SETTLEMENT SHOULD BE THE END OF STORY: A PROPOSED PROCEDURE TO SETTLE HATCH-WAXMAN PARAGRAPH IV LITIGATIONS MODELED AFTER RULE 23 CLASS ACTION SETTLEMENT PROCEDURE

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I. INTRODUCTION

A brand-name pharmaceutical company typically obtains a patent for its newly developed drug in order to protect its intellectual property. If another company expresses its intent to market a generic version of the drug, the Hatch-Waxman Act authorizes the brand-name company to sue preemptively for patent infringement.[1] Parties to the lawsuit may settle at any time, but antitrust issues arise when the settlement involves a "reverse payment" in exchange for delayed generic entry (also called "pay for delay"). The Supreme Court in *Federal Trade Commission v. Actavis, Inc.* described a reverse payment settlement 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.[2]

The Federal Trade Commission (FTC) maintains that this type of settlement violates antitrust laws because it "may lead to higher prices for pharmaceuticals by deterring generic entry, and contribute to increased health care costs that consumers, employers, and federal and state governments are struggling to contain."[3] A counterargument,

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[1] 21 U.S.C. § 355(c)(3)(C) (2010).

[2] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013).

[3] Joshua D. Wright, Comm'r, Fed. Trade Comm'n, Remarks at the Concurrences Journal Annual Dinner: *FTC v. Actavis* and the Future of Reverse Payment Cases (Sept.

however, is that an owner of a valid patent is immune from antitrust violation because he or she has "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States."[4] Pharmaceutical companies in the United States are also free to set drug prices as they wish.[5]

Lower courts have long disagreed as to the standard by which to analyze reverse payment settlement agreements for antitrust violations.[6] The *Actavis* Court resolved the dispute by deciding that such agreements should be analyzed under the rule of reason,[7] which generally requires a fact finder to "weigh[] all of the circumstances of a case in deciding whether a restrictive practice [e.g., a settlement] should be prohibited as imposing an unreasonable restraint on competition."[8] The *Actavis* decision has garnered much criticism for its inadequate guidance,[9] because the Court "[left] to the lower courts the structuring of the present rule-of-reason antitrust litigation."[10] One significant problem is that the Court did not rule out the possibility of "litigat[ing] patent validity to answer the antitrust question,"[11] which defeats the purpose of settling patent infringement cases. Furthermore, the Court did not address whether the term "payment" encompasses non-monetary consideration. Lower courts already

26, 2013), http://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf.

[4] 35 U.S.C. § 154(a)(1) (2013).

[5] Valerie Paris, *Why Do Americans Spend So Much on Pharmaceuticals?*, PBS NEWSHOUR (Feb. 7, 2014, 12:15 PM), http://www.pbs.org/newshour/updates/americans-spend-much-pharmaceuticals/ (discussing that the United States has relatively low levels of price regulation of pharmaceuticals).

[6] *Compare, e.g.*, FTC v. Watson Pharms. Inc., 677 F.3d 1298 (11th Cir. 2012), *with In re* K–Dur Antitrust Litig., 686 F.3d 197 (3d Cir. 2012). Note that *Actavis* rejected the standards put forth by both circuits.

[7] *Actavis*, 133 S. Ct. at 2236.

[8] Leegin Creative Leather Prods. v. PSKS, Inc., 551 U.S. 877, 885 (2007) (quoting Cont'l T. V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49 (1977)).

[9] *See, e.g.*, Lars P. Taavola, *Jumping into the* Actavis *Briar Patch—Insight into How Courts May Structure Reverse Payment Antitrust Proceedings and the Questions That* Actavis *Left Unanswered*, 40 WM. MITCHELL L. REV. 1370 (2014); Kevin D. McDonald, *Because I Said So: On the Competitive Rationale of* FTC v. Actavis, ANTITRUST, Fall 2013, at 36, http://www.jonesday.com/files/Publication/0d7aa5fb-4f61-49b8-807d-e6ae4c967149/Presentation/PublicationAttachment/c363cc02-6322-42ba-a447-ea9d6eafaf61/Fall13-McDonaldC.pdf; James J. O'Connell, *Editor's Note: The Elephant Remains*, ANTITRUST, Fall 2013, at 5, https://www.cov.com/~/media/files/corporate/publications/2013/11/the_elephant_remains.pdf.

[10] *Actavis*, 133 S. Ct. at 2238.

[11] *Id.* at 2236.

disagree on this issue.[12] Because of these ambiguities, pharmaceutical companies struggle to structure their settlement agreements to avoid antitrust scrutiny.

For private parties who wish to bring an antitrust action against settled parties, an initial challenge lies in the identification of settlement agreements—if they are even publicly available.[13] Since about 2004, pharmaceutical settlements have evolved to include a complex mix of side deals as well as non-monetary considerations.[14] Private parties must parse various transactions to determine whether any of them are related to the potentially anticompetitive agreement. Moreover, many private consumers are precluded from seeking remedies under the federal or state antitrust statutes even if they have been injured by overpriced drugs.[15] The situation calls for drastic measures to remedy these problems.

This Comment proposes that Congress adopt a mandatory judicial approval procedure for settling Hatch-Waxman litigations. The procedure is modeled after the process of settling class actions pursuant to the Federal Rule of Civil Procedure 23(e). Part II explains the relevant background information, including the regulatory and legal developments as well as some of the existing problems associated with Hatch-Waxman disputes. Part III describes the proposed procedure in detail and explains why the proposed settlement procedure is superior to the current settlement method. Part IV then concludes by summarizing the proposed procedure and its benefits.

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[12] *Compare, e.g.*, *In re* Loestrin 24 FE Antitrust Litig., 45 F. Supp. 3d 180, 192 (D.R.I. 2014) ("Reading *Actavis*, this Court cannot help but find that it applies solely to monetary settlements."), *with In re* Nexium Esomeprazole Antitrust Litig., 42 F. Supp. 3d 231, 262 (D. Mass. 2014) ("[U]nlawful reverse payments are not limited to monetary payments.").

[13] The FTC and the Department of Justice have access to pharmaceutical settlement agreements, but private parties do not. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461 (2003) [hereinafter MMA].

[14] C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 649 (2009); BUREAU OF COMPETITION, FED. TRADE COMM'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 2012 (2012), http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf.

[15] *See infra* footnotes 91–98 and accompanying text.

II. RELEVANT LEGAL DEVELOPMENTS AND ISSUES IN THE PHARMACEUTICAL INDUSTRY

This Comment can be better understood if the reader is familiar with the legal and economic concerns surrounding the pharmaceutical industry. Subsection A discusses the relationship between the patent system and the pharmaceutical industry. Subsection B describes the purposes of the Hatch-Waxman Act and its pertinent provisions. Subsection C explains the antirust enforcement mechanism and relevant issues. Subsection D summarizes the circuit split that led to the *Actavis* decision, the *Actavis* opinion itself, and its aftermath.

A. *The Role of the Patent System in the Pharmaceutical Industry*[16]

In order to sustain their businesses, brand-name companies[17] must recover their investments in drug development. An estimate shows that "for every 5,000 to 10,000 compounds that enter the discovery pipeline, only five make it to clinical trials, and only one receives approval" from the Food and Drug Administration (FDA).[18] The development of a single new drug takes an average of ten to fifteen years, and the research and development (R&D) investment per drug can be anywhere from $1.2 billion[19] to $5 billion.[20] These high figures are in part due to a high rate of failure—one commentator suggests that 95% of the experimental medicines fail to be both effective and

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[16] This Comment primarily focuses on exclusivity rights conferred by the patent system. The Hatch-Waxman Act and other legislation provide non-patent exclusivity rights for certain new drug applicants. *See, e.g.*, 21 U.S.C. §§ 355(c)(3)(E)(ii)–(iii), 355(j)(5)(F)(ii)–(iv), 355a, 360cc (2010).

[17] For the sake of simplicity, this Comment refers collectively to all companies that develop new drugs and file NDAs as "brand-name companies." In reality, many companies make both new and generic drugs.

[18] PHARM. RESEARCH AND MFRS. OF AM., PHARM. INDUS. PROFILE 2012 30 (2012), http://www.phrma.org/sites/default/files/pdf/phrma_industry_profile.pdf.

[19] *Id.*

[20] Matthew Herper, *The Cost of Creating a New Drug Now $5 Billion, Pushing Big Pharma to Change*, FORBES (Aug. 11, 2013, 11:10 AM), http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/. Note that there are:

> [s]ome caveats, though: drug companies have tax incentives to count costs in research and development, which could inflate the figure; they also are likely to spend extra money in order to get those medicines approved in other countries. Even more important is the fact that some R&D costs come from monitoring the safety of medicines after they become hits to monitor reports of side effects.

Id.

safe for human use.[21] Even if drugs reach the market, only 20% of FDA-approved drugs will recoup the cost of R&D.[22] Furthermore, brand-name companies suffer a dramatic loss in profits when generic products enter the market; competition causes the price of a patented drug to plummet, and within a year of generic entry, an average generic product "takes over ninety percent of the patent holder's unit sales and sells for fifteen percent of the price of the name brand product."[23]

A successful, patent-protected drug is vital for innovators' financial futures and their ability to reinvest in research endeavors. The purpose of the United States patent system—"[t]o promote the [p]rogress of [s]cience and useful [a]rts, by securing for limited [t]imes to . . . [i]nventors the exclusive [r]ight to their [inventions]"[24]—is especially true for pharmaceutical innovations, as "new product development in the pharmaceutical industry is more dependent on patent protection than in many other industries."[25] One study shows "that 60 percent of inventions within the pharmaceutical industry would not have been" possible without the patent system.[26]

Insofar as brand-name companies are dependent on the patent system to recover their R&D investments, there are indications that the companies have gone too far. One strategy frequently employed by brand-name companies is to obtain "secondary" patents, i.e., patents protecting ancillary aspects of a drug other than its active ingredient.[27] These secondary patents essentially extend the overall period of patent protection for a particular drug, but they vary in strength. In fact, many secondary patents are considered "weak," meaning that they are

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[21] *Id.*

[22] *Intellectual Property Protections are Vital to Continuing Innovation in the Biopharmaceutical Industry*, PHRMA, http://www.phrma.org/innovation/intellectual-property (last visited Nov. 4, 2014) ("[O]nly 2 out of every 10 medicines will recoup the money spent on their development.").

[23] *In re* K-Dur Antitrust Litig., 686 F.3d 197, 208 (3d Cir. 2012) (citing FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010), http://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).

[24] U.S. CONST. art. I, § 8.

[25] Brief of Pharm. Research & Mfrs. of Am. (PHRMA) as Amicus Curiae in Support of Respondents at 7, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 769196, at *7.

[26] *Id.*

[27] C. Scott Hemphill & Bhaven N. Sampat, *Drug Patents at the Supreme Court*, SCI., Mar. 2013, at 1386.

likely invalid or not infringed.[28] The holder of a weak patent likely has no right to block the sale of cheaper alternatives to its brand-name drug.[29] Thus, a settlement agreement that operates to exclude competitors from the market is likely anticompetitive when it ends a dispute over a weak patent. On the other hand, even if a settlement excludes competition, it can be deemed pro-competitive if it allows generic entry before the expiration of the patent, especially if the patent is strong.[30] In fact, the *Actavis* Court conceded that settlements with terms permitting the generic company to enter the market before the expiration of the patent "would . . . bring about competition . . . to the consumer's benefit."[31] This is because market entry by generic companies and the resulting decrease in drug prices occur much sooner than they would without such arrangement; all it takes is a single strong patent for a brand-name company to completely dominate the market.

B. *The Hatch-Waxman Act*

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act,[32] to "strike a balance between two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."[33] Prior to the enactment of the Hatch-Waxman Act, the FDA required brand-name and generic companies alike to submit proof of drug safety and efficacy through a New Drug Application (NDA).[34] Brand-name companies were frustrated with the time-

[28] *See, e.g., id.*; *see also* Allison A. Schmitt, Note, *Competition Ahead? The Legal Landscape for Reverse Payment Settlements After* Federal Trade Commission v. Actavis, Inc., 29 BERKELEY TECH. L.J. 493, 503 (2014) (noting that brand-name companies lose most litigations on secondary patents).

[29] *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2231 (2013).

[30] *Id.* at 2237.

[31] *Id.* at 2234.

[32] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.).

[33] Mylan Pharms., Inc. v. FDA, 454 F.3d 270, 272 (4th Cir. 2006) (quoting *aaiPharma Inc. v. Thompson,* 296 F.3d 227, 230 (4th Cir. 2002)); *see also Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments): Statement Before the Senate Comm. on the Judiciary*, 108th Cong. (2003) (statement of Daniel E. Troy, Chief Counsel, FDA), http://www.fda.gov/newsevents/testimony/ucm115033.htm.

[34] 21 U.S.C. § 355(b)(1) (2010); Barbara J. Williams, *A Prescription for Anxiety: An Analysis of Three Brand-Name Drug Companies and Delayed Generic Drug Market Entry*, 40

consuming FDA approval process: the longer the process took, the shorter their remaining patent terms became,[35] and the more money they lost to generic competition.[36] Generic companies were also held back by the pre-Hatch-Waxman requirement to "re-prove" data that had already been established by brand-name companies.[37] Furthermore, generic drug companies could not perform any tests on a patented drug until after the relevant patent(s) expired, because such use could be deemed an act of infringement.[38] These impediments delayed generic entry and prolonged consumers' burden.

The Hatch-Waxman Act addressed these problems in various ways. First, it provided patent term extension for patents covering a new drug product subject to FDA regulatory delays.[39] Second, the Act also freed generic manufacturers from patent infringement liability arising from activities in connection with development of generic drugs.[40] Third, it simplified the application process for generic manufacturers by allowing the submission of an Abbreviated New Drug Application (ANDA).[41]

An ANDA obviates the need for generic companies to obtain all the necessary data from scratch. It relies on the scientific findings of the corresponding NDA to demonstrate the safety and efficacy of a

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NEW ENG. L. REV. 1, 2 (2005).

[35] During the pre-Hatch-Waxman era, a patent term was the greater of twenty years from the date on which the application for the patent was filed in the United States, or seventeen years from the patent grant. *See* MPEP § 2701 (9th ed. Nov. 2015).

[36] The FDA approval process normally takes place after patent acquisition. Williams, *supra* note 34, at 3 n.9 (citing FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 4 (2002) ("[T]he effective terms of many patents were shortened due to the time required for the FDA to ensure the safety and efficacy of the brand-name company's drug product.")).

[37] *Id.* at 2 (citing H.R. REP. NO. 98-857, pt. 2, at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688 (commenting on the state of the law before the enactment of the Hatch-Waxman Act that "with respect to drugs approved after 1962, the FDA has adopted the view that generics must virtually duplicate the same health and safety tests conducted by the original applicant for marketing approval")).

[38] *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 860–61 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984) (holding that the district court erred when it concluded that the generic company's use of the patented compound for commercial development purposes was not infringement even if it was necessary to obtain FDA approval), *superseded by statute*, 35 U.S.C. § 271(e)(1).

[39] 35 U.S.C. § 156(a), (f)(1)(A), (f)(2)(A) (2011).

[40] *Id.* § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .").

[41] 21 U.S.C. § 355(j) (2010).

proposed generic drug as long as the generic company shows that its drug is bioequivalent to the brand-name drug in the NDA.[42] An NDA filer, a brand-name company, may list any patents that it believes to cover its drug in the FDA's compendium called Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."[43] A generic manufacturer seeking FDA approval must include in its ANDA one of the following certifications with respect to each patent listed in the Orange Book: no patent is listed in the Orange Book (Paragraph I); the patent has expired (Paragraph II); the ANDA filer will not sell the proposed generic drug until the Orange Book patent expires (Paragraph III); and the patent listed in the Orange Book is invalid or will not be infringed by the manufacture, use, or sale of the generic company's proposed drug (Paragraph IV).[44] A generic applicant must notify the brand-name company if its ANDA contains a Paragraph IV certification ("Paragraph IV ANDA").[45] Upon receipt of the notice, the brand-name company may do nothing, in which case the FDA may authorize the generic company to market its proposed product.[46] Alternatively, the brand-name company may sue the generic manufacturer because the filing of a Paragraph IV ANDA itself is considered a statutory act of patent infringement.[47] If the brand-name company sues within forty-five days of notice, the FDA may not grant final approval of the ANDA until the earlier of the passage of thirty months or the issuance of a court decision that the patent is invalid or not infringed.[48] Thus, "the mere filing of an infringement . . . can provide additional years of a generic-free market, regardless of the merits of the lawsuit."[49] One commentator observed that at least twelve brand-name companies have actively used their secondary patents to trigger such thirty-month stay of FDA approval.[50]

For the first Paragraph IV ANDA filer ("first-filer"), the Hatch-Waxman Act grants a 180-day exclusivity period, during which other

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[42] *Id.*

[43] § 355(b)(1)(G). Eligible patents issued after the FDA approves an NDA may be listed in the Orange Book if the manufacturer files the patent information within thirty days of issuance. § 355(c)(2).

[44] § 355(j)(2)(A)(vii).

[45] § 355(j)(2)(B).

[46] § 355(j)(5)(B).

[47] 35 U.S.C. § 271(e)(1)–(2).

[48] § 355(j)(5)(B).

[49] Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 J. LEGIS. 21, 26–27 (2002).

[50] *Id.* at 34.

generic companies cannot compete in the market.[51] The drafters of the Hatch-Waxman Act may have envisioned this exclusivity period as a reward for the generic manufacturers who undertake the effort to invalidate weak patents.[52] Ironically, this well-intended incentive has turned into a "'bounty' worth hundreds of millions of dollars for a major drug" due to its potential to keep the drug prices substantially high.[53] Until 1998, the FDA required the first-filers to win the patent infringement lawsuit to retain their exclusivity.[54] Since then, however, the FDA relaxed the requirement to allow the first-filers to retain exclusivity so long as they did not lose.[55] This meant that settling a case did not affect the first-filer's exclusivity right even if the merits of the case remained unresolved.

From a brand-name company's perspective, paying the first-filer to delay its market entry makes economic sense. First, the first-filer's victory leads to a substantial loss of profits, especially in a situation where the patent at issue is the only patent blocking competition.[56] Outcomes of drug patent infringement suits are notoriously unpredictable and error prone, with patents being invalidated "more than 70 percent of the time."[57] "This means that the strongest of patents has a substantial chance of losing after a trial and appeal, just as the weakest of patents has a substantial chance of winning."[58] Furthermore, brand-name companies have little to gain from their own victories because they neither result in damages nor prevent other

[51] § 355(j)(5)(B)(iv). If multiple applicants file on the same day, the FDA may designate more than one applicant as a "first-filer." CTR. FOR DRUG EVALUATION & RESEARCH, U.S. DEP'T. OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY 5–6 (2003), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm072851.pdf.

[52] Schmitt, *supra* note 28, at 499 (citing Brief of Amicus Curiae Intellectual Prop. Owners Ass'n in Support of Respondents at 25, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416)).

[53] C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1560 (2006).

[54] Hemphill, *supra* note 14, at 658.

[55] *Id.*

[56] Michael R. Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1800–01 (2011).

[57] Rudolph J.R. Peritz, *The Competition Question Unasked in* Actavis*: What is the Scope of the Patent Right to Exclude?*, ANTITRUST, Fall 2013, at 45, 49, http://awa2014.concurrences.com/IMG/pdf/fall13-peritzc.pdf.

[58] Brief of Amicus Curiae Intellectual Prop. Owners Ass'n in Support of Respondents at 10, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 871961, at *10.

generic companies from attempting to enter the market.[59] Rather than putting their valuable patents in jeopardy and running the risk of incurring losses, many brand-name companies prefer to settle by sharing their monopoly profits with first-filers.

More significantly, a settlement that delays a first-filer's market entry creates a "bottleneck" period during which a brand-name company is able to engage in supracompetitive pricing of its drug. This is because a first-filer's 180-day exclusivity period begins to run only when the first-filer begins marketing its generic product, or a court renders a judgment of patent invalidity or non-infringement.[60] Thus, subsequent ANDA filers cannot enter the market unless one of them obtains a favorable court judgment against the brand-name company. Brand-name companies avoid the risk of losing altogether by not suing subsequent Paragraph IV ANDA filers.[61] The ANDA filers have little incentive to initiate a declaratory judgment action,[62] because even the winner in such a lawsuit must wait for the first-filer's exclusivity period to run its course, at which time other generics can enter the market and drive down the drug prices.[63]

Congress attempted to rectify the bottleneck problem by adding a forfeiture provision[64] as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).[65] The provision causes a first-filer to lose its exclusivity period when it fails to market its generic drug by the "later of" the two conditions defined in subsections (aa) and (bb) of the Act.[66] Unfortunately, the problem of the bottleneck lingers after the MMA amendments because the new

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[59] *See* Herman, *supra* note 56, at 1800.

[60] Hemphill, *supra* note 14, at 658.

[61] *Id.* at 658–59.

[62] 21 U.S.C. § 355(c)(3)(D) (2010) (establishing that generic drug applicant may file a declaratory judgment action if the NDA holder does not sue on all of the Orange Book listed patents within the forty-five-day period).

[63] Hemphill, *supra* note 14, at 635.

[64] § 355(j)(5)(D).

[65] Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified in scattered sections of 42 U.S.C. and 21 U.S.C.).

[66] The first condition under (aa) is "the earlier of" seventy-five days after the first filer's approval is made effective or thirty months after the ANDA filing. § 355(j)(5)(D)(i)(I)(aa). The second condition under (bb) is seventy-five days after: a court decision, from which no appeal has been taken or can be taken, that the patent is invalid or not infringed; a settlement states that the patent is invalid or not infringed; the patent information for the listed drug is withdrawn by the NDA holder; or the first ANDA filer amends or withdraws the Paragraph IV certification. § 355(j)(5)(D)(i)(I)(bb), (q)(1)(G). *See also* Hemphill, *supra* note 14, at 660–61.

rule still allows first-filers to retain their exclusivity by settling.[67] Furthermore, while the new rule continues to allow subsequent filers to trigger the 180-day exclusivity period by obtaining a court judgment, it now requires that the judgment come from an *appeals* court.[68] Thus, incentives for subsequent filers to challenge patents are further diminished because even after expending their resources to win at the appellate level, the 180-day exclusivity remains with the first-filer.[69] No subsequent ANDA filer is eligible for exclusivity upon the first-filer's forfeiture.[70]

Furthermore, the unique framework of the Hatch-Waxman Act created an inherent power imbalance between brand-name and generic companies. This is because a Paragraph IV litigation occurs before the generic enters the market.[71] Under such circumstance, "[t]he patent owner [i.e., the brand-name company] risks losing its patent, but the alleged infringer does not risk a damage award."[72] From the generic's perspective, the benefit of winning a lawsuit and gaining entry to a lucrative market far outweighs the cost of litigation, and thus justifies a challenge to the patent even with a 1.3% chance of success.[73] The power imbalance may also affect settlement

[67] According to the FDA, as long as there is a possibility that at least one of the conditions in subsection (bb) could still occur, the first-filer would not forfeit its exclusivity. Letter from Gary J. Buehler, Dir., Office of Generic Drugs, Food & Drug Admin., to Marc A. Goshko, Exec. Dir., Teva N. Am. 5 (Jan. 17, 2008), http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM151237.pdf [hereinafter FDA Letter]; *see also* Kurt R. Karst, *Academics Criticize the MMA's Failure-to-Market Forfeiture Provisions as an Anemic Mechanism for Parked Exclusivity and the MMA's DJ Provisions as a Paper Tiger*, FDA LAW BLOG (Apr. 27, 2011), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/04/academics-criticize-the-mmas-failure-to-market-forfeiture-provisions-as-an-anemic-mechanism-for-park.html (explaining that the current statute does not counteract the problem of exclusivity "parking" by first ANDA filers).

[68] § 355(j)(5)(D)(i)(I)(bb); *see also* Hemphill, *supra* note 14, at 661 ("The post-MMA rules make the relevant condition for defeasement an appeals court win, rather than a district court win—a condition now applicable to both post-MMA and pre-MMA drugs.").

[69] Hemphill, *supra* note 53, at 1586 (noting that settling with a first-filer "removes from consideration the most motivated challenger, and the one closest to introducing competition").

[70] § 355(j)(5)(D)(iii); *see also* Hemphill, *supra* note 53, at 1583–84.

[71] § 355(j)(2)(B).

[72] David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1303, 1307 (2010).

[73] Brief of Amicus Curiae Intellectual Prop. Owners Ass'n in Support of Respondents, *supra* note 58, at 24 ("[F]or more than 90% of branded drug sales (measured in dollars), a generic challenger balancing upside gain under Hatch-

negotiations. The generic company, knowing that it has little to lose by litigating, may demand a high settlement amount, and the brand-name company would pay that amount as long as it does not exceed the brand-name company's expected payout from winning the lawsuit.[74] According to one study, brand-name companies can pay generic manufacturers between $1.75 million and $132.5 million for a delay period of between four months and ten years.[75] As explained below, *Actavis* provides slight leverage in negotiations for brand-name companies because "unexplained" and "large" reverse payments raise red flags, but the basic power balance has not changed.

C. *Antitrust Enforcement*

Even after a settlement is reached, the brand-name and generic companies do not live happily ever after. Under the current antitrust enforcement mechanism, parties who have settled a Paragraph IV litigation could face multiple lawsuits instituted by outside parties. The enforcement system is decentralized in the United States, and thus, potential antitrust plaintiffs include the federal government, state governments, and aggrieved individuals and entities. A federal antitrust action may be brought under two federal statutes: the Sherman Act[76] and the Clayton Act.[77] The FTC[78] may initiate an antitrust action under the Sherman Act against parties for collusion (§

Waxman against downside risk limited to litigation costs can justify the challenge if it believes it has at least a 1.3% chance of success.").

[74] Amanda P. Reeves, *Muddying the Settlement Waters: Open Questions and Unintended Consequences Following* FTC v. Actavis, ANTITRUST, Fall 2013, at 9, 12.

[75] John Fazzio, *Pharmaceutical Patent Settlements: Fault Lines at the Intersection of Intellectual Property & Antitrust Law Require a Return to the Rule of Reason*, 11 J. TECH. L. & POL'Y 1, 14 (2006).

[76] Sherman Antitrust Act, 26 Stat. 209 (1890) (codified at 15 U.S.C. §§ 1–7 (2012)).

[77] Clayton Antitrust Act, Pub. L. 63-212, 38 Stat. 730 (1914) (codified at 15 U.S.C. §§ 12–27 (2012); 29 U.S.C. §§ 52–53 (2012)). This Comment assumes that the interstate commerce requirement of the federal statutes is satisfied.

[78] The Antitrust Division of the Department of Justice and the FTC share the responsibility of enforcing federal antitrust laws, but only the Antitrust Division may institute criminal proceedings. 15 U.S.C. §§ 41–58 (2012). Criminal prosecutions, however, are relatively rare in the Hatch-Waxman context because "criminal prosecution in general and imprisonment in particular have been confined to instances of outrageous conduct of undoubted illegality." Molly Wilcox & Jason Yan, *Antitrust Violations*, 51 AM. CRIM. L. REV. 837, 838 n.8 (2014) (quoting 2 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTIRUST LAW § 303b (3d ed. 2006)). Hatch-Waxman settlements do not normally fall within the category of "undoubted illegality" because the issue of patent validity/infringement creates uncertainty as to the legality of the settlements.

1)[79] or against a single party for engaging in a monopoly (§ 2).[80] 15 U.S.C. § 15c also allows state attorneys general to bring civil actions as *parens patriae* on behalf of natural persons who have been injured as a result of a violation of the Sherman Act.[81] The Clayton Act authorizes private individuals who have been injured "by reason of anything forbidden in the antitrust laws" to sue and recover *threefold* the damages, as well as the cost of suit and a reasonable attorney's fee.[82]

Under federal law, a civil antitrust suit must be commenced within four years of accrual.[83] "An antitrust cause of action accrues . . . when a defendant commits an act[] that causes injury to the plaintiff."[84] In the Hatch-Waxman context, this means that the statute of limitations begins to run when settling parties enter into an allegedly unlawful agreement. The statute of limitations, however, is not rigid. In class action lawsuits (which is often the case for private antitrust actions against parties to Paragraph IV settlements), "the filing of a class action tolls the statute of limitations as to all asserted members of the class."[85] The statute of limitations remains tolled for all members of the putative class until class certification is denied. Potential class members "may choose to file their own suits or to intervene as plaintiffs in the pending action."[86] Therefore, parties to Paragraph IV settlements may face antitrust lawsuits from both the FTC and private parties more than four years after the agreement date.

The settling parties could also face state antitrust actions more than four years after they settle. Nearly all states have antitrust laws that typically authorize the state attorneys general to bring criminal or civil actions against antitrust offenders,[87] and many state laws provide remedies for private plaintiffs.[88] State statutes of limitations vary, but some states hold that the limitations period begins when the plaintiff

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[79] 15 U.S.C. § 1 (2011).

[80] *Id.* § 2.

[81] *Id.* § 15c.

[82] *Id.* § 15a. This right of action is generally limited to direct purchasers of price-fixed items, i.e., persons or entities who directly purchase from the antitrust violator. *See also* notes 91–98 and accompanying text.

[83] *Id.* § 15b.

[84] *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 218 (E.D.N.Y. 2003) (citing Zenith Radio Corp. v. Hazeltine Research, 401 U.S. 321, 338 (1971)).

[85] *In re Ciprofloxacin*, 261 F. Supp. 2d at 219 (internal quotation marks omitted).

[86] Crown, Cork & Seal Co., Inc. v. Parker, 462 U.S. 345, 354 (1983).

[87] Wilcox et al., *supra* note 78, at 869.

[88] Kurtis A. Kemper, *Right of Retail Buyer of Price-Fixed Product to Sue Manufacturer on State Antitrust Claim*, 35 A.L.R. 6TH 245, pt. II.B.§ 9 (2008).

discovers the anticompetitive act as opposed to when the defendants settle. For example, in Rhode Island, the plaintiff must commence an action "within four (4) years after the plaintiff discovered, or by the exercise of reasonable diligence should have discovered, the facts relied upon for proof of the conspiracy."[89]

For many injured parties (such as consumers who bought overpriced drugs), one significant hurdle is antitrust standing. Paragraph IV settlements affect people's right to healthcare,[90] yet not every injured person is entitled to recovery even when the federal and state statutes provide private causes of action.[91] Specifically, the indirect purchaser rule limits recovery only to direct purchasers, i.e., persons or entities who purchased price-fixed items *directly* from the antitrust violator.[92] This rule applies to the federal statutes[93] as well as many state statutes that do not specifically repeal the indirect purchaser rule.[94] In the pharmaceutical context, indirect purchasers (e.g., consumers) are precluded from bringing an antitrust action against those companies that caused delayed generic entry by way of a settlement agreement.[95] Thus, indirect purchasers of pharmaceutical

[89] R.I. Gen. Laws § 6-36-23 (2014); *see also* N.J. Stat. Ann. § 56:9-14 (West 2014) ("Any action brought to enforce the provisions of this act shall be barred unless commenced within 4 years after the cause of action arose . . . .").

[90] *See, e.g.*, 155 CONG. REC. H12,623, H12,848 (daily ed. Nov. 7, 2009) (statement of Rep. Braley) ("[T]his bill will do for America what we should have done 100 years ago: provide health care for all Americans as a matter of right, not as a matter of privilege."); 155 CONG. REC. H12,598, H12,619 (daily ed. Nov. 7, 2009) (statement of Rep. Langevin) ("Every American deserves the promise of quality affordable health care, and this is our moment to fulfill that promise."). This Comment refrains from discussing the issue of whether illegal immigrants have the right to healthcare.

[91] For example, Section 4 of the Clayton Act provides a private right of action, authorizing a person injured "by reason of" an allegedly anticompetitive act to sue and recover threefold the damages, as well as the cost of suit and a reasonable attorney's fee. *See* 15 U.S.C. § 15 (2011). Many state laws also provide similar remedies for private plaintiffs. *See* Kemper, *supra* note 88, at pt. II.B.§ 9.

[92] *See generally* Illinois Brick Co. v. Illinois, 431 U.S. 720 (1977). *See also* Kemper, *supra* note 88, at pt. I.§ 2 (explaining that the indirect purchaser rule "generally bars actions by retail buyers against manufacturers of price-fixed products, subject to limited exceptions").

[93] *See, e.g.*, *In re* Terazosin Hydrochloride Antitrust Litig., 160 F. Supp. 2d 1365, 1369 (S.D. Fla. 2001) ("The U.S. Supreme Court has flatly repudiated such efforts to trace damages through multiple levels in a chain of distribution or to apportion damages between direct and indirect purchasers.").

[94] *See, e.g.*, *In re* Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 409 (D. Mass. 2013) ("[E]nd-payors cannot assert antitrust claims under the law of states which have not passed [repealer statutes which specifically grant end-payors the right to sue for antitrust violations].").

[95] Some exceptions apply. For example, in *In re Relafen Antitrust Litigation*, 346 F. Supp. 2d 349, 368, 370 (D. Mass. 2004), retail drug store plaintiffs were allowed

drugs often have no practical avenue to recover damages for overpaid drug products. Even in the states that recently enacted the so-called "repealer" statutes of the indirect purchaser rule (also called "Illinois Brick repealers"), the statutes often apply prospectively.[96] Indirect purchasers in such jurisdictions cannot recover for the overcharges that took place before the enactment of the repealer statutes. In recent years, indirect purchasers have attempted to circumvent this rule by making claims under the state consumer protection statutes and unjust enrichment laws, but their attempts have typically been unsuccessful. For instance, consumer protection statutes have requirements that cannot be easily satisfied since they apply only to courses of conduct that are deceptive and fraudulent as opposed to merely anticompetitive.[97] Many courts have also dismissed unjust enrichment claims brought under state laws because they would otherwise constitute "end-runs" around state antitrust laws and consumer-protection statutes.[98]

Even in states that permit indirect purchasers to bring an antitrust claim, there is the fundamental problem of accessing private settlement agreements. This problem also plagues direct purchasers. As time passes, it would become an increasingly daunting task for anyone to identify any side deals related to the settlement. In *In re Lipitor*, for example, it was not until after limited discovery that all relevant side agreements were revealed: multiple litigations concerning two other drugs in the United States—Accupril and Caduet—as well as twenty-three legal proceedings in thirteen foreign countries.[99] In light of *Actavis*, settlements of Paragraph IV lawsuits will likely become more complex to avoid an appearance of a large, unexplained reverse payment.[100] Individuals who were involved in

recovery for their federal claims even though they were indirect purchasers because they had been expressly assigned the rights of direct purchasers that had opted out of the direct purchaser plaintiffs' class.

[96] *In re* Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 759 (E.D. Pa. 2014) ("[T]he end-payor plaintiffs may not recover for any overcharges incurred before the Oregon and Rhode Island repealer statutes took effect.").

[97] *See, e.g.*, *id.* The case was an antitrust suit in connection with a reverse payment settlement. Claims brought under the consumer protection statutes of Minnesota, Pennsylvania, and Virginia were dismissed because no allegations of deceit were made. *Id.* at 760.

[98] *See, e.g.*, *In re Terazosin*, 160 F. Supp. 2d at 1380 ("State legislatures and courts that adopted the *Illinois Brick* rule against indirect purchaser antitrust suits did not intend to allow an end run around the policies allowing only direct purchasers to recover.") (internal quotation marks omitted).

[99] *In re* Lipitor Antitrust Litig., 46 F. Supp. 3d 523, 532–34 (D.N.J. 2014).

[100] *See* Reeves, *supra* note 74, at 12 ("To eliminate as much risk [of antitrust lawsuit]

settlement negotiations may be unavailable by the time an injured party contemplates an antitrust action. In some instances, settled parties voluntarily publish the terms of their settlement agreements.[101] Nevertheless, "publicly available information contains significant gaps"[102] and may be insufficient for private parties to plead a cause of action that can survive a motion to dismiss, or to recognize an anticompetitive scheme to begin with.

The problem is compounded when a brand-name company strategically enters into a series of settlement agreements with multiple ANDA filers.[103] Such a scheme is difficult to identify and/or prove. Suppose a brand-name company has an extremely weak patent that is blocking competition in a lucrative market. The brand-name company initiates a patent infringement action against the first-filer and then settles, requiring the first-filer to delay its market entry and to retain its 180-day exclusivity. This settlement blocks subsequent filers from entering the market until after the expiration of the agreed-upon delay period plus 180 days, unless one of the subsequent ANDA filers obtains an appellate court judgment that the patent is invalid or not infringed.[104] Suppose further that a number of the subsequent filers decide to challenge the patent. The brand-name company sues and then settles with each of them in order to prevent a court judgment of invalidity or non-infringement. This series of settlements is anticompetitive because, as described above, a weak patent does not warrant its owner to exclude others from competition.[105] Because of the complexities and confidential nature of these agreements,

as possible, companies should . . . avoid structuring settlements that involve unexplained high dollar payments from the branded to the generic company . . . .").

[101] For example, in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188, 197 n.13 (E.D.N.Y. 2003), settled parties had made press releases regarding the settlement and its major terms. Moreover, one of the parties submitted a redacted copy of the settlement agreement in a public SEC filing. As another example, if a generic company challenges a patent before the Patent Trial and Appeal Board, information related to the proceeding becomes public.

[102] Hemphill, *supra* note 14, at 647.

[103] *See, e.g.*, FTC v. Actavis, Inc., 133 S. Ct. 2223, 2229–30 (2013). FTC filed a lawsuit against all settling parties alleging that Solvay, the patentee, colluded with both the first Paragraph IV filer, Actavis, and the subsequent filer, Paddock, to share in Solvay's monopoly profits. *Id.* Solvay agreed to pay the two filers in exchange for delaying market entry. *Id.* at 2229.

[104] 21 U.S.C. § 355(j)(5)(D)(i)(I) (2010); Hemphill, *supra* note 14, at 658. *See also* FDA Letter, *supra* note 67.

[105] *Actavis*, 133 S. Ct. at 2231 ("[A]n *invalidated* patent carries with it no . . . right [to exclude others from competition]. And even a valid patent confers no right to exclude products or processes that do not actually infringe.").

however, antitrust plaintiffs might not be able to identify and attack all such agreements. Thus, a brand-name company might prevail on the individual actions, even if the settlement scheme as a whole is unlawful.

Since settling parties in Hatch-Waxman lawsuits are required to submit their agreements to the FTC,[106] one might argue that the FTC is better-positioned than private parties to bring actions on behalf of the injured members of the public who have no legal recourse. In fact, after *Actavis*, the FTC has reaffirmed its plans to focus on pay for delay settlements.[107] But government agencies have limited resources and cannot satisfy the interests of all individual purchasers. Furthermore, the political climate could shift an agency's focus and resources to another issue at any time. Most significantly, the FTC cannot always be proactive in its approach to consumer protection. Its enforcement actions often take place long after consumers have been injured.

D. *Actavis and Questions Left Unanswered*

i. *FTC v. Actavis, Inc.*

Actavis revolved around agreements that a single brand-name company entered into with three generic companies to settle Paragraph IV litigations. The agreements contained "roughly similar promises," requiring each generic company to not enter the relevant market until sixty-five months before the brand-name company's patent expired and to market the brand-name company's product in return for the payment of "millions of dollars."[108] The FTC initiated an antitrust lawsuit against all parties for "unlawfully agreeing to share in [the brand-name company]'s monopoly profits, abandon their patent challenges, and refrain from launching [cheaper generic drugs] . . . for nine years."[109] As mentioned above, the dilemma in antitrust cases involving reverse payment settlement agreements stems from the unresolved issue of patent strength. The pre-*Actavis* courts disagreed as to the antitrust standard for analyzing reverse payment settlements. Some circuits applied the "scope-of-the-patent" test, under which a

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[106] MMA, *supra* note 13.

[107] *See* José P. Sierra, *FTC Reveals Plans for Reverse Payment Hatch-Waxman Cases*, PHARMARISC.COM (Aug. 5, 2013), http://www.pharmarisc.com/2013/08/ftc-reveals-plans-for-reverse-payment-hatch-waxman-cases/ ("Ending anti-competitive 'pay-for-delay' settlements is a top priority at the Federal Trade Commission, according to FTC Chairwoman Edith Ramirez."). *See also* Wright, *supra* note 3 (interpreting the *Actavis* decision to be a "significant victory for the Commission").

[108] *Actavis*, 133 S. Ct. at 2229.

[109] *Id.* at 2229–30 (internal quotation marks omitted).

reverse payment settlement was immune from antitrust scrutiny so long as the anticompetitive effects fell within the "exclusionary potential" of the patent.[110] Other courts employed the "quick-look" approach, which viewed reverse payment settlements as prima facie evidence of illegality.[111]

The *Actavis* Court resolved the circuit split by holding that courts should employ the rule of reason approach[112] to strike a balance "between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act."[113] In connection with the rule of reason analysis, the Court suggested that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness,"[114] which in turn reveals "the payment's objective . . . to maintain supracompetitive prices to be shared among the patentee and the challenger."[115] The Court further stated that the size of a reverse payment may serve as "a strong indicator of power" possessed by the patentee to bring about anticompetitive harm.[116] The Court rejected the "scope-of-the-patent" analysis because "whether a particular restraint lies beyond the limits of the patent monopoly is a *conclusion* . . . and not . . . its starting point."[117] The Court pointed out that the "scope-of-the-patent" test overlooks the possibility of the patentee's "serious doubts about the patent's survival" and objective of the payment "to maintain supracompetitive prices."[118] In rejecting the "quick look" approach, the Court held that some reverse payments can be justified under antitrust analysis.[119]

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[110] *See, e.g.*, FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1309 (11th Cir. 2012).

[111] *See, e.g.*, *In re* K-Dur Antitrust Litig., 686 F.3d 197, 208 (3d Cir. 2012).

[112] The rule of reason analysis, in general, examines "whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition." Bd. of Trade v. United States, 246 U.S. 231, 238 (1918).

[113] *Actavis*, 133 S. Ct. at 2231 (internal quotation marks omitted).

[114] *Id.* at 2236–37.

[115] *Id.* at 2236.

[116] *Id.*

[117] *Id.* at 2231–32 (internal quotation marks omitted).

[118] *Id.* at 2235, 2236–37.

[119] *Actavis*, 133 S. Ct. at 2237.

ii. The Aftermath of *Actavis*

While *Actavis* resolved the circuit split, it left more questions than answers because the Court left "to the lower courts the structuring of the present rule-of-reason antitrust litigation."[120] One unresolved issue in the aftermath of *Actavis* is the precise definition of the term "payment." There are currently various ways to settle Hatch-Waxman disputes other than what was at issue in *Actavis*. For example, settlements can take the form of a licensing agreement without any money exchanging hands where the brand-name company allows the generic manufacturer to use its patent.[121] Since the issuance of the *Actavis* opinion in June 2013, lower courts have already disagreed on what constitutes "payment." Some judges have held that the *Actavis* decision applies to monetary payments only, while others concluded that payment is not so limited.[122] The FTC agrees with the latter view, noting that a brand-name company's promise not to develop or market its authorized generic (AG)[123] is a form of payment.[124]

Furthermore, the *Actavis* Court did not define what constitutes a "large" payment. The Court only suggested that "strong evidence" of anticompetitive activity may be found when the amount of payment is

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[120] *Id.* at 2238. *See In re* Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 235 (D. Conn. 2015) ("Several district courts have already applied *Actavis*, with not entirely consistent results.") (internal quotation marks omitted).

[121] Fazzio, *supra* note 75, at 13–14.

[122] *Compare, e.g.*, *In re* Loestrin 24 FE Antitrust Litig., 45 F. Supp. 3d 180, 192 (D.R.I. 2014) ("Reading *Actavis*, this Court cannot help but find that it applies solely to monetary settlements . . . ."), *with* King Drug Co. of Florence v. SmithKline Beecham Corp., 791 F.3d 388, 403 (3d Cir. 2015) ("We do not believe *Actavis*'s holding can be limited to reverse payments of cash."), *In re* Nexium Esomeprazole Antitrust Litig., 42 F. Supp. 3d 231, 262 (D. Mass. 2014) ("[U]nlawful reverse payments are not limited to monetary payments.") (internal quotation marks omitted), *In re* Lipitor Antitrust Litig., 46 F. Supp. 3d 523, 543 (D.N.J. 2014) ("In applying *Actavis* here, the non-monetary payment must be converted to a reliable estimate of its monetary value . . . ."), *and In re* Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014) ("'[R]everse payment' is not limited to a cash payment.").

[123] An AG is a generic drug produced by the same brand-name company that issues the corresponding brand-name drug. Brand-name companies can market AGs even during the first-filer's exclusivity period. *See, e.g.*, Alix McKenna, *FTC Report Shows Increase in Pay-for-Delay Drug Settlements*, REGBLOG (June 11, 2013), http://www.regblog.org/2013/06/11/11-mckenna-ftc-report/.

[124] Brief of Fed. Trade Comm'n as Amicus Curiae in Support of Plaintiffs-Appellants at 16–18, King Drug Co. of Florence v. Smithkline Beecham Corp., 791 F.3d 388 (3d Cir. 2015) (No. 14-1243), 2014 WL 1745072, at *16–18 (urging the U.S. Court of Appeals for the Third Circuit to reverse the district court's determination that a brand-name company's commitment not to introduce an authorized generic in exchange for a generic company's promise to drop a challenge to the patent was not a "reverse-payment" under *Actavis*).

larger than what the generic drug would gain in profits if it won the Paragraph IV litigation and entered the market.[125] At the same time, the Court cautioned that a finding of large reverse payment alone is insufficient to conclude illegality because certain reverse payments can have lawful explanations, such as the cost of anticipated litigation, payments for valuable services promised to be rendered by the generic company, or "any other convincing justification."[126]

Yet another uncertainty arising from *Actavis* is when and how the question of patent validity and/or infringement should be considered. According to the Court, "it is *normally* not necessary to litigate patent validity to answer the antitrust question,"[127] and the legal community is largely in agreement that the *Actavis* Court did not wish to entirely disregard the merits of a settled case.[128] A challenge lies in defining the conditions under which the issue of patent validity and infringement must be addressed. Furthermore, in cases where the merits of underlying litigation may not be considered, it is questionable whether antitrust principles alone are sufficient to assess the anticompetitive effects of Paragraph IV settlements. As one commentator points out, "the problem is that the ultimate competitive impact of a pharmaceutical patent settlement is really dependent on the merits of the underlying patent litigation."[129]

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[125] *Actavis*, 133 S. Ct. at 2235 (citing Hemphill, *supra* note 53, at 1581).

[126] *Id.* at 2237.

[127] *Id.* at 2236 (emphasis added).

[128] *See, e.g.*, FTC v. Cephalon, Inc., 36 F. Supp. 3d 527, 531–32 (E.D. Pa. 2014) ("[I]n my view, the use of the word 'normally' reflects the Court's expression that under certain discrete circumstances there could be situations where the validity of the patent should be litigated within a reverse payment antitrust trial."); Taavola, *supra* note 9, at 1406 ("[T]he rule-of-reason approach may encourage the parties, at least in part, to argue the merits of the underlying case."). *See also Actavis*, 133 S. Ct. at 2238 (suggesting that courts structure litigation to avoid both "the use of antitrust theories too abbreviated to permit proper analysis, and . . . consideration of every possible fact or theory").

[129] McDonald, *supra* note 9, at 38 (quoting Thomas B. Leary, Comm'r, Fed. Trade Comm'n, Address Before the Am. Bar Ass'n Antitrust Healthcare Program: Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Pt. II (May 17, 2001), https://www.ftc.gov/public-statements/2001/05/antitrust-issues-settlement-pharmaceutical-patent-disputes-part-ii#N_6_).

III. DETAILS AND ADVANTAGES OF THE PROPOSED JUDICIAL APPROVAL PROCEDURE

Bearing in mind the intricate interrelationships among the Hatch-Waxman Act, antitrust laws, and the public interests, this Comment suggests that Congress implement a mandatory procedure to judicially approve settlement agreements ("proposed procedure" or "proposed settlement procedure") that alleviates many of the problems associated with settling Paragraph IV litigations and similar proceedings.[130] The procedure mirrors the framework of Rule 23(e) of the Federal Rules of Civil Procedure, which requires judicial approval of any "settlement, voluntary dismissal, or compromise of the claims, issues, or defenses of a certified class" in a class action.[131]

Perhaps the initial reaction to applying Rule 23(e) in this context may be that Paragraph IV litigations are not class actions. When parties to a Paragraph IV litigation settle, non-parties (e.g., members of the public) will not be legally bound by the settlement terms in the same way that class members would be bound in a class action settlement. While this is true and could be a potential limitation to applying Rule 23(e), common law sometimes calls for judicial review and approval, particularly if a settlement "affects the rights of non-parties or non-settling parties, or where the settlement is executed by a party acting in a representative capacity."[132]

Addressing the second condition first, one could argue that Paragraph IV filers act for the benefit of the public by virtue of challenging unwarranted patents.[133] In case of Paragraph IV litigations involving weak patents, it is overwhelmingly pro-competitive and beneficial to the public when a Paragraph IV filer prevails. But Paragraph IV filers fall short of playing the "representative" role on behalf of the public: the interests of Paragraph IV filers and the public do not align, because the ultimate goal of Paragraph IV filers in

[130] The proposed procedure focuses on the settlements of actions that were initiated within forty-five days of Paragraph IV notice. The same model, however, may apply to settlements of other types of actions. For example, brand-name companies may strategically choose to initiate a lawsuit based on Paragraph IV filings *after* the expiration of forty-five days or wait for the Paragraph IV filer to file a declaratory judgment action against them. The same anticompetitive concerns discussed in this Comment would apply to settlements of such actions because they can involve a payment, delayed generic entry, and retention of the 180-day exclusivity period.

[131] FED. R. CIV. P. 23(e).

[132] MANUAL FOR COMPLEX LITIGATION (FOURTH) § 13.14 at 172 (2004) [hereinafter MANUAL].

[133] Opderbeck, *supra* note 72, at 1338.

litigation is not necessarily "victory," i.e., invalidating the patent or finding a non-infringement.[134] When a Paragraph IV filer prevails in litigation and enters the market, it is often true that "the *total* profits of the patent holder and the generic manufacturer on the drug in the competitive market will be *lower* than the total profits of the patent holder alone under a patent-conferred monopoly."[135] Therefore, it makes economic sense for a Paragraph IV filer to settle by delaying its market entry and reap the benefit of the resulting monopoly of the patent holder as long as the value of the filer's share exceeds the anticipated gain from litigious victory. A Paragraph IV filer certainly is not acting in a "representative capacity" when it settles an action involving a weak patent because the public is denied access to generic drugs. Furthermore, the existence of a weak patent influences drug availability to the public in the future because a bad patent often causes other companies to forgo R&D in the field it improperly covers.[136] Reduced participation in R&D hampers innovation and results in fewer treatment options for patients.

The first condition—settlements affecting the rights of non-parties or non-settling parties—better describes Paragraph IV settlements because the Hatch-Waxman procedural framework facilitates "litigation specifically intended to benefit parties beyond those named in the action."[137] The purpose of Rule 23(e) is to "assure that any person whose rights would be affected by a dismissal or compromise has the opportunity to contest the proposed action."[138] Similarly, the outcome of a Paragraph IV litigation affects accessibility of drugs for patients who have the right to healthcare.[139] Today, patients on at least one prescription drug make up anywhere from 50%

[134] Robert E. Colletti, *The Role of the Food and Drug Attorney in Hatch-Waxman Lawsuits, Food and Drug Settlements and Negotiations*, *in* INSIDE THE MINDS: FOOD AND DRUG SETTLEMENTS AND NEGOTIATIONS (2006) (discussing various ways in which generic companies benefit from filing an ANDA regardless of first-to-file status).

[135] *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 209 (2d Cir. 2006), *abrogated on other grounds by* FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

[136] FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 1, 5 (2003), http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf.

[137] Opderbeck, *supra* note 72, at 1338.

[138] Pearson v. Skydell, 522 F.2d 171, 176–77 (5th Cir. 1975) (internal quotation marks omitted), *reh'g denied*, 525 F.2d 1407 (5th Cir. 1975), *cert. denied*, 425 U.S. 912 (1976); *see also* Ingram v. Madison Square Garden Ctr., Inc., 482 F. Supp. 426, 428 (S.D.N.Y. 1979) ("The purpose of requiring Court approval of a 'dismissal' or 'compromise' of a class action is to protect the interests of non-party class members.").

[139] *See supra* note 90.

to 70% of the population.[140] The FTC estimates that pay for delay settlements add $35 billion to consumers' out-of-pocket expenses and $12 billion or more to the federal government over a ten year period.[141] In 2013, 21% of adults in the United States discontinued or skipped prescription doses because of high cost.[142]

Furthermore, the current regulatory climate does not necessarily "induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."[143] As with any for-profit enterprise, a brand-name company's decision to invest in research is driven by economic factors. Because pharmaceutical companies can spend up to $5 billion to develop a single drug,[144] each drug that enters the market must generate enough profit to exceed these costs. R&D costs, however, are not the only financial concerns related to product development.[145] A

[140] Wenjun Zhong et al., *Age and Sex Patterns of Drug Prescribing in a Defined American Population*, MAYO CLINIC PROC., July 2013, at 699, http://www.mayoclinicproceedings.org/article/S0025-6196(13)00357-1/pdf; Qiuping Gu et al., *Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007–2008*, NCHS Data Brief No. 42, Sept. 2010, at 6, http://www.cdc.gov/nchs/data/databriefs/db42.pdf.

[141] Jon Leibowitz, Chairman, Fed. Trade Comm'n, Address at the Center for American Progress: "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Healthcare Reform (The $35 Billion Solution) (June 23, 2009), http://www.ftc.gov/sites/default/files/documents/public_statements/pay-delay-settlements-pharmaceutical-industry-how-congress-can-stop-anticompetitive-conduct-protect/090623payfordelayspeech.pdf.

[142] Paris, *supra* note 5 (noting findings in the 2013 Commonwealth Fund International Health Policy Survey).

[143] Mylan Pharm., Inc. v. FDA, 454 F.3d 270, 272 (4th Cir. 2006) (quoting aaiPharma Inc. v. Thompson, 296 F.3d 227, 230 (4th Cir. 2002)).

[144] Herper, *supra* note 20.

[145] Brand-name companies are subject to additional financial strains. For example, since 2011, Section 9008 of the Patient Protection and Affordable Care Act (ACA) "has imposed an annual fee on manufacturers and importers of 'branded prescription drugs,'" but "generic drugs approved under ANDAs are not subject to the fee." Alan M. Kirschenbaum, *Final Rule on Branded Rx Drug Fee Treats All NDAs the Same, but IRS Might Consider a Special Rule for Pre-Hatch-Waxman Paper NDAs*, FDA LAW BLOG (Aug. 24, 2014, 1:20 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/08/final-rule-on-branded-rx-drug-fee-treats-all-ndas-the-same-but-irs-might-consider-a-special-rule-for.html. FDA may require Risk Evaluation Mitigation Strategies (REMS) "as part of the approval of a new product, or . . . when new safety information arises," which cause brand-name companies to incur additional costs. *FDA Basics Webinar: A Brief Overview of Risk Evaluation and Mitigation Strategies (REMS)*, FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm325201.htm (last visited Jan. 7, 2016); *see* 21 U.S.C. § 355(p) (2010). Furthermore,

brand-name company may also take into account the likelihood of generics' market entry,[146] the cost of future litigations (including potential antitrust litigations), and the probability of successful settlement(s).[147] If the occurrence of future antitrust litigation is so unpredictable, companies might overestimate the associated costs and shy away from particular research projects altogether. Even if a brand-name company decides to engage in R&D, uncertainty as to the antitrust legality of settlements may still cause the brand-name company to inflate its non-R&D costs. This overestimation is justifiable since the FTC interprets the *Actavis* decision to be a "significant victory for the Commission."[148] Therefore, brand-name companies will likely factor in expected costs of antitrust litigations when determining drug prices, effectively shifting the costs to consumers.[149] Considering the profound impacts of pharmaceutical litigations on public health and expenses, members of the public affected by Paragraph IV litigations can be said to be analogous to class members in class action lawsuits who are bound by the terms of settlements.

The requirement of judicial approval is not an entirely new concept. Professor C. Scott Hemphill has suggested using Rule 23(e) settlement procedure as a model to settle Paragraph IV litigations, but without exploring the topic in detail.[150] Outside the Hatch-Waxman regime, the concept of judicial approval has been utilized in various contexts to protect defined members of the population. For example, the Federal Rule of Civil Procedure 23.1(c) requires a directive similar to Rule 23(e) approval process to "settle[], voluntarily dismiss[], or compromise[]" a shareholder derivative action.[151] The purpose of such a requirement is "to safeguard the interests of shareholders not directly involved in the action."[152] Another example is New York State's Not-

the ACA provisions mandate drug manufacturers to provide a 50% discount to Medicare Part D beneficiaries for brand-name drugs and biologics purchased during the coverage gap of Part D. BARRY R. FURROW, ET AL., HEALTH LAW: CASES, MATERIALS, AND PROBLEMS 781 (7th ed. 2013). Section 2501 of the ACA also increases the rebates that must be paid by drug manufacturers for pharmaceuticals covered by Medicaid. *Id.* at 856.

[146] Murat C. Mungan, *Reverse Payments, Perverse Incentives*, 27 HARV. J.L. & TECH. 1, 39 (2013).

[147] *Id.*

[148] Wright, *supra* note 3.

[149] Pamela J. Clements, *The Hatch-Waxman Act and the Conflict Between Antitrust Law & Patent Law*, 48 IDEA 381, 401 (2008).

[150] *See* Hemphill, *supra* note 14, at 640.

[151] FED. R. CIV. P. 23.1(c).

[152] Greenspun v. Bogan, 492 F.2d 375, 378 (1st Cir. 1974).

for-Profit Corporation Law, which requires a judicial approval proceeding before a charitable corporation can dispose of its assets.[153] With the state attorney general serving as a statutory party to the proceeding, the purpose of the New York statute is to "ensure that the interests of the ultimate beneficiaries of the corporation, the public, are adequately represented and protected from improvident transactions."[154] Some may argue that a judicial approval requirement undermines the general policy favoring private settlements of expensive and time-consuming patent litigations. The Supreme Court, however, cautioned against acceding to practical concerns when there is "potential for genuine adverse effects on competition."[155] Within the Hatch-Waxman regime, the public interest to balance innovation and competition far outweighs the need to settle in private.

Moreover, there is some indication that sufficient judicial intervention in a Paragraph IV settlement may lead a court to conclude that the agreement is justified. In *In re Effexor Antitrust Litigation*, the District Court of New Jersey held that the payment arrangement as stipulated in the settlement agreement does not raise anticompetitive concerns because the judge who entered a consent decree incorporating the settlement agreement did so after soliciting the FTC's view on antitrust issues concerning the agreement, and the FTC decided not to object within the prescribed period.[156] Courts are generally in consensus that "private settlement agreements entered into during the pendency of litigation that are neither presented to nor approved by the judge presiding over the dispute fall outside the ambit of [antitrust] immunity."[157] Nonetheless, it is doubtful that any

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[153] N.Y. NOT-FOR-PROFIT CORP. LAW § 511 (McKinney 2014).

[154] Manhattan Eye, Ear & Throat Hosp. v. Spitzer, 715 N.Y.S.2d 575, 592 (1999).

[155] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2234 (2013) (quoting FTC v. Indiana Fed'n of Dentists, 474 U.S. 447, 460–61 (2009)).

[156] *In re* Effexor XR Antitrust Litig., No. 11-5479 (PGS) (LHG), 2014 U.S. Dist. LEXIS 142206, at *37–41, *76–78 (D.N.J. Oct. 6, 2014). Note, however, that the opinion does not specifically address the Noerr-Pennington doctrine, and the decision is based on fact-specific analysis.

[157] *In re* Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 395 (D. Mass. 2013) (citing Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 818–19 (D.C. Cir. 2001) and *In re* Cardizem CD Antitrust Litig., 105 F. Supp. 2d 618, 634–36 (E.D. Mich. 2000)). The antitrust immunity being referred to here is called the Noerr-Pennington doctrine, which "grants antitrust immunity to persons and organizations who, with the intent to restrain trade and diminish competition, act in concert to petition the government to adopt laws and implement policies that are anticompetitive in nature." *Id.* at 394 (citing Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 499 (1988)).

consent judgment is per se immune from antitrust scrutiny.[158] In *In re Nexium (Esomeprazole) Antitrust Litigation*, the immunity defense was unsuccessful because "it [was] unclear whether the judge could be fairly said to have endorsed the terms of the settlement agreements."[159] Given the current legal climate, if a reliable procedure is available to judicially approve settlement agreements, courts would be willing to confer immunity to the agreements and thus, the procedure would help to curtail complex and expensive antitrust litigations in the future.

The following subsections describe the proposed procedure. Subsection A sets the ground rules for settling parties that would be applicable throughout the proposed procedure. The proposed procedure consists of two phases: Subsection B discusses the initial evaluation phase; and Subsection C describes the formal hearing phase that enables members of the public to object to questionable settlement agreements. Subsection D explains the importance of keeping the proposed procedure on a strict timeline. This Comment makes no claim that the proposed procedure is ideal, and the procedure likely requires further adjustments. Nonetheless, short of amendments to the Hatch-Waxman Act or antitrust laws, a more preemptive and drastic approach is necessary.

A. *Conditions Imposed on the Settling Parties*

This Comment proposes to impose three conditions on parties who wish to settle. The first two conditions are meant to encourage the parties to negotiate in good faith and to be applied as soon as the parties express their intent to settle: (1) the plaintiff (brand-name company) may dismiss the case only under the condition that it would not preclude the sale of the product proposed in the defendant's ANDA on the basis of the patent at issue; and (2) the defendant may not convert its Paragraph IV certification to Paragraph III certification. The third condition requires the parties to disclose to the court all material information related to the settlement that they are proposing.

The first condition ensures that the plaintiff brand-name company utilizes the proposed procedure in good faith. As discussed more in depth below,[160] brand-name companies benefit from staying

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[158] *Id.* at 395 ("There is little guidance, however, on the question of whether a judge's entry of a consent judgment falls squarely within the scope of Noerr-Pennington.").

[159] *Id.* at 398.

[160] *See* discussion *infra* Part III.D.

Paragraph IV actions. They could abuse the system by filing a Paragraph IV suit with little prospect of winning, deliberately dragging out the lawsuit until the end of the thirty-month stay, initiating the settlement approval process, and finally dismissing the action. The current statutory provision, 21 U.S.C. § 355, discourages such tactics by giving the judge a statutory discretion to shorten the thirty-month stay period when "either party to the action failed to reasonably cooperate in expediting the action."[161] But its deterrent effects are moderate, because even if the thirty-month stay is lifted, the patent at issue is still in force. A future lawsuit remains a possibility for the defendant if it launches its generic product at risk. If the generic company subsequently files a declaratory action, the legal proceeding would prolong the period during which the public is deprived of generic drugs. In a class action, a court approval is required before any voluntary dismissal.[162] The purpose of this requirement "is to protect the interest of non-party class members."[163] Similarly, the proposed settlement procedure should take into account the interests of those in need of generic drugs. Thus, the first condition eliminates uncertainty as to the legal status of the proposed ANDA product upon voluntary dismissal by the plaintiff and allows the generic company to enter the market sooner.

The second condition ensures that the defendant generic company negotiates in good faith. Since the risks associated with Paragraph IV challenges are small, a generic company might file a Paragraph IV ANDA against a strong patent to induce the brand-name patent holder to sue and see how the settlement negotiation plays out. If the defendant finds itself in an unfavorable position, it can back out by converting its ANDA certification from Paragraph IV to III, which attests that the generic company would refrain from selling the proposed product until the patent at issue expires.[164] This would result in dismissal of the action.[165] Not only is such practice a waste of judicial

[161] 21 U.S.C. § 355(j)(5)(B)(iii) (2010).

[162] FED. R. CIV. P. 23(e) (requiring judicial approval of any "settlement, voluntary dismissal, or compromise of the claims, issues, or defenses of a certified class"). But note, "Rule 23(e) does not require court approval when the parties voluntarily dismiss class allegations before class certification. However, in certain situations in which a voluntary dismissal might represent an abuse of the class action process, the court should inquire into the circumstances behind the dismissal." MANUAL, *supra* note 132, § 21.61, at 309 n.948.

[163] *See, e.g.*, Ingram v. Madison Square Garden Ctr., Inc., 482 F. Supp. 426, 428 (S.D.N.Y. 1979). *See also* Malcolm v. Cities Serv. Co., 2 F.R.D. 405, 406 (D. Del. 1942).

[164] 21 U.S.C. § 355(j)(2)(A)(vii).

[165] There has been at least one instance where the defendant's conversion of its

resources, but it also exacerbates the power imbalance[166] between the parties. Therefore, the second condition fosters bona fide challenges to brand-name patents.

The third condition is the disclosure requirement. Under Rule 23(e), parties who agree to settle must "disclose all terms of the [proposed] settlement or compromise" to the court presiding over the class action.[167] The parties must also submit to the court "a statement identifying any agreement made in connection with the proposal,"[168] including any undertakings "that, although seemingly separate, may have influenced the terms of the settlement by trading away possible advantages for the class in return for advantages for others."[169] The settling parties may supplement the disclosure with briefs, motions, or informal presentations.[170]

Similarly, the proposed procedure should require parties to a Paragraph IV litigation to submit their proposed settlement agreement to the court in which their case is pending. The proposed agreement may be in the form of a summary in lieu of a copy of the actual agreement as long as it sufficiently describes all material terms. The court should have discretion to direct the settling parties to submit additional materials that "the court considers relevant to its review of a proposed settlement."[171] The requested information may include any factors indicating the value of the settlement, e.g., the cost of litigation or the total present value of monetary and nonmonetary terms.[172] The

ANDA certification has resulted in a court dismissal. See United Therapeutics Corp. v. Sandoz, Inc., Nos. 3:12-CV-01617 & 3:13-CV-316, 2014 U.S. Dist. LEXIS 121573, at *1 n.1 (D.N.J. Aug. 29, 2014), which notes that:

> Plaintiff's complaints also included allegations that [defendant] Sandoz would infringe [the '222] patent listed in the [Orange Book] . . . . On April 9, 2014, Sandoz converted its paragraph IV certification regarding the '222 patent to a paragraph III certification. On June 2, 2014, in accordance with that decision, the Court dismissed the counts in [plaintiff's] Complaints alleging infringement of the '222 patent without prejudice, along with Sandoz's counterclaims for non-infringement and invalidity of the '222 patent.

[166] *See supra* notes 71–75 and accompanying text.

[167] FED. R. CIV. P. 23(e)(2) (former FED. R. CIV. P. 23(e)(3)) advisory committee's notes to 2003 Amendment.

[168] FED. R. CIV. P. 23(e)(3).

[169] FED. R. CIV. P. 23(e)(2) (former FED. R. CIV. P. 23(e)(3)) advisory committee's notes to 2003 Amendment.

[170] MANUAL, *supra* note 132, § 21.632, at 320–21.

[171] FED. R. CIV. P. 23(e)(2) (former FED. R. CIV. P. 23(e)(3)) advisory committee's notes to 2003 Amendment.

[172] MANUAL, *supra* note 132, § 21.631, at 320. *See also* FED. R. CIV. P. 23(h) advisory committee's notes to 2003 Amendment ("Settlements involving nonmonetary

parties should also be required to disclose any agreement or undertakings that, "although seemingly separate, may have influenced the terms of the settlement by trading away"[173] potential benefits to the public.

The disclosure requirement enables individuals or entities that could be affected by the settlement to view pertinent information and intervene under certain circumstances before the settlement goes into effect. The affected parties no longer need to scour through public records after incurring antitrust injury in hopes of finding useful information. Furthermore, the disclosure requirement enables a court to identify any anticompetitive scheme comprising a series of settlements[174] prior to its fruition because the requirement would be imposed on first-filers and subsequent filers alike. Under Rule 23(e):

> [t]he spirit of [the disclosure requirement] is to compel identification of any agreement or understanding that might have affected the interests of class members by altering what they may be receiving or foregoing. Side agreements might indicate, for example, that the settlement is not reasonable because they may reveal additional funds that might have been paid to the class that are instead paid to selected claimants or their attorneys.[175]

Likewise, the disclosure requirement in the proposed procedure forces the settling parties to put all potentially related transactions on the table, thereby allowing the court to examine the parties' motives and see the big picture. If any of the side agreements signal an anticompetitive concern, the issue can be resolved before an anticompetitive harm takes place. The disclosure requirement also spares the settling parties from expensive discovery in antitrust actions that could take place years after the settlement is entered.

Rule 23(e)(3) does not specify sanction for failure to identify an agreement or an undertaking connected with the settlement,[176] but the Federal Judicial Center suggests reopening the approved settlement if the unidentified materials bear significantly on the settlement's

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provisions for class members also deserve careful scrutiny to ensure that these provisions have actual value to the class."). If necessary, the court should give the settling parties an opportunity to claim the protection of attorney-client privilege and confidentiality. *See* MANUAL, *supra* note 132, § 21.631, at 319.

[173] FED. R. CIV. P. 23(e)(2) (former FED. R. CIV. P. 23(e)(3)) advisory committee's notes to 2003 Amendment.

[174] *See supra* note 103 and accompanying text.

[175] MANUAL, *supra* note 132, § 21.631, at 319.

[176] *Id.* § 21.631, at 320.

reasonableness.[177] The proposed procedure should simulate this sanction by voiding the presumptive legality of an approved agreement as described below.[178]

B. *Initial Evaluation of a Proposed Paragraph IV Settlement*

i. Preliminary Review

Rule 23(e) requires the settling parties to bear the burden of persuading the court that settlement is preferable to litigation by showing that their settlement terms are "fair, reasonable, and adequate."[179] The presiding court preliminarily reviews the proposed settlement agreement and orders a formal hearing (commonly known as a "fairness hearing") only if the court is satisfied with the "fairness, reasonableness, and adequacy" of the settlement terms.[180] These determinations may be made with or without a preliminary hearing,[181] and the court may seek an independent review of provisions that call for closer scrutiny.[182] The settling parties have an opportunity to amend their agreement to overcome the court's objections.[183]

In class actions, factors that may be considered by the court in evaluating a proposed settlement agreement vary depending on the nature of the suit being settled.[184] Some general factors include, but are not limited to: "advantages of the proposed settlement" as opposed to proceeding with the litigation in light of the merits of the claims;[185] whether any attorneys' fees claimed as part of the settlement are

[177] *Id.*

[178] *See infra* Parts III.B.ii & III.C.iii.

[179] MANUAL, *supra* note 132, § 21.631, at 318.

[180] FED. R. CIV. P. 23(e)(2); MANUAL, *supra* note 132, § 21.632, at 321.

[181] MANUAL, *supra* note 132, § 21.632, at 320–21.

[182] Examples of questionable provisions include "unduly preferential treatment of class representatives or segments of the class, inadequate compensation or harms to the classes, the need for subclasses, or excessive compensation for attorneys." *Id.* § 21.632, at 321.

[183] *Id.*

[184] *Id.* § 21.62, at 315.

[185] *Id.* § 21.62, at 316.

reasonable;[186] "the maturity of the underlying substantive issues";[187] "the extent of participation in the settlement negotiations by class members" or their representatives, "a judge, a magistrate judge, or a special master";[188] "the effect of the settlement on other pending actions";[189] what other courts have done with similar settlements;[190] the amount of a monetary relief provided for class members;[191] and the value of non-monetary relief.[192]

Furthermore, the judicial role under Rule 23(e) is limited to approving, disapproving, or imposing conditions on a proposed settlement.[193] In conducting a preliminary review of a class action settlement, the court must "adopt the role of a skeptical client and critically examine" the terms of the proposed settlement.[194] Some circuit courts have even stated that "the district court acts as a fiduciary who must serve as a guardian of the rights of absent class members."[195] To this end, Rule 23(e) authorizes the court to appoint a magistrate judge, guardian *ad litem*, special master, court-appointed expert, or technical advisor who assists in reviewing the terms of a proposed settlement terms, studying how those terms affect the absent class members, and determining their fairness, reasonableness, and adequacy.[196] A court-appointed expert provides testimony and a neutral assessment "regarding the valuation of the settlement" or of its

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[186] *See* FED. R. CIV. P. 23(h); *see also* FED. R. CIV. P. 23(h) advisory committee's notes to 2003 Amendment ("Whether or not there are formal objections, the court must determine whether a fee award is justified and, if so, set a reasonable fee."); *In re* Katrina Canal Breaches Litig., 628 F.3d 185, 196 (5th Cir. 2010) ("We have repeatedly held that a district court abuses its discretion if it approves a class action settlement without determining that any attorneys' fees claimed as part of the settlement are reasonable and that the settlement itself is reasonable in light of those fees.").

[187] MANUAL, *supra* note 132, § 21.62, at 316.

[188] *Id.*

[189] *Id.*

[190] *Id.* § 21.62, at 317.

[191] *Id.*

[192] *In re* Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions, 148 F.3d 283, 316–24 (3d Cir. 1998).

[193] Hanlon v. Chrysler Corp., 150 F.3d 1011, 1026 (9th Cir. 1998) ("The settlement must stand or fall in its entirety."); *but cf. In re* Auction Houses Antitrust Litig., No. 00-CV-0648, 2001 WL 170792, at *18 (S.D.N.Y. Feb. 22, 2001) (conditioning approval of a settlement on parties' adopting changes specified by the district court).

[194] MANUAL, *supra* note 132, § 21.61, at 310.

[195] Grunin v. Int'l House of Pancakes, 513 F.2d 114, 123 (8th Cir. 1975). *See also* Reynolds v. Beneficial Nat'l Bank, 288 F.3d 277, 279–80 (7th Cir. 2002); *In re* Cendant Corp. Litig., 264 F.3d 201, 231 (3d Cir. 2001).

[196] MANUAL, *supra* note 132, § 21.632, at 321 & § 21.644, at 329.

legality.[197] The court must determine whether such testimony will "assist the trier of fact to understand the evidence or determine a fact in issue."[198]

Similar to the Rule 23(e) procedure, the settling parties in the proposed procedure should bear the burden of persuading the court that their agreement is not unreasonably anticompetitive. The court's role should be limited to approving or disapproving a proposed agreement. The presiding judge may not draft nor rewrite an agreement, though he or she may make suggestions. In order to effectively fulfill its role, the court should appoint at least one neutral expert advisor to assist the court in identifying and examining any antitrust issues concerning the agreement terms. This is important to ensure the quality of review given the complexities of the Hatch-Waxman system and antitrust analysis. Furthermore, as discussed in more details below,[199] an appointed expert is instrumental in facilitating the judicial review as expeditiously as possible.

Moreover, the court in the proposed procedure should play the "role of a skeptical client and critically examine"[200] the proposed agreement for its potentially anticompetitive effects. This aspect is crucial in order to protect the public interest, especially when the adversarial nature of litigation is lost after parties agree to settle. As the Hatch-Waxman Act encourages litigation to resolve patent disputes,[201] the court's role as a "skeptical client" helps to retain an adversarial flavor to the settlement process and to take into account interests of non-parties who would be affected by the settlement. Also, within the proposed settlement framework, courts are in a unique position to mitigate the settling parties' power imbalance. For example, the court may raise concerns when the generic company demands payment that is unreasonably high or a market entry date that is too soon. This way, the court can protect the brand-name company's need to recover its investment in research, which ensures continued development of new drugs. Furthermore, by allowing generic entry at an appropriate time prior to the patent expiration, it can facilitate an equitable and pro-competitive timing to introduce lower-cost generic drugs into the market.

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[197] *Id.* § 21.632 at 321.

[198] FED. R. EVID. 702; *see also* MANUAL, *supra* note 132, § 21.632, at 321.

[199] See discussion *infra* Part III.D.

[200] MANUAL, *supra* note 132, § 21.61, at 310.

[201] This is indicative by the automatic thirty-month stay of ANDA approval and 180-day exclusivity period for first-filers. 21 U.S.C. § 355(j)(5)(B)(iii), (iv) (2010).

The court undertaking the proposed procedure may, just as in the Rule 23(e) procedure, evaluate the settling parties' agreement with or without a preliminary hearing. This Comment, however, proposes to diverge from Rule 23 by authorizing the court to issue a *final* (but appealable) approval at this stage. This suggestion is largely motivated by the need to expedite Paragraph IV settlement processes as explained below.[202] There may be various ways to accomplish this step, but this Comment proposes a two-prong analysis: the first prong comprising a categorical test; and the second involving the rule of reason analysis.

Under the first prong, the court may apply pre-defined factors to decide whether to order a formal hearing. For example, the court may set the threshold "Settlement Competition Index (SCI)" beyond which a formal hearing must be ordered.[203] If a proposed agreement's SCI falls below a threshold value and thereby fails to trigger a formal hearing order, the court may proceed to the second prong. Since the settling parties have the burden of persuasion, they should be required to submit any requisite calculations and/or analysis to the court, and the court's advisor may assist the judge in evaluating their work. With the development of case law in the area, this prong should evolve into a streamlined process.

If the triggering factors are not found in the first prong, the court should proceed to the second prong and conduct the rule of reason analysis, which has been employed in various antitrust cases to interpret the federal Sherman Act[204] and state antitrust laws.[205] In applying the rule of reason, the court must balance anticompetitive

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[202] See discussion *infra* Part III.D.

[203] Opderbeck, *supra* note 72, at 1328–48. Alternatively, a certain amount of valuable consideration from the patentee may be a triggering factor. For instance, the amount of considerations may be calculated using the method proposed in Aaron Edlin et al., *Activating* Actavis, ANTITRUST, Fall 2013, at 16, 18. If the "otherwise unexplained" portion of the patentee's payment exceeds a predetermined limit, a formal hearing may be ordered. *See id.*

[204] *See, e.g.*, Leegin Creative Leather Prods. v. PSKS, Inc., 551 U.S. 877, 885 (2007) ("The rule of reason is the accepted standard for testing whether a practice restrains trade in violation of § 1 [of the Sherman Act]."); Texaco Inc. v. Dagher, 547 U.S. 1, 5 (2006) ("[T]his Court presumptively applies rule of reason analysis, under which antitrust plaintiffs must demonstrate that a particular contract or combination is in fact unreasonable and anticompetitive before it will be found unlawful."); United States v. United States Gypsum Co., 333 U.S. 364, 400–01 (1948) ("We apply the 'rule of reason' of *Standard Oil Co.* v. *United States*, 221 U.S. 1, to efforts to monopolize through patents as well as in non-patent fields.").

[205] Wilcox et al., *supra* note 78, at 869 (discussing that many state laws track the Sherman Act).

harms and pro-competitive benefits to determine whether the proposed agreement as a whole would unreasonably restrict competition in the relevant market.[206] If the court determines that the proposed agreement raises antitrust concerns, it must order a formal hearing.

One advantage of the second prong is that the court may freely consider the merits of the case in applying the rule of reason analysis because the case being settled is a patent infringement action and thus is not bound by *Actavis*. This aspect is particularly significant because "the likelihood that the patent will be held invalid or not infringed is key to evaluating whether a settlement violates antitrust law."[207] It would be necessary to take into account the maturity of the underlying patent issue and "the probable outcome of a trial on the merits."[208] Additional factors that the court should consider include, in no specific order and with no single factor being dispositive: the proposed market entry date of the generic drug;[209] whether there are other companies that settled with respect to the same drug at issue;[210] whether there are other agreements entered into by the same settling parties;[211] any other potentially anticompetitive provisions (e.g., no AG provision[212]); the extent of antitrust injury to drug purchasers (e.g., the extent of overcharge[213]); the brand-name company's market power in a defined market;[214] the value of net considerations flowing from the brand-name company to the generic company;[215] and how other courts have treated similar settlements in the past.[216] With respect to the last

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[206] *Id.* at 840.

[207] Opderbeck, *supra* note 72, at 1336. *See also supra* note 129 and accompanying text.

[208] MANUAL, *supra* note 132, § 21.62, at 316.

[209] *See, e.g.*, *supra* notes 30, 31, 73 and accompanying text. *See also* discussion *supra* Part III.B.i regarding the court's mitigation of power imbalance.

[210] *See, e.g.*, *supra* notes 103–05 and accompanying text.

[211] *See, e.g.*, *supra* note 99 and accompanying text.

[212] *See supra* note 123 and accompanying text.

[213] *See, e.g.*, *supra* notes 140–42 and accompanying text.

[214] "[T]he conclusion that a particular tying arrangement involving a patent is unlawful 'must be supported by proof of power in the relevant market rather than by a mere presumption thereof.'" Opderbeck, *supra* note 72, at 1331 (quoting Illinois Tool Works, Inc. v. Indep. Ink, Inc. 547 U.S. 28, 43 (2006)).

[215] *See, e.g.*, Edlin et al., *supra* note 203, at 18 (describing a net consideration as a total value of any consideration flowing from the patentee to the claimed infringer minus the sum of the patentee's avoided litigation costs and the value of goods, services, or other consideration from the alleged infringer).

[216] *See* discussion *infra* Parts III.B.ii & III.C.iii (discussing the notion that court opinions create precedents).

factor, certain forms of settlement may be considered a "safe-harbor." For instance, the Supreme Court stated in *Actavis* that parties "may, as in other industries, settle . . . 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."[217]

ii. Parties' Options After Preliminary Review

Under Rule 23, if a court approves a proposed settlement, an order of approval should include the court's findings and reasoning.[218] An approved agreement is presumed legal, and both the court and the parties must abide by the approved settlement terms.[219] If the court's decision is appealed, the decision is reviewed under the abuse of discretion standard.[220] "An abuse of discretion may be found where the 'district court's decision rests upon a clearly erroneous finding of fact, an errant conclusion of law, or an improper application of law to fact.'"[221] Nevertheless, "[w]hether an incorrect legal standard has been used is an issue of law to be reviewed *de novo*."[222]

As discussed earlier, the proposed procedure allows the court to issue an official approval if the court concludes, after the two-prong analysis, that the proposed agreement does not violate the antitrust laws. Similar to Rule 23(e), the court should be required to publish a detailed explanation of the court's findings and reasons for its decision. This requirement serves the important purpose of building precedents. As more lawsuits are settled via the proposed procedure, the settlement procedure would require fewer costs and less time because parties and courts can rely on prior decisions. Settling parties may structure their agreements in conformity with past court opinions, and this would improve predictability of the volume of future antitrust lawsuits in the Hatch-Waxman realm.

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[217] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013).

[218] MANUAL, *supra* note 132, § 13.14, at 172.

[219] Klier v. Elf Atochem N. Am., Inc., 658 F.3d 468, 475–76 (5th Cir. 2011).

[220] *See, e.g.*, *In re* Nutella Mktg. & Sales Practices Litig., 589 F. App'x 53, 58 (3d Cir. 2014) ("We review a district court's decision to . . . approve a settlement under the abuse of discretion standard."); Isby v. Bayh, 75 F.3d 1191, 1196 (7th Cir. 1996) ("[W]e review the determination of the district court [with respect to the approved settlement] only for an abuse of discretion.").

[221] *In re Nutella*, 589 F. App'x at 58 (quoting *In re* Warfarin Sodium Antitrust Litig., 391 F.3d 516, 527 (3d Cir. 2004) (quoting *In re* Gen. Motors Corp. Pick-Up Truck Fuel Tank Prod. Liab. Litig., 55 F.3d 768, 783 (3d Cir. 1995))).

[222] *Id.* (quoting Rodriguez v. Nat'l City Bank, 726 F.3d 372, 377 (3d Cir. 2013) (quoting Marcus v. BMW of N. Am., LLC, 687 F.3d 583, 590 (3d Cir. 2012))).

Parties in the proposed procedure should submit their approved agreement to the FTC and the Antitrust Division of the United States Department of Justice pursuant to the current regulation.[223] One significant difference from the current practice is that a judicially approved agreement in the proposed procedure would be presumed legal, and the FTC must appeal the agreement instead of initiating an antitrust suit if it wishes to challenge the decision. Again, this arrangement enhances parties' confidence that the approved agreement is legal and reduces future antitrust litigations.[224] While the appellate court may review the district court's decision only under the abuse of discretion standard, the presumptive legality may be void if the settling parties failed to disclose information in connection with the agreement prior to the approval either deliberately or inadvertently.

If the judge determines that a formal hearing is required, the settling parties should choose to: (1) move forward with the hearing; (2) amend the proposed agreement to remove any obstacles to court approval within a specified time limit; (3) continue to litigate (pursuant to the Hatch-Waxman objectives); or (4) dismiss the case under the condition that the plaintiff would not sue the defendant based on the product proposed in the ANDA. If an amendment does not result in court approval, the parties must proceed with the formal hearing or continue to litigate. The parties may not appeal at this time.

C. *Formal Hearing*

i. The Court's Notice to the FTC and the Public

Under Rule 23, the court must alert all class members to their "opportunity to present their views" and hear others' arguments regarding the settlement terms.[225] Members who wish to object to the settlement (the "objectors") must file written statements of their objections within a specified time and notify the court if they also intend to appear at the fairness hearing.[226] Class counsel—attorneys representing a class—must communicate any proposed settlement

[223] MMA, *supra* note 13.

[224] *See also infra* text accompanying notes 252–54.

[225] MANUAL, *supra* note 132, § 21.633, at 321–22.

[226] *Id.* § 21.633, at 322.

terms to class representatives[227] and, ultimately, to all class members.[228] Class counsel may convey information to class members in a variety of ways, such as holding a meeting (especially if the class is small), or by creating a toll-free telephone number or a website to provide settlement details and court-approved answers to frequently asked questions.[229] An objector who testifies at the hearing may be "any class member who does not opt out" or any party to the settlement, such as "a shareholder of a corporation involved in the settlement."[230]

In the proposed procedure, the court should notify (or instruct the settling parties to notify) the FTC and members of the public before holding a formal hearing. Notices may be provided in publications such as the Federal Register, magazines, newspapers, and trade journals.[231] It may also be appropriate to post notices on websites or "in public places likely to be frequented by" potential objectors.[232] The notice should include, for example, brief descriptions of the proposed agreement, where additional information can be found, and instructions on how to file objections within a specified time and on how to notify the court if the objectors also intend to appear and testify at the formal hearing. Settling parties may initially bear the cost of preparing and distributing the notice and later share it with objectors in agreed-upon proportions. Alternative arrangements are also possible.

Objectors should include any members of the public, such as consumers, wholesalers, retailers, and insurance companies, regardless of their potential status as direct or indirect purchasers.[233] Thus, members of the public have the opportunity to object to a proposed agreement before it could injure them. Moreover, the presence of objectors would help to reinforce the adversarial character of the proceeding.[234] Any issues must be resolved before the agreement's

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[227] A class representative is "a person named in the complaint as the plaintiff and who has been determined by the court to be a legally 'adequate' person to represent the interests of the class." *The Federal Class Action Practice Manual, Glossary of Legal Terms Used in Class Action Litigation*, CLASS ACTION LITIG. INFO., http://www.classactionlitigation.com/glossary.html (last visited Jan. 7, 2016).

[228] MANUAL, *supra* note 132, § 21.641, at 323.

[229] *Id.* § 21.641, at 323–24.

[230] *Id.* § 21.643, at 326.

[231] *See, e.g.*, *id.* § 21.311, at 287–88 (discussing various methods of distributing certification notices to unidentifiable class members after reasonable effort).

[232] *Id.* § 21.311, at 292.

[233] The proposed procedure may raise an issue of objector standing. This Comment refrains from exploring the topic.

[234] See *supra* note 201 and accompanying text.

approval. Those who fail to object during the specified time—including the FTC—forfeit their right to object, appeal, or initiate an antitrust action on the basis of the approved agreement in the future. This way, the proposed procedure alleviates settled parties' concern that they might face antitrust liability years after their settlement takes place. Both the objectors and settling parties may rely on previous court decisions because the proposed procedure requires all courts to prepare written opinions.

The court may appoint a public counsel, similar to a class counsel, to be responsible for overseeing the notification procedure, and communicating and coordinating with the objectors to consolidate similar arguments. If no objection is raised within the specified time period, the court should still hold a hearing perhaps with its advisor(s) as an adversary to the settling parties.

ii. The Burden-Shifting Approach

In class action settlements, a court may approve a settlement only if it is "fair, reasonable, and adequate."[235] At a Rule 23 fairness hearing, settling parties may "present witnesses, experts, and affidavits or declarations."[236] Objectors may also testify.[237] Objectors may act individually or on behalf of class members.[238] The court may set time limits on objectors' arguments and refuse "to hear the same objections more than once."[239] If objections are withdrawn, the court must approve the withdrawal.[240] If withdrawn objections result in modifications to the settlement terms, the withdrawal is considered as part of the settlement.[241] The court may grant additional discovery if it is necessary for the objectors to demonstrate the inadequacy of the settlement.[242] The discovery, however, should be limited and conditioned on a showing of need.[243]

In the proposed procedure, the court should apply the rule of reason analysis with a burden-shifting approach at the formal hearing.[244] The burden-shifting approach would require the objectors

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[235] FED. R. CIV. P. 23(e)(2).

[236] MANUAL, *supra* note 132, § 21.634, at 322.

[237] *Id.*

[238] *Id.* § 21.643, at 327.

[239] *Id.* § 21.634, at 322.

[240] FED. R. CIV. P. 23(e)(5); MANUAL, *supra* note 132, § 21.643, at 328.

[241] MANUAL, *supra* note 132, § 21.643, at 328.

[242] *Id.* § 21.643, at 327–28.

[243] *Id.* § 21.643, at 328.

[244] James A. Keyte & Karen Lent, *Reasonable as A Matter of Law: The Evolving Role of*

to first demonstrate likely anticompetitive effects of the settlement agreement in a well-defined antitrust market. If the objectors are successful, the settling parties must offer a pro-competitive justification(s) for their proposed settlement. If the settling parties are successful, the objectors must show that the settling parties' justification(s) can be achieved through materially less restrictive alternatives. If the objectors are successful, the court must weigh the overall anticompetitive and pro-competitive effects to determine the reasonableness of the settlement agreement. The court may follow the general practice outlined in Rule 23 regarding limited discovery, witnesses, experts, affidavits or declarations, and withdrawal. The court must approve withdrawal of any objector,[245] and if withdrawn objections result in modifications to the settlement terms, the withdrawal should be considered as part of the settlement. Even in the absence or scarcity of objections, the court should consider diverse interests of the affected parties and requisite factors before reaching its decision.[246]

iii. Parties' Options After the Formal Hearing

According to Rule 23(e), the court must ensure that there is a sufficient record of the basis and justification for the court's conclusion[247] and explain the findings to class members and the appellate court in sufficient written detail.[248] As mentioned previously, an approved agreement is presumed legal,[249] and the court's decision is reviewed under the abuse of discretion standard.[250] The proposed procedure should be set up in a way that improves predictability and diminishes the likelihood that settled companies would face future antitrust liability. Therefore, the courts' decisions in the proposed

the Court in Rule of Reason Cases, ANTITRUST, Summer 2014, at 62, 62 (discussing how most courts employ a burden-shifting approach for antitrust claims that are not subject to a per se rule or quick look approach); *see also* Thomas F. Cotter, FTC v. Actavis, Inc.*: When is the Rule of Reason Not the Rule of Reason?*, 15 MINN. J.L. SCI. & TECH. 41, 43–44 (2014).

[245] *See* discussion *infra* Part III.D regarding objectors.

[246] *See* MANUAL, *supra* note 132, § 21.635, at 322–23.

[247] *Id.*

[248] FED. R. CIV. P. 23(e)(2) (former FED. R. CIV. P. 23(e)(3)) advisory committee's notes to 2003 Amendment.

[249] Klier v. Elf Atochem N. Am., Inc., 658 F.3d 468, 475–76 (5th Cir. 2011).

[250] *See, e.g.*, *In re* Nutella Mktg. & Sales Practices Litig., 589 F. App'x 53, 58 (3d Cir. 2014) ("We review a district court's decision to . . . approve a settlement under the abuse of discretion standard."); Isby v. Bayh, 75 F.3d 1191, 1196 (7th Cir. 1996) ("[W]e review the determination of the district court [with respect to the approved settlement] only for an abuse of discretion.").

procedure should also be published, resulting in more consistent decisions nationwide. This would also aid future Paragraph IV litigants to structure their agreements if they wish to settle.

Furthermore, if the court approves an agreement in the proposed procedure, the parties to the agreement should be allowed to act immediately in accordance with the agreement. Only those who timely objected may appeal the decision. The agreement is presumptively legal and will be reviewed under a deferential standard, i.e., the abuse of discretion standard as described above. As suggested earlier, if the settling parties failed to disclose information in connection with the agreement prior to the approval, the presumptive legality should be void. A *de novo* review is proper only in limited circumstances such as the parties' failure to disclose pertinent side agreements or a clearly erroneous application of law. Even if the approved agreement is ultimately found unlawful, the settled parties should not be held liable in future antitrust suits or penalized for their actions in accordance with the agreement during the appeal period.

If the court disapproves the agreement after the formal hearing, the settling parties may: (1) continue to litigate the patent infringement case (in accordance with the objectives of the Hatch-Waxman Act); (2) amend the agreement within a specified time only to the extent that it removes or corrects the anticompetitive aspect(s) of the agreement; (3) appeal within a specified period; or (4) dismiss the case under the condition that the plaintiff will not sue the defendant based on the product proposed in its ANDA. In the interest of saving time,[251] the amended agreement of option (2) would not be subject to a formal hearing, and if it does not result in an approval, the parties must: (1) litigate; (3) appeal; or (4) dismiss. If the proposed agreement is rejected on appeal, the parties may not attempt to settle or amend again. The parties must choose between options (1) and (4).

The improved predictability and confidence in the legality of their settlements would encourage the brand-name companies to invest in R&D and would relieve them from unnecessarily inflating the non-R&D costs associated with their drugs. One commentator on reverse payment settlements has proposed a model that demonstrates the effect of the shift in legality of reverse payment settlements.[252] According to the model, switching from a regime that legalizes reverse payment settlements to a regime that illegalizes the settlements

[251] *See* discussion *infra* Part III.D.

[252] Mungan, *supra* note 146, at 41–44.

increases incentives for brand-name companies to develop stronger inventions rather than weaker inventions, therefore strengthening their patents.[253] The model also shows that a move toward illegalization of reverse payment settlement deters generics from entering the market when the patent is strong.[254] The proposed procedure does not illegalize reverse payment settlements, but rather makes it difficult for brand-name companies to rely on unlawful ones. If this model accurately forecasts the behaviors of brand-name and generic companies, the proposed procedure would encourage strong innovation.

D. *A Strict Timeline is Required to Avoid Delays in the Settlement Process*

One significant challenge in implementing the proposed procedure is to keep the procedure on a strict timeline and not to let it serve as a substitute for a stay of Paragraph IV litigations.[255] In class actions, objections delay final resolution of a settlement by requiring the court to consider objectors' arguments.[256] While bona fide objectors can be beneficial, as they assist the court in identifying areas of a settlement that need improvement,[257] the resulting "holdup" becomes more severe when objectors appeal, which can take years.[258] Appeals are costly to class counsel as well as to non-objecting class members because they are typically not entitled to payment "until the legal process has run its course."[259] In contrast, objectors incur relatively low cost because their pay is not dependent on settlement approval, and they are able to minimize appellate litigation fees by recycling widely applicable principles on which to base their objections.[260] Furthermore, an objector has an occasional incentive of winning attorney fees if it succeeds in making changes to the settlement in a way that benefits the class.[261] The prospect of delay and

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[253] *Id.* at 43–44.

[254] *Id.* at 41–42.

[255] According to one estimate, even a one-year delay in generic entry costs consumers about $661 million per drug. Hemphill, *supra* note 14, at 650 n.85.

[256] Brian T. Fitzpatrick, *The End of Objector Blackmail?*, 62 VAND. L. REV. 1623, 1624 (2009).

[257] MANUAL, *supra* note 132, § 21.643, at 326.

[258] Fitzpatrick, *supra* note 256, at 1624.

[259] John E. Lopatka & D. Brooks Smith, *Class Action Professional Objectors: What to Do About Them?*, 39 FLA. ST. U. L. REV. 865, 865, 882 (2012).

[260] *Id.* at 865, 878.

[261] MANUAL, *supra* note 132, § 21.643, at 326.

financial loss has prompted many class counsels to pay objectors out of their own pockets to withdraw the appeals.[262] This dynamic has given rise to a lawyer-driven phenomenon called "objector blackmail" by which class members extract a payoff from class counsel by threatening to file meritless appeals.[263] Attorneys who routinely seek out class actions and object on behalf of class members are called "professional objectors,"[264] of whom "[f]ederal courts are increasingly weary."[265]

Paragraph IV litigations are different from class actions in this regard because monetary awards are typically not involved,[266] and attorneys for both sides are paid by their clients. Moreover, a settlement holdup would be desirable for both litigants in the Hatch-Waxman regime. If the proposed settlement procedure can be dragged out as long as possible, the brand-name company benefits from maintaining its status quo during that time—i.e., the ability to charge monopoly prices—even if the proposed settlement is ultimately rejected. The defendant generic company might play along if it believes the later payout would outweigh the overall cost.

Furthermore, when a brand-name company owns multiple patents of varying strengths covering a single drug, both the brand-name and generic companies would likely benefit from prolonging the settlement procedure. For example, one commentator pointed out a situation in which a generic company prevails in a Paragraph IV litigation involving a weak patent but there remains a strong patent covering the same drug as the weak one.[267] Because the strong patent continues to block competition, the prevailing generic company is effectively barred from marketing its generic product until the expiration of the strong patent's term. If the generic company is a first-filer, its victory, which happens long before the expiration of the strong patent, would result in a premature period of exclusivity that would expire pursuant to the forfeiture provision.[268] It would not be feasible to wait to file an ANDA against the weak patent until the strong patent

[262] Fitzpatrick, *supra* note 256, at 1624.

[263] *Id.*

[264] *Id.* at 1624–25; *see also* Lopatka & Smith, *supra* note 259, at 865–66.

[265] O'Keefe v. Mercedes-Benz USA, L.L.C., 214 F.R.D. 266, 295 n.26 (E.D. Pa. 2003).

[266] Note, however, that filing a frivolous claim might result in an award of attorneys' fees to the other party. *See, e.g.*, Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc., 549 F.3d 1381, 1391 (Fed. Cir. 2008) (affirming the trial court's award of over $16 million in attorneys' fees to plaintiff brand-name company because of defendant generic firm's baseless challenge to the brand-name's patent).

[267] Herman, *supra* note 56, at 1789.

[268] 21 U.S.C. § 355(j)(5)(D) (2010).

is about to expire because winning the first-filer status is a race against other generic companies. For these reasons, generic first-filers have begun to request a stay of the Paragraph IV litigation for the weak patent until closer to the expiration date of the strong patent.[269] A stay, followed by a generic victory, would allow the first-filing generic to retain its 180-day exclusivity period and create a bottleneck even after the strong patent expires. This "stay" scheme also benefits the brand-name company because the exclusivity period running beyond the expiry date of the last standing patent works to prevent full competition.

In view of the forgoing, the proposed procedure should proceed on a strict schedule and allow extension of deadlines only in extraordinary circumstances. The aforementioned two-prong analysis during the preliminary review phase[270] and appointment of an expert advisor[271] are intended to facilitate a timely completion of the court's analysis. Additional tactics can be implemented to ensure expediency of the proposed approval process, such as requiring the settling parties to make their submissions as concise as possible, creating a template for the court's opinion, and expediting the appeal process. The court should also have the power to terminate a settlement procedure if it finds that settling parties are not negotiating in good faith or to impose sanctions on a frivolous objector. Also, settling parties must be prohibited from giving, lending, or promising valuable consideration to or for any person, or from inducing another to object or appeal in the proposed procedure. Finally, objectors should be required to disclose their sponsors or any inducements they received during a relevant time period. The inducements could come from not only the settling parties, but also other generic companies interested in the relevant market. The court should be cognizant of the financial relationships among objectors and settling parties when considering their arguments.

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[269] Herman, *supra* note 56, at 1789, 1808–13 (describing two cases involving a motion to stay: Abbott Labs. v. Matrix Labs., Inc., No. 09-CV-1586, 2009 WL 3719214, at *3 (N.D. Ill. Nov. 5, 2009), and Millennium Pharm., Inc. v. Teva Parenteral Meds., Inc., Nos. 09-CV-105, 09-CV-204, 10-CV-137, 2010 WL 1507655, at *1 (D. Del. Apr. 14, 2010)). In *Abbott*, the district court granted the defendant's motion to stay the Paragraph IV litigation for five years, which is about two years before the latest expiring patent was set to expire. In *Millennium*, the court denied the defendant's motion to stay the Paragraph IV litigation for about two years.

[270] *See* discussion *supra* Part III.B.i regarding the two-prong analysis.

[271] *See* discussion *supra* Part III.B.i regarding expert advisor.

IV. CONCLUSION

The current method of settling Paragraph IV litigations is replete with problems. Because the *Actavis* framework is full of uncertainties, settling parties currently cannot ensure the antitrust legality of their agreements. Parties who have settled could be subject to antitrust scrutiny several years after the settlement, which requires them to revisit their settled case and incur additional costs. The power imbalance between brand-name and generic companies in Paragraph IV litigations, as well as the anticipated antitrust lawsuits, may cause brand-name companies to divert resources from R&D and shift costs to consumers. On the other hand, affected members of the public cannot intervene before Paragraph IV settlements are finalized and are unable to escape the effects of the settlement terms. Many consumers who are injured as a result of a Paragraph IV settlement have no legal recourse under the indirect purchaser rule, and even those consumers who are entitled to bring an antitrust action may not have access to relevant information.

The proposed procedure modeled after Rule 23(e) attempts to alleviate these problems. For parties to Paragraph IV settlements, the proposed procedure provides a process through which these parties can obtain judicial approval of their agreement. Once approved, the agreement is presumptively legal, which protects the settled parties from future antitrust scrutiny. Moreover, since courts would be required to issue an opinion describing their reasons for approval or disapproval of each proposed agreement, parties who wish to settle in the future would be able to utilize past court decisions as a guide to structure their agreement.

The proposed procedure also addresses some of the public's concerns. First, settling parties would be required to submit their proposed agreement to the court before they can settle. The court has the authority to reject any unreasonably anticompetitive agreement and therefore prevent antitrust injury to the public. Second, settling parties must also submit any ancillary agreements in connection with their proposed agreement. This obviates the need for interested members of the public to search for related side deals. If settling parties fail to disclose any material information, their agreement would lose its presumptive legality. Third, the proposed procedure provides an opportunity for members of the public to object to a proposed agreement before it goes into effect. Fourth, the settling parties must adhere to a strict timeline, and the parties' options become limited once they express their intent to settle. This restricts the parties' ability

to manipulate the settlement procedure.

The proposed procedure is intended to improve certainty as to the antitrust legality of Paragraph IV settlements and prevent unnecessary injury to the public. This Comment makes no claim that the proposed procedure is ideal, and it would likely require further adjustments. Nonetheless, the current mechanisms for settlement and antitrust enforcement do not adequately balance the competing needs to promote pharmaceutical innovation and to protect the public welfare. A more preemptive and drastic approach is necessary and desirable, especially in the absence of changes to the Hatch-Waxman Act or antitrust laws.