both legislative and legal standards and apportioning burdens of proof to parties who might otherwise withhold the evidence under claims of privilege is key to more meaningful enforcement efforts against the anticompetitive abuses of pay-for-delay settlement agreements. Though beyond the scope of this Note, it is clear that legislation reforming the patent regime will also be necessary for a meaningful path forward. At the moment, AB 824 provides the clearest and most comprehensive standards to guide courts in their antitrust analyses of settlement agreements with reverse payments. This guidance is necessary when defendants are consistently able to take advantage of vagueness to avoid detection and enforcement. A federal version of AB 824 would close some of the current regulatory loopholes and provide clarity and fairness without impeding good faith dispute settlements.

Part IV.A will use an in-depth application of the *Actavis* framework to the *Humira* allegations to show that for antitrust analysis purposes, biologics should be treated the same as small molecule drugs. Not only does the behavior at issue mirror the way that

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(S.D.N.Y. Sept. 13, 2016) ("Courts must determine the anticompetitive effect of such settlements by considering traditional antitrust factors[.]").

205. *See infra* Part IV.A.1 (going through the *Actavis* considerations in detail).

206. *In re* Humira, 465 F. Supp. 3d at 839 ("*Actavis* identifies a settlement that allows early entry but without the patentee paying a competitor to stay out of the market as one type of agreement that is not an antitrust problem. This makes sense because such settlements increase competition by cutting monopolies short." (citations omitted)).

reverse payments work in the small molecule sphere — as evidenced by the court's use of the *Actavis* framework in *In re Humira* — but recent congressional treatment further supports treating biologics and small molecule drugs the same for antitrust purposes. Part IV.B concludes by advocating for a federal version of AB 824 that closes legal loopholes and subjects all pharmaceutical drugs to similar antitrust legal standards.

A. MOLECULE SIZE DOESN'T MATTER: *ACTAVIS*'S SPIRIT APPLIES TO BIOLOGICS

Neither the regulatory pathway for drug approval nor the size of a drug's molecules change the business incentives for gaming the competitive landscape. Though the *In re Humira* district court applies *Actavis* without hesitation to Humira, a biologic, it erroneously focused on the timing of market entry instead of the core precepts of *Actavis*.[207] During appellate review, the Seventh Circuit should explicitly reconcile the treatment of similar biologic drug settlement agreements with *Actavis* to provide clarity for lower courts going forward.

The application of *Actavis* to reverse payment agreements concerning biologics is proper for three reasons. First, the reasoning behind *Actavis* directly applies to market allocation agreements made in the course of patent infringement litigation, regardless of whether that litigation arises under the Hatch-Waxman Act or the BPCIA. In both cases, the concerns about settlements motivated by consideration other than the parties' assessments of the underlying patents' strengths are the same. Second, subjecting biologic settlement agreements to antitrust scrutiny falls within the congressional intent of the BPCIA and is consistent with the many legislative proposals that treat biologic and small molecule drug patent settlement agreement similarly. Third, such an application supports public policy considerations.

1. Actavis *Considerations Applied to Biologic Humira's Settlements*

The *Humira* complaint focuses primarily on the use of settlement agreements to engage in market allocations — a traditionally

207. *Id.* at 827–29.

per se violation.[208] However, it argues in the alternative that the *Actavis* rule of reason applies to "a patent settlement agreement between a brand and generic manufacturer . . . when the brand provides the generic manufacturer a 'large and unjustified' payment in exchange for the generic manufacturer dropping its challenge."[209] The agreements at issue in the *Humira* complaint trigger the five *Actavis* considerations, and thus the alternate argument should succeed and the district court opinion should be overturned on appeal.

In the words of the *Actavis* court, the agreements at issue have the potential for "genuine adverse effects on competition."[210] These agreements have resulted in de facto market allocations between Europe and the U.S.,[211] and have successfully prevented biosimilar entry into the U.S. market for seven years.[212] This is an example where "[t]he patentee and the challenger gain; the consumer loses."[213] As explained *supra*, the practical effects of these agreements are continuously increasing U.S. prices without biosimilar competition.[214]

Second, these agreements are not always justified.[215] While the Court awaits the procompetitive justifications proffered by AbbVie for their seven agreements that delayed competition, AbbVie's CEO explicitly stated his intention to "vigorously" enforce AbbVie's patents as part of its business strategy to force delay via litigation.[216] AbbVie's company presentations similarly "tout[ed] its 'Broad U.S. Humira Patent Estate' as a strategy to prevent

208. *Humira* Complaint, *supra* note 39, ¶¶ 13–14, 209 (allowing AbbVie to "charge inflated prices — capturing nearly $20 billion in 2018 revenues — while allowing biosimilars to sell in the European market, where drug prices — and hence profits — are generally much lower. . . . Simply put, AbbVie has cooked up a monopoly maintenance scheme that has U.S. patients paying higher monopoly prices while patients in Europe benefit from competition.").

209. *Id.* ¶ 210 (citing FTC v. Actavis, Inc., 570 U.S. 136, 158 (2013)).

210. *See Actavis*, 570 U.S. at 153.

211. *Humira* Complaint, *supra* note 39, ¶¶ 13–14.

212. *Id.* ¶¶ 59, 92.

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

214. *See supra* notes 193 to 196 and accompanying text (explaining how the *Humira* district court improperly used the European market as a procompetitive justification for the reverse payments at issue).

215. *Actavis*, 570 U.S. at 156.

216. *Humira* Complaint, *supra* note 39, ¶ 73 (citing Andrew Pollack, *Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions*, N.Y. TIMES (July 15, 2016), https//:www.nytimes.com/2016/07/16/business/makers-of-humira-and-enbrel-using-new-drug-patents-to-delay-generic-versions.html [https//:perma.cc/V4DK-GWWD]).

biosimilar competition through at least 2023."[217] This indicates anticompetitive intent behind these agreements.

Third, under *Actavis*, the patentee must possess power to bring about harm in practice.[218] AbbVie's position as market leader with the top-selling U.S. drug, its extensive patent estate and artificially extended patent monopoly, and its successful foreclosure of the U.S. market to competing biosimilars all demonstrate that AbbVie has been able to impede the market and harm consumers.[219] Because AbbVie holds and asserts patent coverage for Humira, its market share of sales in the U.S. is close to 100%.[220]

Fourth, and most critically, *Actavis* notes that an "unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival" and might be explained by anticompetitive motives.[221] Beyond the AbbVie CEO's stated intent to impede biosimilar competition,[222] the sheer number of settlements and the vast disparate treatment of U.S. and non-U.S. markets should be suspicious. Furthermore, in the U.K., to avoid an adverse judgment and in the middle of litigation, AbbVie revoked or de-designated three patents that were the basis of patent infringement claims being litigated.[223] The *Humira* district court denied that the settlement's U.S. and EU staggered market entry dates were a form of quid pro quo because AbbVie was not restricted from selling Humira in Europe, and thus was an exercise of their patent rights.[224] However, the effects of the agreements,[225] the history of patent invalidation in the U.K., and the size of the rewards — including avoiding lengthy and costly litigation — demonstrate a likelihood that the agreements are

217. *Id.* ¶ 74 (citing Gonzalez*, supra* note 175).
218. *Actavis*, 570 U.S. at 157.
219. *Humira* Complaint, *supra* note 39, ¶¶ 57, 68, 74, 77.
220. *Id.* ¶ 114.
221. *Actavis*, 570 U.S. at 157.
222. *See supra* text accompanying note 193.
223. *Humira* Complaint, *supra* note 39, ¶¶ 80–81 ("[A] United Kingdom High Court decision [ ] 'reached a final ruling on invalidity . . . despite the fact that AbbVie . . . revoked or de-designated its patents with respect to the United Kingdom during the proceedings[ ]' . . . [where] 'the intention and objective effect . . . is to shield its patent portfolio from examination of validity whilst continuing to file further divisionals and to threaten infringement proceedings against biosimilars[.]").
224. *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 836–38 (N.D. Ill. 2020) (No. 19-CV-1873).
225. *See supra* notes 193–196 (noting that the U.S. Humira prices have gone up absent any biosimilar competition while prices in the EU have declined expressly due to increased competition).

anticompetitive. Though the district court claims that the case "doesn't depend on the competitive benefits in one market (Europe) justifying the effects in another (the U.S.),"[226] the opinion repeatedly emphasizes the early European market entry to justify the agreements' procompetitiveness.[227] Fifth and finally, parties are not prevented from settling lawsuits without large and unjustified payments.[228]

Taking all of the *Actavis* considerations into account, it is clear that the same economic incentives to artificially extend small molecule patent-granted monopolies also exist in the biologic sphere. Though the payment amounts to Humira's biosimilar competitors are not public, the transfer of other valuable consideration (e.g., access to the European market and limited U.S. competition upon entry) and the aggregate value of all seven agreements demonstrate a transfer of value that likely exceeds saved litigation costs. In fact, aggregating the total revenues conferred from U.S. Humira sales since 2018 — the year AbbVie began entering its settlement agreements — indicates that AbbVie has received $28.5 billion in net revenue for 2018 and 2019, of which at least $3.827 billion can be accredited to the extended and preserved monopoly pricing.[229] The harmful effects are similarly clear from the continued large price increases only in the U.S.[230] Though the enormous value

226. *In re* Humira, 465 F. Supp. at 842.

227. *Id.* at 824, 842, 845, 846.

228. FTC v. Actavis, 570 U.S. 136, 158 (2013) ("Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.").

229. Even this number likely understates the value of these agreements as Humira's price would inevitably decrease upon competitors' market entry, diminishing the constant used in this calculation. *See* Amended *Humira* Complaint, *supra* note 175, ¶ 43 ("Once a generic hits the market, it quickly erodes the sales of the corresponding drug, often capturing 80% or more of the market within the first six months after launch, 90% of the brand's unit drug sales after a year[.]"); Premus, *supra* note 128 at 281–82 (suggesting that the introduction of a biosimilar results in a 30% discount of the original RB price). The Author derived the $3.827 billion number using AbbVie's FY2019 Financial Report that shows that U.S. sales of Humira resulted in $14.864 billion in FY2019, $13.685 billion in FY2018, and $12.361 billion in FY2017 in *net* revenues. Using the FY2017 number as the constant (as it was prior to the agreements at issue), the additional net revenue derived from the U.S. monopoly prices, after the settlement agreements, is valued at $3.827 billion. During the same period, international Humira sales increased from $6.066 billion in FY2017 to $6.251 billion in FY2018 before decreasing to $4.305 billion in FY2019. AbbVie 2019 Annual Report, *supra* note 196, at 38.

230. *See supra* note 40 and accompanying text (noting that Humira had one of the largest price increases for pharmaceuticals in 2020, increasing the annual cost to $72,000 per patient).

flowing to AbbVie from these agreements is clear, the nature and value transferred to its biosimilar competitors is not as clear. While procompetitive justifications for these agreements are not readily apparent, AbbVie's foreign patent conduct suggests the parties understood the frailties of Humira's patent position and secured some consideration for staying out of the highly lucrative U.S. market.

The court rejected the notion that the competitors' near-immediate entry into the European market, despite the delayed U.S. entry dates, was a form of quid pro quo, and found that because competitors were able to enter the European market early, the settlements qualified for the *Actavis* exception discussed above.[231] This line of reasoning does a particular disservice to U.S. patients and distorts *Actavis* such that companies seeking to extend monopoly pricing in the U.S. can do so easily at the smaller expense of increased competition in global markets already subject to higher regulatory and legal standards — not to mention their stricter price controls. The *In re Humira* district court reasoning leads to a dangerous anticompetitive slippery slope — one where U.S. patients continue to be subjected to supracompetitive prices long after other countries get the benefits of lower prices from competition.

2. *BPCIA's Spirit Does Not Exclude Settlements from Antitrust Scrutiny*

For all intents and purposes, the BPCIA is modeled off of the Hatch-Waxman Act.[232] Its goal is similarly two-fold: to promote innovation in biologic drugs and to promote the consumer's interests in greater competition and more affordable drugs.[233] Echoing the procompetitive reasoning behind the Hatch-Waxman Act, Congress took industry experience with the Hatch-Waxman Act into consideration, "import[ing] a familiar and successful compromise between biologics manufacturers' desire for a limited monopoly to incentivize innovation and consumers' need for broad access to

231. *In re* Humira, 465 F. Supp. 3d at 824, 842, 845, 846; *see also id.* at 841 ("There is also a broader reason to uphold these agreements under antitrust review: encouraging patent litigants to settle worldwide patent disputes. Any early entry date in one region could always be considered a transfer of value in return for a later entry date in another region.").

232. *See supra* Part II.C (discussing the regulatory background and legislative intent of the BPCIA).

233. *See supra* notes 126–127.

biotherapies."[234] During the hearings on the 2009 BPCIA, Congress heard vigorous debates on the appropriate length of market exclusivity that should be granted to biologic manufacturers.[235] While the BPCIA ended up granting a twelve-year period of exclusivity to manufacturers to "promote innovation and to convince companies to invest in biologics[,]" every FTC budget proposal since 2009 has called for a reduction in the exclusivity period to "foster greater [follow-on] biologic competition and reduce the cost burden on patients and payers associated with these drugs."[236]

Courts must also take consumer needs into account when considering BPCIA-related settlement agreements. Affordability is critical for consumers, particularly when biologics are increasingly expensive as well as more popular and prevalent.[237] *Actavis* acknowledged the "general procompetitive thrust" behind the Hatch-Waxman Act that requires disclosure of settlement terms to federal antitrust regulators, subjecting these agreements to antitrust scrutiny.[238] Though disclosure was not initially required by the BPCIA, the mere fact that disclosure of "agreements between biologic and biosimilar companies that relate to the manufacture, marketing, or sale of biologic and biosimilar products" to antitrust agencies is now required via the Patient Right to Know Drug Prices Act supports extending antitrust scrutiny and *Actavis* to biologic products.[239] Other recent congressional acts support the finding that in the antitrust sphere, the size of the molecule does not matter and both biologics and small molecules companies should be required to follow the same antitrust laws.[240]

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234. Premus, *supra* note 128, at 273 (citing Joanna M. Shepherd, *Biologic Drugs, Biosimilars, and Barriers to Entry*, 25 HEALTH MATRIX 139, 161 (2015), http//:scholarlycommons.law.case.edu/healthmatrix/vol25/iss1/8/ [https//:perma.cc/8DNM-AEJU]).

235. *Id.* at 271.

236. *Id.* at 272.

237. *See supra* Part II.C (discussing the nature of the biologic market and how biologic drugs are increasingly seen as the future source for pharmaceutical revenues).

238. FTC v. Actavis, 570 U.S. 136, 152 (2013).

239. *See* Jonathan Berman et al., *New Law Requires Disclosure of Biologic Patent Settlement Agreements to Antitrust Authorities*, LEXOLOGY (Oct. 17, 2018), https//:www.lexology.com/library/detail.aspx?g=b3ed2b4b-11a1-419b-8b56-5586c60ba15a [https//:perma.cc/25YN-UG5H] ("It is no surprise that biologic product agreements now receive parallel treatment to small-molecule drug agreements. The Act demonstrates the continued [ ] focus on drug prices and adds to the growing attention from authorities and private litigants to antitrust issues related to biologic drugs.").

240. Signed into law in 2020, the CREATES Act condemns anticompetitive gaming of FDA requirements for sample sharing and abuse of the REMS program for *both biologics and small molecule drugs*. *See* Donna Yesner & Jacqueline Berman, *Congress to Pharma: Hand Over Those Samples*, Morgan Lewis (Jan. 8, 2020), https//:www.morganlewis.com/

3. *Public Policy Demands Antitrust Scrutiny for Biologics*

Subjecting large molecule manufacturers to antitrust scrutiny helps ensure that companies are motivated by innovation and consumer needs and that U.S. patients, health insurance providers, and tax dollars are not wasted through the illegal extension of monopoly prices. Despite concerns that antitrust scrutiny will dampen innovation,[241] and thus incentives for competition, empirical evidence on the effects of generic filings after *Actavis* suggests those concerns are misguided.[242] With the lucrative U.S. biosimilar market virtually untapped, and large molecule drugs poised to become more prevalent, pharmaceutical manufacturers will undoubtedly be incentivized by these profit opportunities to continue to innovate and create cheaper alternatives to biologics.

The projected cost savings from biosimilar products, particularly those that would be deemed interchangeable, are substantial. Industry estimates show that a successful biosimilar market entry results in a fifteen to thirty percent discount for drug treatments.[243] These savings would also likely stop patients from skipping doses or otherwise not adhering to doctor-prescribed medication plans to save money. Reducing these costs could result in savings between $100 to $300 billion in avoidable health care costs that are currently attributed to nonadherence.[244] These savings are very clearly in the interest of the U.S. healthcare budgets,

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blogs/asprescribed/2020/01/congress-to-pharma-hand-over-those-samples [https//:perma.cc/5UKF-RA95]. Similarly, the Stop STALLING Act that aims to enable the FTC to deter the filing of sham citizen petitions that are actually an attempt to interfere with approval of a competing drug also targets *both biologic and small molecule manufacturers*. *See* Stop STALLING Act, S. 1224, 116th Cong. (2019).

241. *See Actavis*, 570 U.S. at 176 (Roberts, C.J., dissenting) ("The irony of all this is that the majority's decision may very well discourage generics from challenging pharmaceutical patents in the first place. . . . Taking the prospect of settlements off the table . . . puts a damper on the generic's expected value going into litigation and decreases its incentive to sue in the first place.").

242. Premus, *supra* note 128, at 280 ("An empirical study that looked at the number of paragraph IV ANDAs filed within twelve months after *Actavis* noted that there was an increase in the number of filings as compared to the previous four years. These findings indicate that generic competition 'appears to have actually accelerated in the wake of the *Actavis* decision.'" (citation omitted)).

243. *Id.* at 281–82 ("For example, Enbrel, a biologic drug used for the treatment of rheumatoid arthritis costs approximately $48,472.32 over the course of a year. While currently no follow-on biologic version exists, if one were introduced with pricing at 15 to 30% below the cost of the reference product, the cost per year would range from $33,930.62 to $41,201.47. This would provide a cost savings ranging from $7,270.85 to $14,541.70 per year.").

244. *Id.* at 282.

taxpayers, and public health. By reducing companies' abilities to game the system, it is U.S. patients who win.

B. NEW LEGISLATIVE TREATMENT: CLOSING THE REGULATORY LOOPHOLES

While the generic industry has challenged AB 824 on the basis of federal preemption, due process, and dormant commerce clause concerns,[245] the challenges have not been successful and would be further blunted were a federal version of the law created. The new California law provides clarity for lower courts and requires drug companies to produce evidence often concealed under claims of privilege. By providing clear guidelines and preventing judicial "shortcuts" that presume untested patents to be valid and infringed, courts will be less likely to prolong judicial proceedings and dismiss meritorious challenges to anticompetitive agreements. It also reduces the waste of judicial resources analyzing irrelevant factors — such as whether a drug falls under the Hatch-Waxman Act or the BPCIA.

AB 824 achieves this goal in three main ways. First, AB 824 clarifies that for antitrust regulatory purposes, biologic drugs should be treated the same as small molecule drugs.[246] Second, to protect against over-regulation, it provides robust exceptions so that permissible settlement agreements, including those with significant payments that are shown to be procompetitive, will not be subject to expensive litigation.[247] Third, it adjusts burdens of proof in accordance with the directions of the California Supreme Court in *In re Cipro Cases I & II*[248] to reduce gamesmanship that unduly defeats meaningful enforcement actions.

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245. *See* Ford, *supra* note 159. Whenever a new stringent state law passes, federal preemption almost always is a concern. However, the bill has been signed into law and the Ninth Circuit dismissed the challenge. Ass'n for Accessible Meds. v. Becerra, No. 2:19-cv-02281, 2019 WL 7370421 (E.D. Cal. Dec. 31, 2019) (denying a preliminary injunction motion seeking to bar Act's enforcement), *aff'd*, 822 F. App'x 532 (9th Cir. 2020) (holding the plaintiff lacked standing and ordering dismissal). The generic pharmaceutical industry trade organization has since filed a second suit, Ass'n for Accessible Meds. v. Becerra, No. 2:20-cv-01708-TLN-DB (E.D. Cal. Sept. 14, 2020), and a new motion for preliminary injunction, which is pending as of this writing.

246. CAL. HEALTH & SAFETY CODE §§ 134000(d), (e) (West 2020) (covering both the BPCIA and the Hatch-Waxman, and explicitly including biologics and biosimilars).

247. *Id.* §§ 134002(a)(2)(A)–(F).

248. *In re* Cipro Cases I & II, 61 Cal. 4th 116, 348 P.3d 845 (2015).

By focusing on payment as "anything of value," AB 824 "allows courts to avoid the 'turducken'[249] approach of 'deciding a patent case within an antitrust case about the settlement of the patent case.'"[250] More importantly, it permits government enforcers to bring suits based on the existence of some consideration, without first having to show that the payments are "large" and "unjustified" to survive a motion to dismiss. Instead, AB 824 relies on defendants to justify the size and amount of the consideration provided in exchange for its rival's agreement to delay competition.[251] This aligns the proof with the parties possessing the evidence, thereby reducing the incentives of companies to these agreements to withhold evidence and defeat enforcement actions. AB 824 also incentivizes companies to maintain proper records for settlement purposes.

Lastly, by creating a burden shifting scheme, the law allows all parties to faithfully investigate any suspicious settlement arrangements, while still giving plenty of space for companies to settle disputes legally with reasonable or no payments. However, it does create a rebuttable presumption where payments are present, and also provides a presumption that the relevant product markets are the relevant branded drug and any biosimilar or generic versions to prevent dilatory and wasteful litigation on what is usually a foregone conclusion.[252] While some drug companies have argued that the presumptions will prevent them from settling patent litigation,[253] the law clearly allows them to settle without making

249. A turducken is a legendary culinary feat in which a duck is stuffed into a chicken, which is then stuffed into a turkey, before being cooked. *See* Amanda Hesser, *Turkey Finds Its Inner Duck (and Chicken)*, N.Y. TIMES (Nov. 20, 2002), https//:www.nytimes.com/2002/11/20/dining/turkey-finds-its-inner-duck-and-chicken.html [https//:perma.cc/BSU2-W6DL].

250. Carrier Brief, *supra* note 163, at 16 (internal citation added) (quoting FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012)). "Assessment of patent issues requires a court to formulate a prediction about the odds of a hypothetical litigation (which would center on issues of pure patent law) to ascertain what the settlement's competitive effects should be compared against. In light of the difficulties this would present, several authors and courts have taken to calling this the "turducken" approach." Erik Hovenkamp, *Antitrust Law and Patent Settlement Design*, 32 HARV. J.L. & TECH. 417, 437 (2019).

251. CAL. HEALTH & SAFETY CODE §§ 134002(a)(2)(C) (also providing an exception should no forecasts be available capping the payment to $250,000).

252. *Id.* § 134002(c). The relevant product market presumption essentially assures that a branded drug manufacturer whose patent is still being enforced will be considered a monopolist, making the essential question whether the manufacturer is a legal monopolist as afforded by its patent.

253. *See* Complaint, Ass'n for Accessible Meds. v. Becerra, No. 2:19-cv-02281, 2019 WL 7370421 (E.D. Cal. Dec. 31, 2019), *aff'd*, 822 F. App'x 532 (9th Cir. 2020).

excessive payments, and also to settle in any way in which they can demonstrate is procompetitive.[254]

V. CONCLUSION

As U.S. drug prices continue to soar, even for drugs that have been patented for almost a century and whose original patents have long since expired, it is clear that the system needs updating. The *In re Humira* litigation, which examines reverse payments that artificially extend a biologic brand drug exclusivity period and that divide markets between biosimilar competitors on a continental basis, is a prime opportunity to strengthen and clarify U.S. jurisprudence on reverse payments and market allocations. Not only can biologic drug regulation be brought into line with small molecule drugs, but the case provides a critical opening to resolve the conflicting legal treatment of reverse payments and what constitutes a payment or a transfer of value. It demonstrates that the regulatory pathway to approval does not diminish the opportunities for anticompetitive abuse, nor is it dispositive in determining levels of antitrust scrutiny. At its core, reverse payment case law is about improperly inducing rivals not to compete — manufacturing method be damned. By clarifying the law through legislation in this complicated area, the risks of decisions that fail to apply existing law such as in *In re Humira* might be avoided as well.

Extending antitrust scrutiny and the *Actavis* framework to biologic and biosimilar drugs falls in line with the Supreme Court precedent and analysis as well as with the congressional intent behind a multitude of adopted and proposed laws. Adopting a federal version of California's AB 824 and establishing a truncated rule of reason along with a burden-shifting scheme would significantly clarify the current circuit split and provide guidance for lower courts when analyzing *Actavis*-type reverse payments. Most importantly, and easily accomplished with an explicit ruling in *In re Humira* on appeal, the courts should firmly establish that *Actavis* subjects biologic manufacturers to antitrust scrutiny. While a

254. *See* Ford et al., *supra* note 159 ("California's new law truncates that rule of reason analysis by establishing a presumption of anticompetitive effect[.]"); Brad Albert et al., *supra* note 17 (noting that since AB 824 came into effect, "the most common patent settlements — those in which the generic agrees not to sell for some period but then gets a non-exclusive license to enter prior to patent expiration without compensation — have not disappeared" and that in the first nine months of 2020 "appear to have increased slightly since the law took effect as compared to the same period in 2019").

new, clarified standard would be helpful, the requisite doctrine exists. It is only up to the courts and agencies to actually enforce it without misinterpretation and unnecessary litigation.