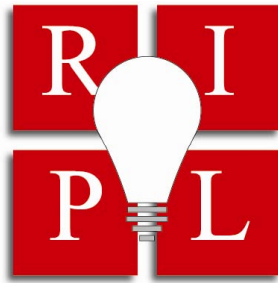


# THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



## DELAYING COMPETITION: HOW SOUND PUBLIC POLICY AND RIGOROUS ANTITRUST SCRUTINY CAN BE APPLIED TO CONTROVERSIAL PATENT SETTLEMENTS

SAM HENSEL

### ABSTRACT

The rising costs of prescription drugs are a growing concern for many Americans. The restraint of trade for pharmaceutical drugs is a cause of rising costs for consumers, as companies seek to push potential competitors out of the market to maintain profits. This unlawful restraint of trade will be discussed in this comment. Specifically, this comment will focus on "Pay for Delay" agreements, mostly between generic versus brand name pharmaceutical manufacturers. The proliferation of these agreements only leads to an unsustainable market that discourages innovation and advancement, and promotes fraud, as invalid patents are used as leverage to prevent generics from providing more choices to consumers in a more competitive market. This comment will also address a regulatory structure that can prevent parties from forming "Pay for Delay" agreements, while balancing between respecting the rights of patent holders, protecting consumers, and promoting market competition.

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*Cite as Sam Hensel, Delaying Competition: How sound public policy and rigorous antitrust scrutiny can be applied to controversial patent settlements, 17 J. MARSHALL REV. INTELL. PROP. L. 655 (2018).*

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SAM HENSEL\*

I. INTRODUCTION

How do we as a society want to handle the rising cost of prescription and over-the-counter pharmaceuticals? Should pharmaceutical drugs be a luxury only for those who can afford it? The rising costs of prescription drugs are a growing concern for millions of Americans. Perhaps no greater example of pain inflicted by high pharmaceutical prices exists than the infamous case of Martin Shkreli, the former CEO of Turing Pharmaceuticals, Inc.<sup>1</sup> Shkreli, branded the “the most hated man in America,” obtained an exclusive manufacturing license for Deraprim, which alleviates the effects of HIV/AIDS.<sup>2</sup> Shkreli hiked the price of Deraprim from \$13.50 to \$750 per capsule.<sup>3</sup>

The restraint of trade for pharmaceutical drugs is a cause of rising costs for consumers, as companies can restrain trade in a number of ways in order to maximize profit potential.<sup>4</sup> Such practices sometimes violate longstanding antitrust principles in the Sherman and Clayton Antitrust Acts.<sup>5</sup> The unlawful restraint of trade that is largely the subject of this comment is called a “reverse payment” settlement agreement, also known as a “Pay for Delay” agreement.<sup>6</sup> According to the Federal Trade Commission (FTC), these deals alone cost consumers \$3.5 billion annually.<sup>7</sup> Pay for delay agreements originate over disputes concerning whether a brand name drug manufacturer holds a valid patent against generic drug manufacturers.<sup>8</sup> When the parties settle, the brand name effectively pays the generic manufacturer a large sum of money not to enter the market to sell its bioequivalent drug.<sup>9</sup> The generic is thus paid not to compete, and the lack of market competition sticks consumers with higher prices as the brand rakes in larger profits.<sup>10</sup>

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<sup>1</sup> Phil McCausland, *Fraud Trial for Martin Shkreli, ‘Most Hated Man in America,’ Begins Monday*, NBC NEWS (Jun. 25, 2017, 8:14 PM), <http://www.nbcnews.com/news/us-news/fraud-trial-martin-shkreli-most-hated-man-america-begins-monday-n-776581>.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013) (endorsing Petitioner’s allegation in ¶ 45 of Brief).

<sup>5</sup> *Id.* at 2227.

<sup>6</sup> FED. TRADE COMM’N, *PAY FOR DELAY* (2017), <https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay>

<sup>7</sup> *Id.*

<sup>8</sup> *Actavis*, 133 S. Ct. at 2223 – 2224.

<sup>9</sup> *Id.* A generic drug is deemed “bioequivalent” if it contains the same active pharmaceutical ingredient as the brand drug and has the same dosage and form. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) (2011), as amended by the Food and Drug Administration Amendments Act of 2007, Public Law 110-85, 121 Stat. 823 (Sept. 27, 2007).

<sup>10</sup> *Id.* at 1159.

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As courts have taken up enforcement, drug manufacturers are creating increasingly complex settlement structures in an attempt to mask the anticompetitive effects of their agreements.<sup>11</sup> This comment makes the case for more aggressive government action taken to protect the economic interests of ordinary Americans while also respecting the intellectual property rights of putative patent holders. Legislative and regulatory proposals are currently under review to ensure rigorous enforcement by the FTC against pay for delay agreements and other unfair restraints of trade.<sup>12</sup>

Part I of this comment provides the necessary background on the Hatch-Waxman Act, the Supreme Court's landmark decision in *FTC v. Actavis*, the lower court's jurisprudence on post-*Actavis* lower-court jurisprudence, and relevant regulations and legislation. Part II provides an in-depth analysis of the FTC and courts' approaches to pay for delay agreements. Part III examines current and potential legislative proposals and whether it would be prudent for them to go a step further than the courts' holdings in prioritizing consumer welfare over abuses of patent rights. Part III provides a proposal to remedy the legal problems found in antitrust enforcement against pay for delay agreements in a way that recognizes the interests of consumers as a priority.

## II. BACKGROUND

The relevant history of pay for delay agreements begins with the Drug Price Competition and Patent Reform Act of 1984, also known as the Hatch-Waxman Act ("Hatch-Waxman").<sup>13</sup> Hatch-Waxman created procedures for resolving patent disputes between brand and generic manufactures.<sup>14</sup> When a generic seeks approval for a drug from the Food and Drug Administration (FDA), they must assure them that their product will not infringe a patent.<sup>15</sup> A generic may grant the FDA this assurance by claiming that the existing patent is invalid, thus obviating any potential for infringement through the drug's manufacture, use, or sale.<sup>16</sup>

Of course, this option (known as a 'Paragraph IV') frequently provokes litigation by the patentee.<sup>17</sup> Brands file infringement claims against the generic to quiet title to their patent.<sup>18</sup> Should the brand bring an infringement suit within 45 days of the

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<sup>11</sup> Joshua D. Wright, *Antitrust Analysis of Reverse Payment Settlements After Actavis: Three Questions and Proposed Answers*, FEDERAL TRADE COMMISSION (Sept. 25, 2017, 10:15 PM) <https://www.ftc.gov/public-statements/2014/10/antitrust-analysis-reverse-payment-settlements-after-actavis-three>.

<sup>12</sup> PRESERVE ACCESS TO AFFORDABLE GENERICS ACT, S. 124, 115th Cong. (2017).

<sup>13</sup> While Paragraph IV-inspired settlements did not exist prior to Hatch-Waxman, the Supreme Court held as early as 1931 that the settlement of patent litigation does not by itself violate antitrust. *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163, 171 (1931).

<sup>14</sup> *Actavis*, 133 S. Ct. at 2224.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.* This option is in fact only one of four ways to obtain approval. A generic ANDA may also (1) assert that no patent for the drug is in existence, (2) the existing patent has expired, or (3) the patent will expire in a time frame that will not infringe upon the patentee's rights upon the FDA's approval of the drug.

<sup>17</sup> See 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit an application . . . for a drug claimed in a patent or the use of which is claimed in a patent.").

<sup>18</sup> *Actavis*, 133 S. Ct. at 2224.

Paragraph IV filing, the FDA is required to delay their approval of the generic drug for 30 months while the litigation is resolved.<sup>19</sup> If the courts adjudicate the validity of the patent, the FDA honors that ruling. But if the 30-month period expires without determining the patent's validity, the FDA may grant approval to the generic in question.<sup>20</sup>

Pursuant to Hatch-Waxman, the first manufacturer to file its application is entitled to a 180-day exclusivity period where no other generic can compete with the brand, thus providing generic manufacturers with a large incentive to be first in line.<sup>21</sup> In fact, the Generic Pharmaceutical Association indicated in 2006 that a majority of their potential profits are derived from the sale of generic drugs during this 180-day exclusivity period.<sup>22</sup>

Of course, some patent infringement disputes between brand and generic manufacturers are resolved by settlements. Enter the “reverse payment settlement agreement.” In his opinion in *Actavis*, Justice Breyer provides an illustration of such a payment as follows:

Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a ‘reverse payment’ settlement agreement.<sup>23</sup>

As Breyer explained, a settlement agreement that has the power to reduce competition in the market can violate the Sherman Antitrust Act.<sup>24</sup> *FTC v. Actavis* involved a brand name manufacturer named Solvay Pharmaceuticals that successfully

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<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Id.* at 2224 – 2225.

<sup>22</sup> *Id.* at 2225.

<sup>23</sup> *Actavis*, 133 S. Ct. at 2223.

<sup>24</sup> *Id.* Approved by Congress in 1890, the Sherman Act responded to populist anger over large companies engaging in a variety of practices, often involving product and service monopolization, that left consumers paying high prices for goods and services while companies raked in record profits. *See also* *Munn v. Illinois*, 94 U.S. 113 (1876).

§ 1 of the Sherman Act prohibits “every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States.” § 2 of the Sherman Act makes it unlawful to “monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations.” The Sherman Act's goal is “not to protect businesses from the working of the market; it is to protect the public from the failure of the market.” The Supreme Court has held that antitrust scrutiny under the Sherman Act should be conducted to view the practical, anticompetitive effects of the scheme in question rather than the form. *See* *Am. Needle, Inc. v. NFL*, 560 U.S. 183, 191 – 92 (2010).

Since the Sherman Act's passage, the Department of Justice's Antitrust Division and the Federal Trade Commission (FTC) have divided and coordinated responsibility for federal enforcement against anticompetitive practices in commerce.

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filed a New Drug Application (NDA) for their product, AndroGel.<sup>25</sup> Later that year, a generic manufacturer named Actavis, Inc.<sup>26</sup> filed a Paragraph IV application for their generic equivalent to AndroGel.<sup>27</sup> Solvay commenced patent infringement litigation against Actavis.<sup>28</sup> More than 30 months passed and the FDA approved Actavis' application, thus granting it its 180-day exclusivity period guaranteed under Hatch-Waxman.<sup>29</sup> However, the parties reached a settlement before the court could reach a judgment on the validity of the patent.<sup>30</sup>

According to the settlement, Actavis and the other generic applicants party to the litigation would refrain from entering its generic product for another 9 years. In exchange, Solvay agreed to pay \$19 to \$30 million annually to Actavis over the 9-year period, and an additional \$72 million to the remaining generic applicants who would be entitled to enter the market following Actavis's 180-day exclusivity period.<sup>31</sup> The FTC brought action against the settling parties, alleging that respondents violated 15 U.S.C. § 45 by engaging in monopoly profit-sharing at the expense of market competition for a 9-year period.<sup>32</sup>

The Eleventh Circuit affirmed the District Court in favor of the defendants. "Absent sham litigation or fraud in obtaining the patent," the Court wrote, "a reverse payment settlement agreement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."<sup>33</sup> The Supreme Court reversed.<sup>34</sup> Noting ample precedent for finding Sherman Act violations in patent law, the Court held that pay for delay can violate the Sherman Act and are thus subject to scrutiny under the "Rule of Reason" analysis.<sup>35</sup>

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<sup>25</sup> FTC v. Actavis, Inc., 133 S. Ct. 2223, 2225 (2013).

<sup>26</sup> Then d/b/a Watson Pharmaceuticals, Inc.

<sup>27</sup> See generally *Actavis*, 133 S. Ct.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Actavis*, 133 S. Ct.

<sup>32</sup> *Id.* at 2226 (§ 5 of the Federal Trade Commission Act is brought by the FTC against defendants who commit practices that violate the Sherman Act.).

<sup>33</sup> *Id.* at 1158; See also *Joblove v. Barr Labs, Inc.* (In re Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 212 (2d Cir. 2006) ("We generally agree, then, with the Eleventh Circuit . . . that simply because a brand name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law, unless the exclusionary effects of the agreement exceed the scope of the patent's protection.").

<sup>34</sup> *Actavis*, at 2223. The Supreme Court held for the FTC by a 5-3 vote. Justice Roberts dissented, joined by Justices Thomas and Scalia. Justice Alito did not participate in this decision. *Id.*

<sup>35</sup> *Id.* at 2225. Justice Breyer concerns for why pay for delay agreements should subject to antitrust scrutiny even if they are not per se Sherman Act violations included, among others, that (1) Anticompetitive effects of pay for delay agreements are at least sometimes unjustified. Some agreements cover attorney and litigation expenses, but others have adverse effects on market competition. The burden of proof is on antitrust defendants to demonstrate that legitimate needs justify their agreement under the "Rule of Reason" test. (2) Antitrust action is more feasible than Chief Justice Roberts believed in his dissent. A pay for delay agreement implies that the patentee has reason to doubt its patent's validity. Otherwise, brand manufacturers would have less incentive to settle a case they should otherwise win and pay generic would-be competitors not to enter the market.

Under the Rule of Reason test, the plaintiff must prove that the agreement has an actual harmful effect on market competition. The plaintiff may do this by weighing all the circumstances of the case. A reduction of output, increase in price, or deterioration in quality of goods and services are

The Court explained in dicta that the likelihood of a pay for delay agreement violating antitrust law depends on its “size, scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”<sup>36</sup> However, the Court offered threadbare insight into how antitrust litigation under the “Rule of Reason” approach should be structured to determine whether a reverse payment is unlawful, leaving it to the lower courts to determine.<sup>37</sup> Justice Roberts dissented, in large part echoing the reasoning of the Eleventh Circuit in their application of the “scope of the patent” test. Roberts emphasized the property rights of the patentee over the exigencies of antitrust enforcement.<sup>38</sup>

In 2015, the Third Circuit held that pay for delay agreements can be found to violate the Sherman Act by virtue of the anticompetitive effects they have on the market.<sup>39</sup> In *King Drug*, the parties’ settlement contained a “No-AG [Authorized Generic]” agreement where the generic induced the brand not to market a generic bioequivalent.<sup>40</sup> Despite the lack of a cash payment as seen in *Actavis*, the Third Circuit found the No-AG agreement to be an impermissible violation of antitrust law due to its anticompetitive effects.<sup>41</sup>

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all relevant factors in offering proof. *United States v. Brown Univ.*, 5 F.3d 658, 668 – 69 (3d Cir. 1993). The burden then shifts to the defendants, who must show that the agreement serves a legitimate business purpose that outweighs anticompetitive effects. If successful, the burden shifts back to the plaintiff to argue that the legitimate ends of the agreement could have been accomplished through less restrictive alternatives. *Addamax v. Open Software Found, Inc.*, 888 F. Supp. 274, 279 (D. Mass. 1995).

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* The FTC urged the Supreme Court to adopt the “Quick-Look” analysis. “Quick-look” stands for the proposition that a reverse payment settlement agreement is presumptively unlawful. In *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 775 (1999), the Court held that the burden rests on the defendants to demonstrate precompetitive effects of their settlement, and that “Quick-Look” is appropriate only where “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets . . . quick-look analysis carries the day when the great likelihood of anticompetitive effects can be easily ascertained.” *Id.* at 770.

<sup>38</sup> *Id.* at 1159 – 60.

<sup>39</sup> *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 403 – 04 (3d Cir. 2015), cert. denied, 137 S. Ct. 446, 196 L.Ed. 2d 328 (2016). The Third Circuit held the proceedings in abeyance while waiting for the outcome of the *Actavis* decision before their holding with respect to whether “no-AG” agreements should be similarly scrutinized. *Id.* at 399.

<sup>40</sup> *Id.* at 397.

<sup>41</sup> *Id.* at 405. See also *Rochester Drug Co-Operative, Inc. v. Warner Chilcott Co.* (In Re Loestrin 24 Fe Antitrust Litig.), 814 F.3d 538 (1d Cir. 2016) (holding that a non-cash pay for delay agreement has anticompetitive effects).

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In *In re Lipitor Antitrust Litigation*, the Third Circuit held plaintiffs challenging a pay for delay agreement are not required to plead a standard higher than what is required by *Twombly* and *Iqbal*.<sup>42,43</sup>

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<sup>42</sup> *In re Lipitor Antitrust Litig.*, 2017 U.S. App. LEXIS 15825 (2017). This case was in fact a consolidated appeal concerning Pfizer's Lipitor product and Wyeth, Inc.'s antidepressant, Effexor XR. Teva became the first generic filer and gained its 180-day exclusivity period. Wyeth then filed a patent infringement claim against Teva.

The parties settled, with Teva agreeing to delay entry of their generic drug until July 2010, or seven years prior to the expiration of the patent, thus allowing Wyeth a monopoly over a market worth approximately \$500 million. Wyeth agreed not to launch an AG to compete with Teva's upon their entry into the market. In exchange, Teva would have to pay Wyeth royalties as a portion of their profit from their generic drug's market entry.

The Effexor plaintiffs, a class of direct-purchasers and retailers, brought action alleging that Wyeth's patent was fraudulently obtained and that the patents are being enforced through sham litigation, and that the pay for delay agreement between the two companies was an unlawful restraint of trade. The Effexor plaintiffs alleged Wyeth settled because they knew they would lose because their Effexor patent was fraudulent. Moreover, U.S. drug purchasers paid billions of dollars more than they otherwise would have had to had market competition not been stifled by Wyeth and Teva's settlement agreement.

The Court first relied on its precedent in *King Drug* to hold that the parties had plausibly pled an unlawful reverse payment agreement, thus obviating the plaintiffs' need to provide more specific economic calculations to lend further support to their allegations. The Court said that, like in *King Drug*, the district court erred in holding the plaintiffs to a higher standard than what the standard set forth by *Twombly* and *Iqbal* require.

The Effexor plaintiffs alleged that the Wyeth/Teva No-AG agreement is unjustified because the litigation costs between Wyeth and Teva, worth between \$5-10 million, are a fraction of the \$500 million payment Wyeth effectively made to Teva, and that Wyeth and Teva's No-AG agreement lacks precompetitive value.

The Effexor defendants argued in response that (1) the agreement is "traditional" in that it provides for Teva paying royalties to Wyeth, (2) the complaints do not include allegations concerning the royalty licensing agreements that make the settlement agreement lawful. The Court rejects these arguments, pointing out that the lack of allegations concerning the appropriateness of the royalty agreement does not run counter to the plausibility of an unlawful no-AG agreement. The Court left open the possibility that the royalty agreements may provide a helpful defense for settling defendants, but royalty agreements do not discount the sufficiency with which the plaintiffs made plausible claims.

The Effexor defendants contended that the submission of the contents of their settlement agreement to the FTC nullified antitrust scrutiny. They argued that (1) by submitting the agreement to the FTC, Wyeth lacked anticompetitive intent, (2) While not dispositive, the lack of anticompetitive intent is an important factor in determining whether a pay for delay agreement should be viewed as unlawful, and (3) the FTC's failure to object, saying only that it reserves the right to object later, effectively sanctioned the settlement agreement.

The Third Circuit found these arguments unconvincing, stating that unlawful agreements are not immune from scrutiny simply because they were submitted to a regulatory agency for review.

Defendants' submission of the settlement agreement infers only that they complied with the consent decree and does not speak to the question of whether or not the parties harbored antitrust intent. Furthermore, intent has never been an element of an antitrust claim and does not shield anticompetitive conduct from liability.

The Third Circuit also rejected the argument that the FTC's inaction implied that the settlement agreement was permissible. As the Court pointed out, a number of factors may determine whether a regulatory agency takes action, including an assessment of whether a violation occurred, the prudent allocation of resources, or decisions made to perhaps only prosecute the largest or the most egregious cases. Thus, the Court said, no consideration should be granted to the silence or inaction of the FTC, particularly when the FTC stated explicitly that they reserve the right to take later action on the agreement at any time permitted by law.

<sup>43</sup> *Bell Atlantic Corp. v. Twombly*, 548 U.S. 903 (2006); *Ashcroft v. Iqbal*, 554 U.S. 902 (2008).



Emboldened in the years since *Actavis*, lawmakers and regulators have taken action to reduce the harm pay for delay agreements inflict on consumers and taxpayers. The Preserve Access to Affordable Generics Act, introduced by Senator Amy Klobuchar would, *inter alia*, (1) authorize the FTC to initiate antitrust proceedings in regards to *any* agreement between parties with respect to a pharmaceutical patent infringement claim, (2) declare pay for delay agreements presumptively unlawful instead of using the Rule of Reason analysis, (3) create definitive exceptions for when it is permissible for a patentee to delay the entry of market competition, (4) eliminate the 180-day exclusivity period for generics if the pay for delay agreement is found unlawful, (5) grant the FTC exclusive authority to litigate against anticompetitive practices relating to pay for delay agreements, and (6) create a 6-year statute of limitations for enforcement.<sup>44</sup>

In early 2017, Democratic Congressional leadership unveiled “A Better Deal” policy platform that emphasized cracking down on monopolies, mergers, and other abuses of economic power.<sup>45</sup> The proposal called for a consumer competition advocate that would provide research and recommendations for investigation to the FTC when anticompetitive activity is found. The policy proposal made specific references to regulating anticompetitive behavior by several industries, though it made no express mention of the pharmaceutical industry.<sup>46</sup>

### III. ANALYSIS

The “scope of the patent” test employed by Justice Roberts in his *Actavis* dissent would likely do the least to alleviate financial stress brought upon consumers by pay for delay agreements. The “scope of the patent” test makes exceptions only for sham litigation settlements and when the patent giving rise to the dispute was obtained fraudulently.<sup>47</sup> While the “scope of the patent” test emphasizes the value of exclusive property rights held by patentees over the objectives antitrust law works to satisfy, its structure accomplishes neither.

The undervalued benefit of *Actavis*, its lower court progeny, and the legislative and regulatory proposals discussed *supra*, is their assistance in determining by way of litigation whether patents being challenged under Paragraph IV are invalid and/or fraudulent.<sup>48</sup> Opportunities for courts to determine validity or fraud are foreclosed by pay for delay settlements because the courts are denied the opportunity to adjudicate the issue.<sup>49</sup>

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<sup>44</sup> S. 124, 115th Cong. (2017).

<sup>45</sup> *A Better Deal*, Press Release, Office of Representative Nancy Pelosi, House Minority Leader, (July 22, 2017).

<sup>46</sup> *Id.*

<sup>47</sup> *FTC v. Actavis*, 133 S. Ct. 2223, 2239 (2013).

<sup>48</sup> *Id.* at 2234. (“The [Eleventh] Circuit’s related underlying concern consists of its fear that antitrust scrutiny of a reverse payment settlement agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement.”).

<sup>49</sup> *Id.* at 2236. (“The [Eleventh] Circuit’s holding [in favor of the scope of the patent’ test] does avoid the need to litigate the patent’s validity.”).

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The “scope of the patent” test has the potential to conceal invalid patents from court scrutiny. Without determining the validity of the patent, manufacturers who no longer hold (or may have never held) a valid claim to a patent can share monopoly profits with a would-be competitor for a pharmaceutical product they may not actually own. Subjecting pay for delay agreements to antitrust scrutiny will compel parties to litigate over and decide patent validity. Encouraging and incentivizing manufacturers to challenge patent validity promotes market competition and helps ensure that the “Orange Book” is up to date and not riddled with outdated patents.<sup>50</sup>

Despite Justice Roberts’s concerns, patentees restrained from engaging in pay for delay settlements still have exclusive property rights that are afforded by patent ownership. Justice Roberts did not suggest that brand manufacturers may not still market their product, refuse to license it, and turn a profit.<sup>51</sup> As Justice Roberts points out, the purpose of patents is to encourage innovation and to “exclude others from profiting by the patented invention.”<sup>52</sup> Pay for delay agreements do not prevent others from profiting from the patent; in fact, they do just the opposite because the patentee shares their profits with a would-be competitor. The practice of engaging in pay for delay settlement agreements as a matter of right is not consistent with the purpose of granting patents.

The Rule of Reason approach endorsed by *Actavis* has provided the FTC and private plaintiffs with the tools necessary to make successful claims against manufacturers engaging in pay for delay agreements.<sup>53</sup> Indeed, the number of pay for delay agreements has withered annually since the *Actavis* decision.<sup>54</sup>

The Rule of Reason appears sensible for giving each party its turn to present its case in logical and methodical order. Under the Rule, courts hear of the anti-competitive effects of the settlement agreement, the legitimate needs (if any) of the defendants, and it allows them to make a determination as to whether those needs outweigh the negative, anticompetitive effects of the agreement.<sup>55</sup>

The Rule of Reason’s flaw is its requirement that the plaintiff prove a *prima facie* case before the burden shifts to the defendant to establish its defense.<sup>56</sup> Under this

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<sup>50</sup> The Approved Drug Products with Therapeutic Equivalence Evaluations, nicknamed the “Orange Book,” contains the full list of approved New Drug Applications submitted by brand name manufacturers. In re Actos End-Payor Antitrust Litig., 848 F.3d 89, 94 (2d Cir. 2017).

<sup>51</sup> *Actavis*, at 2238.

<sup>52</sup> *Id.* See *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). U.S. CONST. art. I, § 8, cl. 8. ([the Congress shall have the power] “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”).

<sup>53</sup> See *supra*, n. 41.

<sup>54</sup> Diane Bartz, *Controversial ‘pay-for-delay’ deals drop after FTC’s win in top court*, REUTERS (Oct. 25, 2017, 2:12 AM), <http://www.reuters.com/article/us-pharmaceuticals-patent-ftc/controversial-pay-for-delay-deals-drop-after-ftcs-win-in-top-court-idUSKCN0UR2JA20160113>; See also Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, FEDERAL TRADE COMMISSION (2014), <https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf>

(“The number of settlements potentially involving pay for delay decreased significantly in the wake of the *Actavis* decision. For example, the number of potential pay-for-delay settlements in FY 2014 is roughly half the number in FY 2012, the last complete year before the *Actavis* decision”).

<sup>55</sup> *Addamax v. Open Software Found, Inc.*, 888 F. Supp. 274, 279 (D. Mass. 1995).

<sup>56</sup> *Id.*

regimen, defendants have had moderate success in deflecting antitrust claims against them that perhaps should have moved forward in district court.<sup>57</sup>

The mission of the FTC to enforce antitrust law is obstructed by the burden placed upon them by the Rule of Reason to prove a *prima facie* antitrust claim. Antitrust defendants working under the Rule of Reason can get claims challenging pay for delay agreements dismissed without having to prove to courts whether they have a legitimate business interest. In contrast, the Quick Look approach places this burden on the defendants more swiftly.<sup>58</sup>

The FTC and antitrust plaintiffs are more likely to win under the Quick Look analysis, and reduce the number of pay for delay settlements. Under this analysis, the issue the parties will dispute is whether the settlement has precompetitive effects, not whether the settlement serves a legitimate business interest.<sup>59</sup> Therefore, antitrust defendants could have incentive under the Quick Look analysis to structure their settlements in a way that both benefits their business interests while avoiding anticompetitive harm to consumers.

While the Quick Look analysis helpfully shifts the burden to antitrust defendants to prove precompetitive effects, it is limited by its capacity only to work to restrict settlements that “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.”<sup>60</sup>

As drug manufacturers have adapted to the FTC’s campaign against pay for delay agreements in the years following *Actavis*, manufacturers have structured agreements with greater complexity beyond the scope of what the Quick Look analysis has traditionally succeeded at curtailing.<sup>61</sup> Thus, a broader and more encompassing approach may be needed.

<sup>57</sup> See *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523 (2014). (District Court dismissed complaint for failing to meet pleading standard); *King Drug* (District Court dismissed for plaintiff’s failure to assert existence of traditional pay for delay agreement). In *In re Lamictal Purchaser Antitrust Litig.*, 2014 WL 282755 (D.N.J. 2014) and in *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180 (D.R.I. 2014), courts attempted to read *Actavis* more narrowly by finding that non-cash payments do not apply.

<sup>58</sup> See *supra*, n. 44.

<sup>59</sup> *Chicago Professional Sports Limited Partnership v. National Basketball Ass’n.*, 961 F. 2d 667, 674 – 76 (7th Cir. 1992). (Quick Look analysis utilized after rejection of arguments trying to justify agreement by pointing to precompetitive effects.)

<sup>60</sup> See *supra*, n. 44.

<sup>61</sup> Joshua D. Wright, *Antitrust Analysis of Reverse Payment Settlements After Actavis: Three Questions and Proposed Answers*, FEDERAL TRADE COMMISSION (Sept. 25, 2017, 10:15 PM) <https://www.ftc.gov/public-statements/2014/10/antitrust-analysis-reverse-payment-settlements-after-actavis-three>. (“Clever parties have an even stronger incentive to make their non-cash reverse payments as complicated as possible.”)

For example, suppose a brand manufacturer holds Patents A and B. A generic files a Paragraph IV claim for Patent A, but not Patent B. The brand claims infringement, and the parties’ settlement involves the brand paying the manufacturer to stay out of the market for the contested patent for the remainder of its life, but grants them a license to market the drug protected by Patent B. The agreement is thus both precompetitive and anticompetitive.

Some would argue that *Actavis* and § 1 of the Sherman Act requires an analysis that holistically considers the harms and benefits of the conduct in question. This analysis would allow a trier of fact to reasonably find a defendants’ settlement to be lawful.

Another approach argues that the precompetitive benefits to consumers from the second patent are irrelevant because the markets for the drugs are different. A patentee granting a license to market

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Senator Klobuchar's S. 124 does much to correct the fragility in antitrust enforcement against pay for delay agreements.<sup>62</sup> First, S. 124 supplants the courts' Rule of Reason approach in favor of a tough new standard. Instead of placing the burden of stating a claim on the FTC or private plaintiffs, pay for delay agreements are presumed to have anticompetitive effects and thus violate the Federal Trade Commission Act.<sup>63</sup> Settling parties can successfully fend off antitrust scrutiny only if the precompetitive effects of their agreement outweigh the anticompetitive effects, or if the settlement is limited in its coverage to ancillary expenditures (i.e. litigation costs.) This standard provides the FTC with a powerful tool to crack down on pay for delay agreements. S. 124 codifies *King Drug's* holding that non-cash settlements are still "payments" and would thus avert a split from the Third Circuit.<sup>64,65</sup>

S. 124's requirement that settling parties submit their agreement to the FTC within 30 days of its formation helps provide for timely review that respects both the business interests of settling parties seeking quick clarity as to whether their agreement is acceptable. However, S. 124 sets a six-year statute of limitations for the FTC to bring an objection until antitrust claims are barred.<sup>66</sup> The FTC may want to use the generous amount of time afforded to file a claim observing whether the settlement has precompetitive or anticompetitive effects.<sup>67</sup>

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antidepressants, for example, does not resolve the anticompetitive effects of their pay for delay agreement with a generic to lower cholesterol. Beyond this example, the demand for one drug is always going to be lesser or greater than the demand for another drug.

Appellate courts have not determined whether a "give and take" type of settlement is permissible. Analyzing such settlements with the Rule of Reason allows defendants to make a more compelling argument that their legitimate business interests outweigh anticompetitive harm diminished by the settlement's structure. Courts deferential to business interests may be mollified by the settlements' structure as antitrust concerns are alleviated.

<sup>62</sup> S. 124, 115th Cong. (2017). ("Preserve Access to Affordable Generics Act.").

<sup>63</sup> Former FTC Chairwoman Edith Ramirez supported this proposition in spite of Actavis because it would enhance clarity, create a stronger deterrent effect, and help the FTC move more quickly to stop pay for delay agreements. *Pay for Delay Deals: Limiting Competition and Costing Consumers*, Statement before the Subcomm. on Antitrust, Competition Policy, and Consumer Rights of the S. Comm. on the Judiciary, 113th Cong. (July 23, 2013) (prepared statement of the Fed. Trade Comm'n presented by Chairwoman Edith Ramirez), available at [http://www.ftc.gov/sites/default/files/documents/public\\_statements/prepred-statement-federal-trade-commission-pay-for-delay-deals-limiting-competition-and-costing/130723payfordelay.pdf](http://www.ftc.gov/sites/default/files/documents/public_statements/prepred-statement-federal-trade-commission-pay-for-delay-deals-limiting-competition-and-costing/130723payfordelay.pdf).

<sup>64</sup> *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 404 (3d Cir. 2015). ("We believe this no-AG agreement falls under Actavis's rule because it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition.").

<sup>65</sup> S. 124, § 27. ("an agreement shall be presumed to have anticompetitive effects and shall be a violation of this section if (i) an ANDA filer received *anything of value*, including an exclusive license") (Emphasis added).

<sup>66</sup> S. 124, § 7. ("The Federal Trade Commission shall commence any enforcement proceeding . . . not later than 6 years after the date on which the parties to the agreement file the Note of Agreement as provided by . . . 21 U.S.C. § 355.").

<sup>67</sup> Former Commissioner Joshua Wright's analysis of the settlement structure that contains both pro and anticompetitive effects comes to mind as an example of the FTC's hypothetical approach to confronting a relatively novel settlement structure, one that has pro and anticompetitive effects. Wright suggested "the law, sound economics and common sense require us to balance." Joshua D. Wright, *Antitrust Analysis of Reverse Payment Settlements After Actavis: Three Questions and Proposed Answers*, FEDERAL TRADE COMMISSION (Sept. 25, 2017, 10:15 PM)

S. 124's provision allowing settling parties a right to appeal to federal courts is reasonable. Settling parties may be reluctant to risk costs from futile litigation on top of potential treble damages from the FTC's findings. Power would be largely given to the FTC, not courts, to determine whether settlements violate antitrust law.

S. 124 wisely incentivizes generic manufacturers to avoid engaging in pay for delay agreements in favor of pursuing a resolution to the validity of the disputed patent. This is because forfeiting a generic's 180-day exclusivity period following the expiration of the brand's patent for engaging in a pay for delay agreement defeats the generic manufacturer's purpose in entering the settlement in the first place.

The 180-day exclusivity period accounts for the vast majority of generic drug industry profits.<sup>68</sup> A pay for delay settlement allows generic manufacturers to receive the payments from brands until the expiration of the patent *in addition to* the 180-day exclusivity period they are statutorily entitled to for being first to file an NDA.<sup>69</sup> S. 124's amendment may help deter generic manufacturers' willingness to engage in pay for delay settlements, compel answers to the validity of a challenged patent through the courts, and still allow generic first-time filers to maintain their profitability.<sup>70</sup>

Lastly, S. 124 grants the FTC the exclusive authority to challenge pay for delay agreements in court. This authority carries both risks and rewards. The FTC's mission is in part to promote market competition and combat anticompetitive practices.<sup>71</sup> They enjoy a wealth of talent, expertise, and experience, and is thus arguably best equipped to detect anti-competition and challenge it when appropriate.<sup>72</sup> However, the FTC could be potentially impeded by present and future White House Administrations that do not prioritize its cause.<sup>73</sup> An FTC unable to challenge pay for

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<https://www.ftc.gov/public-statements/2014/10/antitrust-analysis-reverse-payment-settlements-after-actavis-three>.

GENERIC PHARMACEUTICALS, United States Note, Directorate for Financial and Enterprise Affairs, Competition Committee (June 2014). ("Finally, the FTC's efforts . . . are not limited to competition matters threatening immediate competitive harm").

<sup>68</sup> *Actavis*, at 2257 (quoting statement by Generic Pharmaceutical Association, Petr's Br. at 6.)

<sup>69</sup> *Id.* at 2246.

<sup>70</sup> The proliferation of generic drugs into the market, leading to generic substitution, lowers prescription drug costs for consumers. In fact, generic competitors entering the market for the first time at a price that averages around 80% of the brand manufacturer's bioequivalent. Subsequent entry by competing generics have the potential to lower the market price even further, thus providing consumers with even greater savings. FED. TRADE COMM'N, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impacts*, Final Authorized Generic Report at 48 (Aug. 2011), <http://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>. Consumers stand to save a lot from generic competition following patent challenges that move forward. "Generic competition following successful patent challenges involving just four major brand name drugs saved consumers an estimated \$9 billion." GENERIC PHARMACEUTICALS, *supra* n. 67.

<sup>71</sup> FED. TRADE COMM'N, WHAT WE DO, <https://www.ftc.gov/about-ftc/what-we-do>.

<sup>72</sup> FED. TRADE COMM'N, COMMISSIONERS, <https://www.ftc.gov/about-ftc/commissioners>; FED. TRADE COMM'N, CAREERS, <https://www.ftc.gov/about-ftc/careers-ftc>. ("We have over 1,000 staff, from investigators, to attorneys, to specialists in information technology, public affairs, financial management, public policy, and many other fields.").

<sup>73</sup> Currently, the five-member Commission only has two of five positions filled, by Acting Chairwoman and Commissioner Maureen K. Ohlhausen and Commissioner Terrell McSweeney, both of whom have served in their positions since the Obama Administration. Max Greenwood, *Trump to nominate DC antitrust attorney to lead FTC: THE HILL*, <http://thehill.com/policy/finance/356143-trump-to-nominate-dc-antitrust-attorney-to-lead-ftc-report>.

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delay agreements would leave consumers without a remedy if the FTC declines to fulfill its role when necessary. In *King Drug* and others, antitrust action was brought by private plaintiffs.<sup>74</sup> S. 124 would prevent them from doing so again.<sup>75</sup>

The “A Better Deal” policy proposals specifically mention requiring regulators to take action antitrust necessary.<sup>76</sup> In addition, there has been broad agreement among Democratic and Republican Commissioners on the FTC for cracking down on pay for delay agreements.<sup>77</sup> The Commission has considered enforcement against pay for delay agreements to be a top regulatory priority.<sup>78</sup>

The exclusive authority of the FTC to bring action against settling parties puts the Commission’s policy experts in charge of the process. This is especially important when settlement structures have both precompetitive and anticompetitive effects. Private plaintiffs with only layman’s knowledge of the law, economics, and the pharmaceutical industry could otherwise be successful in court at dismantling agreements that FTC policy experts deem to overall be healthy for market competition by promoting lower drug prices for consumers. Thus, granting exclusive authority to the FTC to challenge pay for delay settlement agreements is more likely to lead to a better outcome for consumers and their budgets.

Despite the proliferation of pay for delay agreements, the courts have moved in the right direction since *Actavis* in limiting them.

#### IV. PROPOSAL

*Actavis* was narrowly decided by the Supreme Court by a 5-3 decision, with Justice Alito taking no part in the decision.<sup>79</sup> As the composition of the Court undergoes

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The remaining three positions remained unfilled, though nominations have recently been filed and are awaiting Senate confirmation. *Id.*

<sup>74</sup> *King Drug*, 791 F.3d 388, at 393. (“Plaintiffs here, direct purchasers of the brand-name drug Lamictal, sued Lamictal’s producer, SmithKline Beecham Corporation . . . and Teva Pharmaceutical Industries Ltd . . . a manufacturer of generic Lamictal, for violation of Sections 1 and 2 of the Sherman Act”).

<sup>75</sup> S. 124, 115th Cong. (2017).

<sup>76</sup> Press Release, Office of Representative Nancy Pelosi, House Minority Leader, *A Better Deal*, (July 22, 2017).

The [consumer competition] advocate’s recommendations would be made public, and the regulators would be required, if they choose not to pursue a recommended investigation, to publicly justify why . . . Regulators would be . . . required to take corrective measures if they find abusive monopolistic conditions where previously approved measures fail to make good on their intended outcomes.

<sup>77</sup> *Antitrust Concerns and the FDA Approval Process: Before the H. Comm. on the Judiciary*, 115th Cong. 14 (2017) (prepared statement of Markus H. Meier, Acting Director, Bureau of Competition, U.S. Federal Trade Commission); Oversight of the Federal Trade Commission Bureau of Competition and the Department of Justice Division, Statement before the Subcomm. On Courts and Competition Policy of the H. Comm. On the Judiciary, 111th Cong. (July 27, 2010) (prepared statement of the Fed. Trade Comm’n presented by Chairman Jon Leibowitz), [http://www.ftc.gov/sites/default/files/documents/public\\_statements/prepared-statement-federal-trade-commission-oversight-federal-trade-commission-bureau-competition/100727antitrustoversight.pdf](http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-oversight-federal-trade-commission-bureau-competition/100727antitrustoversight.pdf). In addition, S. 124 is co-sponsored by Senator Charles Grassley, the Chairman of the Judiciary Committee.

<sup>78</sup> *Id.* at 1.

<sup>79</sup> *FTC v. Actavis*, 133 S. Ct. 2223 (2013).

further changes, the potential for it to overturn *Actavis* and supplant its holding with Justice Roberts’s “scope of the patent” test is arguably high. The dissolution of the *Actavis* holding would further invalidate the lower courts’ jurisprudence stemming from it.

In the years following *Actavis*, the courts have permitted the FTC to advocate more effectively on behalf of consumers to ensure they pay no greater than market value for pharmaceuticals.<sup>80</sup> In order to protect the FTC’s progress in enforcing antitrust law against pay for delay agreements, Congress must step forward to codify the principles of *Actavis*, or even go steps further, as S. 124 does.

Many of S. 124’s provisions should be swiftly adopted.<sup>81</sup> First, Congress should abandon the “Rule of Reason” approach and declare pay for delay agreements to be presumptively unlawful.<sup>82</sup> This is the first and arguably one of the largest steps that can be taken to help limit pay for delay. Congress should allow for the FTC to be the sole entity responsible for bringing legal challenges to pay for delay agreements. The FTC is better equipped to determine what will and will not harm consumers.<sup>83</sup>

If suits were permitted to be brought by private litigants after S. 124’s 6-year deadline, they should be barred if the FTC determined that an agreement is pro-competitive. Generic manufacturers found to have violated antitrust law by engaging in pay for delay should, as S. 124 calls for, have their 180-day exclusivity period forfeited.

This regulatory structure creates a multi-tiered defense that would prevent harm to consumers. First, generic manufacturers would be deterred from agreeing with brand manufacturers who offer to pay them to stay out of the market. At least some generic manufacturers would decide it unworthy to risk receiving attention from the

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<sup>80</sup> Diane Bartz, *Controversial ‘pay-for-delay’ deals drop after FTC’s win in top court*, REUTERS (Oct. 25, 2017, 2:12 AM), <http://www.reuters.com/article/us-pharmaceuticals-patent-ftc/controversial-pay-for-delay-deals-drop-after-ftcs-win-in-top-court-idUSKCN0UR2JA20160113>; See also *Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, FEDERAL TRADE COMMISSION (2014), <https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf>. (“The number of settlements potentially involving pay for delay decreased significantly in the wake of the *Actavis* decision. For example, the number of potential pay-for-delay settlements in FY 2014 is roughly half the number in FY 2012, the last complete year before the *Actavis* decision”).

<sup>81</sup> S. 124, 115th Cong. (2017).

<sup>82</sup> *Id.*

Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and shall be a violation of this section if – (i) an ANDA filer receives anything of value, including an exclusive license; and (ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.

<sup>83</sup> GENERIC PHARMACEUTICALS, United States Note, Directorate for Financial and Enterprise Affairs, Competition Committee, (June 2014).

the FTC’s efforts in the generic pharmaceutical sector are not limited only to competition matters threatening immediate competitive harm. The FTC monitors developments in the pharmaceutical sector to inform both current and future enforcement and advocacy. New business models, technological innovations, and new or modified laws and regulations may affect pharmaceutical competition. The FTC responds to these changes through research, policy recommendations and advocacy, and, when appropriate, enforcement actions to ensure that consumers benefit from these changes.

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FTC. The arguably more profitable path for them would be to reject reverse payment settlement offers and stand by their Paragraph IV declaration. The litigation's resolution would clarify the disputed patent's validity and if the generic is successful, it is entitled to 180 days of generic market exclusivity.<sup>84</sup> Consumers would be unharmed by this process, and the intellectual property rights of the owner of a valid patent would be protected.

Manufacturers willing to take the risk are more likely to lose under S. 124's standard than through the Rule of Reason. The FTC's expertise, zealous motivation, and deference granted by the courts would make pay for delay agreements unlikely to survive, unless manufacturers are able to convince them that their agreement provides a justified, net positive to market competition that benefits consumers. However, the FTC may want to consider that even a net positive may be insufficient, if a settlement agreement too severely hurts competition in one market even though it greatly benefits competition in a different market. A comparison of marketplace demand for each pharmaceutical taking part in the formula may be a helpful place to observe. Some may argue that the similarities and differences of the types of pharmaceuticals involved in the settlement should play a factor.<sup>85</sup> Such determinations should be made by experts at the FTC.

In addition to S. 124, Congress should require the FTC to require manufacturers that lose in court to establish an account in escrow to compensate consumers who have paid supracompetitive prices for pharmaceuticals. The amount to be paid should be, at minimum, the difference between the profits made by selling at the price above market value and the profit that would have been made from sales made at fair market value.

The FTC has successfully obtained settlements from companies engaged in anticompetitive activity on behalf of consumers before.<sup>86</sup> Language should be inserted

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<sup>84</sup> In an infringement suit brought by a brand manufacturer against the generic, the generic has had a success rate of 73%, indicating that Paragraph IV challenges are far more likely than not to lead to market competition. *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, EXEC. SUMMARY (July 2002) <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

<sup>85</sup> Joshua D. Wright, *Antitrust Analysis of Reverse Payment Settlements After Actavis: Three Questions and Proposed Answers*, FEDERAL TRADE COMMISSION (Sept. 25, 2017, 10:15 PM) <https://www.ftc.gov/public-statements/2014/10/antitrust-analysis-reverse-payment-settlements-after-actavis-three>.

Another position might be to say that any consumer benefits that occur in the market for Drug 2 should not count under the law because the markets for Drug 1 and Drug 2 are different, or are not sufficiently related, to render consumer benefits from increased competition over Drug 2 cognizable under Section 1 [of the Sherman Act.] I think the law, sound economics, and common sense require us to balance.

<sup>86</sup> *FTC v. Cephalon, Inc.*, 100 F. Supp. 3d 433 (E.D. Pa. 2015). Here, the FTC sought "disgorgement" of a portion of Cephalon's profits for the sale of their premier product Provigil, which treats narcolepsy and other sleep disorders. *Id.* at 435. "Disgorgement" is an equitable remedy meant to prevent unjust enrichment. *Edmonson v. Lincoln Nat. Life Ins. Co.*, 725 F. 3d 406, 415 (3d Cir. 2013) (citing *S.E.C. v. Huffman*, 996 F. 2d 800, 802 (5th Cir. 1993)). Cephalon settled with generic drug manufacturers who sought to market their bioequivalent versions of Provigil by paying them millions in exchange for their abstention from the market for 6 years. *Cephalon*, at 435. Following Actavis in 2013, the FTC sought to look for "some redress of the consumer harm that's been caused by the years and years of delayed generic entry." *Id.* at 436. The FTC then sought disgorgement of Cephalon's illegal profits pursuant to § 13(b) of the Federal Trade Commission Act, which allows for the plaintiff to seek necessary equitable relief to rectify injustice and avoid recurrence (higher prices imposed upon consumers by illegal restraint of competition). *Id.* at 435.



into § 13(b) of the Federal Trade Commission Act specifying that disgorgement of funds to recover economic losses on behalf of consumers is required when appropriate.<sup>87</sup> The language should allow for the FTC to seek disgorgement of profits at any point within S. 124's proposed 6-month statute of limitations.

As pay for delay agreements have the potential to not demonstrate anticompetitive effect until late, the profits obtained from uncompetitive pay for delay agreements could balloon by the end of the statutory period, indicating a great deal of harm to consumers. Disgorgement of profits made from anticompetitive pricing will cure financial injury to consumers struggling to afford their medication. The power to return ill-gotten gains back to consumers can be seen as the final layer of the FTC's defense on behalf of consumers.

These proposed alterations and additions to S. 124 could potentially go a long way in deterring the proliferation of pay for delay agreements, or in the alternative recovering ill-gotten gains from consumers when manufacturers engage in anticompetitive conduct.

## V. CONCLUSION

Karen Winkler of Clarkston, Michigan has multiple sclerosis.<sup>88</sup> Among MS's many symptoms is fatigue. She obtained a prescription from her doctor for Provigil to help her with her sleep schedule.<sup>89</sup> The year she was diagnosed, Cephalon made a profit of \$475 million from the drug. In 2008, a 6-month supply of Provigil cost her \$300. By 2010, it cost her \$700.<sup>90</sup> Around that time, her husband had to take a pay cut, so they had to dip into savings and their retirement. "And with three young kids," she said, she "felt guilty that I was taking away from the family budget."<sup>91</sup>

The consequences of relaxed antitrust law have real effects on every day people and their families, like that of Mrs. Winkler's.<sup>92</sup> The inflated cost of drugs on

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Cephalon sought to dismiss on grounds that (1) disgorgement is not encompassed within § 13(b) of the Act, and (2) even if it was, it would not be permitted in their case to do so because it would not be equitable. *Id.* at 436. The District Court held for the FTC and read disgorgement into § 13(b). *Id.* at 439. As the Court noted, eight different Circuit Courts of Appeals have each reached the same conclusion. *Id.*

Cephalon contended in the alternative that equitable remedies are not appropriate if disgorgement is read into § 13(b) because the FTC did not invoke it in their prayer for relief. *Id.* at 439. The Court noted that the FTC's prayer for relief included "such other equitable relief as the Court finds necessary to redress and prevent recurrence of Cephalon's violation of § 5(a) of the FTC Act" before holding that their prayer was sufficient to ask the Court for disgorgement. *Id.*

<sup>87</sup> See *Cephalon*, at 439; See also 15 U.S.C. § 45(a) (2017).

<sup>88</sup> Megan Thompson, *Are Generic Drugs Being Delayed to Market?*, PBS (Nov. 13, 2017, 10:26 PM), <https://www.pbs.org/newshour/show/generic-drugs-delayed-market>.

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> Wells Wilkinson, *Delay of Generics Hurts Consumer and Taxpayer Wallets and Patient Health*, COMMUNITY CATALYST (Nov. 14, 2017, 9:06 AM), <https://www.communitycatalyst.org/blog/delay-of-generics-hurts-consumer-and-taxpayer-wallets-and-patient-health#.Wg9YobT81ol>.

Overall, these so-called settlements have caused consumers and their health plans to pay tens of billions right into the pockets of the brand-name drug companies . . . For the millions who are underinsured, delaying a generic can force

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consumers has the potential to take up more and more of the average household's budget until it is pushed past their breaking point.<sup>93</sup>

Pay for delay agreements allow generic manufacturers to obtain profits directly from brand manufacturers who may not even hold a valid patent, instead of making a profit by competing against them. The proliferation of these agreements can only lead to a lethargic and unsustainable market that discourages innovation and advancement and promotes fraud, as invalid patents could be constantly used as leverage to prevent generics from providing potentially great alternative pharmaceuticals to consumers.

A regulatory structure that prevents parties from forming pay for delay agreements respects the rights of valid patent holders, protects consumers, and promotes market competition. This structure requires, among other things, a generic manufacturer's forfeiture of their 180-day exclusivity period upon a finding of antitrust liability, a legal standard that presumes pay for delay agreements to be unlawful, a compensatory fund for consumers forced to pay supracompetitive prices for pharmaceuticals, and exclusive authority by the FTC to litigate. The Federal Trade Commission's campaign against pay for delay agreements must be facilitated, not obstructed by the judiciary or by Congress. Lives depend on it.

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patients to pay thousands of dollars a year, or go without needed medicine. One story we collected from a consumer from Kansas describes his struggle to afford Provigil, whose generic was delayed from 2006 to 2011 by pay for delay. He reported: '[Despite] paying almost \$17,000 in annual premiums for my family [health insurance plan] last year, I was paying around \$650/month [for Provigil] . . . That is out of pocket money I have to come up with until later in the year when I reach my deductible [sic] and I can enjoy a few months of only paying \$60/month. I cannot describe to you how much stress and difficulty this has caused for me and my family the last several years.'

<sup>93</sup>Aimee Picchi, *Prognosis for RX in 2017: more painful drug-price hikes*, CBS (Nov. 13, 2017, 10:47 PM), <https://www.cbsnews.com/news/drug-prices-to-rise-12-percent-in-2017/>.