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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

Chika Seidel*

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 anytime, 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 healthcare costs that consumers, employers, and federal and state governments are struggling to contain.”³ A counterargument to this 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,

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¹ 21 U.S.C. § 355(c)(3)(C) (2013).

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

offering for sale, or selling the invention throughout the United States”⁴ Pharmaceutical companies in the United States are also free to set 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 disagree on this issue.¹² Because of these ambiguities, pharmaceutical companies struggle to structure their settlement agreements to avoid antitrust

⁴ 35 U.S.C. § 154(a)(1) (2013).

⁵ Valerie Paris, *Why do Americans Spend So Much on Pharmaceuticals?* PBS NEWS HOUR (Feb. 7, 2014, 12:15 PM EST), <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 Pharmaceuticals, 677 F.3d 1298 (11th Cir. 2012), with *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012).

⁷ *Actavis*, 133 S. Ct., at 2236 (2013).

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*, 28 FALL ANTITRUST 36 (2013); James J. O’Connell, *Editor’s Note: The Elephant Remains*, 28 FALL ANTITRUST 5 (2013).

¹⁰ *Actavis*, 133 S. Ct. at 2238.

¹¹ *Id.* at 2236.

¹² *Compare, e.g., In re Lamictal Direct Purchaser Antitrust Litig.*, 12-CV-995 WHW, 2014 WL 282755, at *6-7 (D.N.J. Jan. 24, 2014) (“the Supreme Court considered a reverse payment to involve an exchange of money” and therefore did “not extend the holding of *Actavis* to the non-monetary facts before it.”), with *In re Loestrin 24 FE Antitrust Litig.*, No. 13-MD-2472-S-PAS, 2014 U.S. Dist. LEXIS 123322, at *34 (D.R.I. Sept. 4, 2014) (“Reading *Actavis*, this Court cannot help but find that it applies solely to monetary settlements”).

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 will propose a mandatory judicial approval process for settling Hatch-Waxman litigations modeled after the process of settling class actions pursuant to the Federal Rule of Civil Procedure 23(e). Part II will explain 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 will describe the proposed procedure in detail. Part IV will explain why the proposed settlement procedure is superior to the current settlement method. Part V will conclude by summarizing the prominent problems associated with the current method as well as the proposed procedure and its benefits.

II. Relevant Legal Developments in the Pharmaceutical Industry

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 (MMA), Pub. L. No. 108–173, § 1112, 117 Stat. 2066, 2461–63.

¹⁴ C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 649 tbl.2 (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, <http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf>.

¹⁵ See discussion *infra* Part IV.A.

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 summarizes the circuit split that led to the *Actavis* decision, *Actavis* opinion itself, and its aftermath.

A. The Role of Patent System in the Pharmaceutical Industry¹⁶

In order to sustain their businesses, brand-name companies¹⁷ must recover their investments in drug development. An estimate shows that for every 5000 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 research and development (R&D) investment per drug could cost anywhere from \$1.2 billion¹⁹ to \$5 billion.²⁰ These high figures are in part due to high rate of failure—95% of the experimental medicines fail to be both effective and safe for human use.²¹ Even if they 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

¹⁶ This Comment 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. § 355a, 21 U.S.C. §§ 360aa–ee, 21 U.S.C. § 355(c)(3)(E)(iii), (j)(5)(F)(iii)–(iv), 21 U.S.C. § 355(c)(3) (E)(ii), (j)(5)(F)(ii)).

¹⁷ For 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 brand-name and generic drugs.

¹⁸ Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2012* pp. 29.

¹⁹ *Id.*

²⁰ Matthew Harper, *The Cost of Creating a New Drug Now \$5 Billion, Pushing Pharma to Change*, FORBES (Aug. 1, 2013, 11:10 AM) <http://www.forbes.com/sites/matthewharper/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.*

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 November 4, 2014) (“[O]nly two out of every 10 medicines will recoup the money spent on their development.”).

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 future and their ability to reinvest in research endeavors. The purpose of the United States patent system—“[t]o promote the progress of science and useful arts, by securing for limited times to . . . inventors the exclusive right 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% 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 likely invalid or not infringed.²⁸ The holder of a weak patent probably has no right to block the sale of cheaper

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 (2010), at 8, <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 Pharmaceutical Research and Manufacturers of America (PHRMA) as Amicus Curiae In Support of Respondents at 7, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416) (citation omitted).

²⁶ *Id.*

²⁷ C. Scott Hemphill & Bhaven N. Sampat, Drug Patents at the Supreme Court, 339 Sci. 1386, 1386 (2013).

²⁸ *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 (discussing that brand-name companies lose most litigations on secondary patents).

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 on terms of permitting the generic company to enter the market before the expiration of the patent “would bring about competition . . . to the consumer’s benefit.”³¹

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-consuming FDA approval process, because the longer the process took, the shorter

²⁹ *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 (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.).

³³ *Mylan Pharm., Inc. v. U.S. Food And Drug Admin.*, 454 F.3d 270, 272 (4th Cir. 2006) (quoting *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230 (4th Cir. 2002)); *see also* Daniel E. Troy, Chief Counsel, U.S. Food and Drug Administration, Statement before the Senate Committee on the Judiciary, Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) (Aug. 2003), <http://www.fda.gov/newsevents/testimony/ucml15033.htm>.

³⁴ 21 U.S.C. § 355(b)(1); Barbara J. Williams, *A Prescription for Anxiety: An Analysis of Three Brand-Name Drug Companies and Delayed Generic Drug Market Entry*, 40 NEW ENG. L. REV. 1, 2 (2005).

the remainder of their patent life 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 implementing Abbreviated New Drug Applications (“ANDAs”).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

³⁵ During the pre-Hatch-Waxman era, a patent term used to be 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. MANUAL OF PATENT EXAMINING PROCEDURE, Ed. 9, § 270.

³⁶ The FDA approval process often took place after patent acquisition. Williams, *supra* note 34, at 3 (citing Fed. Trade Comm’n, Generic Drug Entry Prior to Patent Expiration: An FTC Study i, p. 4 (July 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 Williams, *supra* note 34, at 2 (citing H.R. Rep. No. 98-857, pt. 2, at 4 (1984) (the House Report 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 Prod., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 860-861 (Fed. Cir. 1984), cert. denied 469 U.S. 856 (1984), *superseded by statute*, 35 U.S.C. § 271(e)(1) (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).

³⁹ § 156(a), (f)(1)(A), and (f)(2)(A).

⁴⁰ *Id.* § 271(e)(1) (“It shall not be an act of infringement to make use, offer for sale, 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).

and efficacy of a 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 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 action can provide “additional years of a

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).

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 generic companies cannot compete in the market.⁵¹ The drafters of the Hatch-Waxman Act may have envisioned the 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 1998, 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

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.

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.” U.S. DEPT. OF HEALTH AND HUMAN SERVICES, THE FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY, at 5–6 (July 2003), <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm072851.pdf>.

⁵² Schmitt, *supra* note 28, at 499 (citing Brief for the Intellectual Property Owners Association as Amicus Curiae Supporting 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, *Aggregate Approach*, *supra* note 14, at 658.

⁵⁵ *Id.*

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

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 victory because it likely collects no damages and does not prevent other 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 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

⁵⁷ Rudolph J.R. Peritz, *The Competition Question Unmasked In Actavis: What is the Scope of the Patent Right to Exclude?*, 28 ANTITRUST ABA 45, 49 (2013).

⁵⁸ Brief for the Intellectual Property Owners Association as Amicus Curiae Supporting Respondents at 17, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416).

⁵⁹ Herman, *supra* note 56, at 1800.

⁶⁰ Hemphill, *Aggregate Approach*, *supra* note 14, at 658.

⁶¹ *Id.*

⁶² 21 U.S.C. § 355(c)(3)(D) (A 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, *Aggregate Approach*, *supra* note 14, at 658.

Congress attempted to rectify the bottleneck problem by adding a forfeiture provision⁶⁴ 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 proposed drug by the “later of” the two conditions defined in subsections (aa) and (bb).⁶⁶ Unfortunately, the problem of bottleneck lingers after the MMA amendments because the new 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

C. *Actavis* and Questions Left Unanswered

⁶⁴ § 355(j)(5)(D).

⁶⁵ Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified in scattered sections of U.S. Code, including § 355).

⁶⁶ The first condition under (aa) is “the earlier of” seventy-five days after the first filer’s approval is made effective and seventy-five days after 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 reaches a similar result; 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, *Aggregate Approach*, *supra* note 14, at 660–61.

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>; *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-mmars-failure-to-market-forfeiture-provisions-as-an-anemic-mechanism-for-park.html (discussing 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, *Aggregate Approach*, *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, *Paying for Delay*, *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, *Paying for Delay*, *supra* note 53, at 1583–84.

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’s product in return for the payment of “millions of dollars.”⁷¹ 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.’”⁷² 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 reverse payment settlement was immune from antitrust scrutiny so long as the anticompetitive effects fell within the “exclusionary potential” of the patent.⁷³ Other courts employed the “quick-look” approach, which viewed reverse payment settlements as *prima facie* evidence of illegality.⁷⁴

The *Actavis* Court resolved the circuit split by holding that courts should employ the rule of reason approach⁷⁵ to strike a balance “between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act.”⁷⁶ In connection with the rule of reason analysis, the Court suggested that “the size of the unexplained reverse payment

⁷¹ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013).

⁷² *Id.* at 2229–30.

⁷³ *See, e.g.*, *FTC v. Watson Pharmaceuticals*, 677 F.3d 1298 (11th Cir. 2012).

⁷⁴ *See, e.g.*, *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 208 (3d Cir. 2012).

⁷⁵ 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 of Chicago v. United States*, 246 U.S. 231, 238 (1918).

⁷⁶ *Actavis*, 133 S. Ct. at 2231.

can provide a workable surrogate for a patent's weakness,"⁷⁷ which in turn reveals "the payment's objective [] to maintain supracompetitive prices to be shared among the patentee and the challenger."⁷⁸ 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.⁷⁹ 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* ... not its starting point."⁸⁰ 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."⁸¹ In rejecting the "quick look" approach, the Court held that some reverse payments can be justified under antitrust analysis.⁸²

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."⁸³ 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.⁸⁴ Since the issuance of the *Actavis* opinion in June 2013, district court judges have already disagreed on what constitutes "payment." Some judges have held that *Actavis* decision applies to

⁷⁷ *Id.* at 2236–37.

⁷⁸ *Id.* at 2238.

⁷⁹ *Id.* at 2236.

⁸⁰ *Id.* at 2236–37.

⁸¹ *Id.* at 2235, 2236–37.

⁸² *Actavis*, 133 S. Ct. at 2237.

⁸³ *Id.* at 2238.

⁸⁴ John Fazio, *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, 13–14 (2006).

monetary payments only, while others concluded that payment is not limited to monetary payments.⁸⁵ The FTC agrees with the latter view, noting that a brand-name company's promise not to develop or market its authorized generic⁸⁶ (AG) is a form of payment.⁸⁷

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 larger than what the generic would gain in profits if it won the Paragraph IV litigation and entered the market.⁸⁸ 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, and "any other convincing justification."⁸⁹

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,"⁹⁰ and the legal community is

⁸⁵ Compare, e.g., *In re Lamictal Direct Purchaser Antitrust Litig.*, 12-CV-995 WHW, 2014 WL 282755, at *6–7 (D.N.J. Jan. 24, 2014) ("[T]he Supreme Court considered a reverse payment to involve an exchange of money" and therefore did "not extend the holding of *Actavis* to the non-monetary facts before it."), and *In re Loestrin 24 FE Antitrust Litig.*, No. 13-MD-2472-S-PAS, 2014 U.S. Dist. LEXIS 123322, at *34 (D.R.I. Sept. 4, 2014) ("Reading *Actavis*, this Court cannot help but find that it applies solely to monetary settlements"), with *In re Lipitor Antitrust Litig.*, No. 12-CV-02389, 2014 U.S. Dist. LEXIS 127877, at *62 (D.N.J. Sept. 12, 2014) (In applying *Actavis* here, the non-monetary payment must be converted to a reliable estimate of its monetary value), *In re Niaspan Antitrust Litig.*, No. 13-MD-2460, 2014 U.S. Dist. LEXIS 124818, at *32 (E.D. Pa. Sept. 5, 2014) ("[R]everse payment' is not limited to a cash payment."), and *In re Nexium Eesomeprazole Antitrust Litig.*, No. 12-MD-02409, 2014 U.S. Dist. LEXIS 126954, at *75 (D. Mass. Sept. 4, 2014) ("[U]nlawful reverse payments are not limited to monetary payments.").

⁸⁶ 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*, REDBLOG (June 11, 2013) <http://www.regblog.org/2013/06/11/11-mckenna-ftc-report/>.

⁸⁷ Brief of Fed. Trade Comm'n as Amicus Curiae in Support of Plaintiffs-Appellants, on appeal from *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-CV-995, 2014 WL 282755 (D.N.J. Jan. 24, 2014) (No. 14-1243) (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*).

⁸⁸ *Actavis*, 133 S. Ct. at 2235 (citing Hemphill, *Paying for Delay*, *supra* note 53, at 1581).

⁸⁹ *Id.* at 2237.

⁹⁰ *Id.* at 2236 (emphasis added).

largely in agreement that the *Actavis* Court did not wish to disregard the merits of a settled case entirely.⁹¹ 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”⁹²

III. Details of the Proposed Judicial Approval Procedure

Bearing in mind the intricate interrelationship among the Hatch-Waxman Act, antitrust laws, and the public interests, this Comment proposes a judicial approval procedure (“proposed procedure” or “proposed settlement procedure”) that alleviates many of the problems associated with settling Paragraph IV litigations.⁹³ The procedure mirrors the framework of Rule 23(e) of the Federal Rules of Civil Procedure,⁹⁴ which requires judicial approval of any “settlement,

⁹¹ See, e.g., *FTC v. Cephalon, Inc.*, No. 08-CV-2141, 2014 U.S. Dist. LEXIS 102958, at *15 (E.D. Pa. July 29, 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.”); Lars P. Taavola, *The 30th Anniversary of the Hatch-Waxman Act: 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, 1406 (2014) (“[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 (The Court cautions against “the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory.”).

⁹² Kevin McDonald, *Because I Said So: On the Competitive Rationale of FTC v. Actavis*, 28 ANTITRUST ABA 36, 38 (2013) (quoting Thomas B. Leary, Comm’r, Fed. Trade Comm’n, *Antitrust Issues in the Settlement of Pharmaceuticals Patent Disputes*, Part II at n.27, Address Before the American Bar Association Healthcare Program (May 17, 2001), available at <http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.shtm>).

⁹³ The proposed procedure focuses on the settlements of actions that were initiated within forty-five days of Paragraph IV notice. However, the same model may apply to settlements of other types of actions based on Paragraph IV certifications. 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.

⁹⁴ At least one commentator has casually suggested using Rule 23(e) settlement procedure as a model to settle Paragraph IV litigations, but without exploring the topic in detail. See Hemphill, *Aggregate Approach*, *supra* note 14, at 640.

voluntary dismissal, or compromise of the claims, issues, or defenses of a certified class” in a class action.⁹⁵

Perhaps the initial reaction to adopting Rule 23(e) 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 class members would be bound in a class action settlement. However, 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.”⁹⁶ The Hatch-Waxman lawsuits satisfy both criteria. First, the Hatch-Waxman procedural framework is “intended to benefit parties beyond those named in the action.”⁹⁷ The outcome of a Paragraph IV litigation affects accessibility of drugs for patients who have the right to healthcare⁹⁸ but are non-parties to the action. It also 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.⁹⁹ Reduced participation in R&D hampers innovation and results in fewer treatment options for patients.

Second, Paragraph IV filers act in place of the public by virtue of challenging unwarranted patents.¹⁰⁰ In case of Paragraph IV litigations involving weak patents, it is overwhelmingly procompetitive and beneficial to the public when a Paragraph IV filer prevails. But the interests

⁹⁵ FED. R. CIV. P. 23(e).

⁹⁶ MANUAL FOR COMPLEX LITIGATION (Fourth) § 13.14 at 172 (2004) [hereinafter “MANUAL”].

⁹⁷ David W. Opderbeck, *Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation*, 98 GEO. L.J. 1303, 1338 (June 2010).

⁹⁸ See, e.g., 155 Cong. Rec. H12,623, H12,848 (daily ed. Nov. 7, 2009) (“[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.”) (statement of Rep. Braley); 155 Cong. Rec. H12,598, H12,619 (daily ed. Nov. 7, 2009) (“Every American deserves the promise of quality affordable health care, and this is our moment to fulfill that promise.”) (statement of Rep. Langevin). This Comment refrains from discussing the issue of whether illegal immigrants have the right to healthcare.

⁹⁹ FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, at 5 (2003), <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf>.

¹⁰⁰ Opderbeck, *supra* note 97, at 1338.

of Paragraph IV filers and the public do not exactly align, because victory in litigation is not necessarily the ultimate goal of Paragraph IV filers.¹⁰¹ 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.”¹⁰² 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 as long as the value of the filer’s share exceeds the anticipated gain from litigious victory. A Paragraph IV filer no longer acts in a representative capacity when it settles an action involving a weak patent, because the public is denied access to generic drugs.

Today, patients who are on at least one prescription drug make up anywhere from 50% to 70% of the population.¹⁰³ 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.¹⁰⁴ In 2013, 21% of adults in the United States discontinued or skipped prescription doses because of high cost.¹⁰⁵ Considering the profound impact of pharmaceutical litigations on public health, members of the public affected by Paragraph IV litigations are analogous to class members in class action lawsuits.

The requirement of judicial approval is not a new concept. The Federal Rule of Civil

¹⁰¹ 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).

¹⁰² *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 209 (2d Cir. 2006).

¹⁰³ Qiuping Gu et al., *Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007-2008*, NCHS Data Brief No. 42, at 6 (2010), <http://www.cdc.gov/nchs/data/databriefs/db42.pdf>; Wenjun Zhong, et al., *Age and Sex Patterns of Drug Prescribing in a Defined American Population*, 88 MAYO CLINIC PROCEEDINGS 7, <http://dx.doi.org/10.1016/j.mayocp.2013.04.021>.

¹⁰⁴ 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.

¹⁰⁵ Paris, *supra* note 5 (citing 2013 Commonwealth Fund International Health Policy Survey).

Procedure 23.1(c) requires a directive similar to Rule 23(e) approval process to “settle[], voluntarily dismiss[], or compromise[]” a shareholder derivative action.¹⁰⁶ Another example is New York State’s Not-for-Profit Corporation Law, which requires a judicial approval proceeding before a charitable corporation can dispose of its assets.¹⁰⁷ 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.”¹⁰⁸ Some may argue that a judicial approval requirement undermines the general policy favoring settlements of expensive and time-consuming patent litigations. The Supreme Court, however, cautioned against acceding to such practical concerns when there is “potential for genuine adverse effects on competition.”¹⁰⁹ Within the Hatch-Waxman regime, the public interest to balance innovation and competition far outweighs the need to settle in private.

The following subsections describe the proposed procedure which consists of two phases. Subsection A discusses the initial evaluation phase. Subsection B describes the formal hearing phase that enables members of the public to object to questionable settlement agreements. Subsection C provides additional remarks regarding the proposed procedure.

A. Initial Evaluation of a Proposed Paragraph IV Settlement

i. The Requirements for Settling Parties

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.¹¹⁰ The settling parties bear

¹⁰⁶ FED. R. CIV. P. 23.1(c).

¹⁰⁷ N.Y. NOT-FOR-PROFIT CORP. LAW § 511 (McKinney 2014).

¹⁰⁸ *Manhattan Eye, Ear, and Throat Hosp. v. Spitzer*, 715 N.Y.S.2d 575 (1999).

¹⁰⁹ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2234 (2013).

¹¹⁰ FED. R. CIV. P. 23(e)(2) [former FED. R. CIV. P. 23(e)(3)] advisory committee notes to 2003 Amendments, ¶ 2.

the burden of persuading the court that settlement is preferable to litigation by showing that the settlement terms are “fair, reasonable, and adequate.”¹¹¹ The parties must also submit to the court “a statement identifying any agreement made in connection with the proposal,”¹¹² 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.”¹¹³ The disclosure may be supplemented by briefs, motions, or informal presentations by the settling parties.¹¹⁴

Similarly, the proposed procedure requires parties to a Paragraph IV litigation to submit their proposed settlement agreement to the court in which their case is pending. The settling parties bear the burden of persuading the court that their agreement is not unreasonably anticompetitive. The submitted 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 parties should also be required to disclose any agreement or undertakings that, “although seemingly separate, may have influenced the terms of the settlement”¹¹⁵ by trading away potential benefits to the public. Such disclosure includes other settlements and pending actions involving the same parties. “Doubts should be resolved in favor of identification.”¹¹⁶ Rule 23(e)(3) does not specify sanctions for failure to identify an agreement or an undertaking connected with the settlement,¹¹⁷ but the Federal Judicial Center suggests to reopen the approved settlement if the unidentified materials bear significantly on the

¹¹¹ MANUAL, § 21.631, at 318.

¹¹² FED. R. CIV. P. 23(e)(3).

¹¹³ FED. R. CIV. P. 23(e)(2) [former FED. R. CIV. P. 23(e)(3)] advisory committee notes to 2003 Amendments, ¶ 2.

¹¹⁴ MANUAL, § 21.632, at 320–21.

¹¹⁵ FED. R. CIV. P. 23(e)(2) [former FED. R. CIV. P. 23(e)(3)] advisory committee notes to 2003 Amendments, ¶ 2.

¹¹⁶ *Id.*

¹¹⁷ MANUAL, § 21.631, at 320.

settlement's reasonableness.¹¹⁸ The proposed procedure should simulate this sanction by voiding the presumptive legality of an approved agreement as described below.¹¹⁹

ii. The Court's Role

The judicial role under Rule 23(e) is limited to approving, disapproving, or imposing conditions on a proposed settlement.¹²⁰ 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.¹²¹ This aspect is crucial, because once parties agree to settle, the adversarial nature of litigation is lost. 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.”¹²² The court has discretion to direct the settling parties to submit additional materials in order to fully consider the proposed settlement. 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.¹²³ The settling parties are given an opportunity to claim the protection of attorney-client privilege and confidentiality.¹²⁴

Similar to the Rule 23(e) procedure, the court's role in the proposed procedure should be limited to approving, disapproving, or imposing conditions on a proposed settlement. The presiding judge may not draft nor rewrite an agreement, though he or she may make suggestions.

¹¹⁸ *Id.*

¹¹⁹ *See infra* Part III.A.iv.

¹²⁰ *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).

¹²¹ John E. Lopatka & D. Brooks Smith, *Class Action Professional Objectors: What to Do About Them?*, 39 FLA. ST. U. L. REV. 865, 889 (2012).

¹²² *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).

¹²³ MANUAL, § 21.631, at 320. *See also* FED. R. CIV. P. 23 advisory committee notes to 2003 Amendments, note to Subdivision (h) (“Settlements involving nonmonetary provisions for class members also deserve careful scrutiny to ensure that these provisions have actual value to the class”).

¹²⁴ MANUAL, § 21.631, at 319.

The court must play the “role of a skeptical client and critically examine”¹²⁵ the proposed agreement for its potentially anticompetitive effects. The court may, at its discretion, direct the parties to submit additional information or briefs which “the court considers relevant to its review of a proposed settlement,”¹²⁶ but it must provide an opportunity for the settling parties to claim work-product or other confidentiality. In order to create a record for appellate review, the court should consider and record all materials submitted to the court.

Rule 23(e) further 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.¹²⁷ A court-appointed expert provides a neutral assessment and testimony regarding the valuation of the settlement or of its legality.¹²⁸ The judge must determine whether such testimony will “assist the trier of fact to understand the evidence or determine a fact in issue.”¹²⁹

In the proposed procedure, the court must appoint at least one expert advisor who would assist the court in identifying as well as examining any 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,¹³⁰ an appointed expert is instrumental in facilitating the judicial review as expeditiously as possible.

iii. The Court’s Preliminary Review of a Proposed Agreement

¹²⁵ Lopatka, *supra* note 121, at 889.

¹²⁶ FED. R. CIV. P. 23(e)(2) [former FED. R. CIV. P. 23(e)(3)] advisory committee notes to 2003 Amendments, ¶ 2.

¹²⁷ MANUAL, § 21.632, at 321 & § 21.644, at 329.

¹²⁸ *Id.* § 21.632 at 321.

¹²⁹ FED. R. EVID. 702; *see also* MANUAL, § 21.632, at 321.

¹³⁰ See discussion *infra* Part III.C. **Error! Reference source not found.**

Rule 23(e) requires the court to preliminarily review a proposed settlement agreement and order 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.¹³¹ The court also makes a preliminary determination that the proposed class satisfies the statutory criteria.¹³² The judge may make these determinations with or without a preliminary hearing¹³³ and seek an independent review of provisions that call for closer scrutiny.¹³⁴ The settling parties have an opportunity to amend their agreement to overcome the court’s objections.¹³⁵

In class actions, factors that may be considered by the judge in evaluating a proposed settlement agreement vary depending on the nature of the suit being settled.¹³⁶ 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;¹³⁷ whether any attorneys’ fees claimed as part of the settlement are reasonable;¹³⁸ the maturity of the underlying substantive issues;¹³⁹ the extent of participation in the settlement negotiations by class members or their representatives, a judge, a magistrate judge, or a special master;¹⁴⁰ the effect of the settlement on

¹³¹ MANUAL, § 21.632, at 321; FED. R. CIV. P. 23(e)(2).

¹³² *Id.* § 21.632, at 321.

¹³³ *Id.* § 21.632, at 320–21.

¹³⁴ 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.

¹³⁵ *Id.* § 21.632, at 321.

¹³⁶ *Id.* § 21.62, at 315.

¹³⁷ MANUAL, § 21.62, at 316.

¹³⁸ See FED. R. CIV. P. 23(h); see also FED. R. CIV. P. 23(h) advisory committee notes to 2003 Amendments, ¶ 3 (“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.”).

¹³⁹ MANUAL, § 21.62, at 316.

¹⁴⁰ *Id.*

other pending actions;¹⁴¹ what other courts have done with similar settlements;¹⁴² the amount of a monetary relief provided for class members;¹⁴³ and the value of non-monetary relief.¹⁴⁴

Similarly, a court undertaking the proposed procedure may evaluate the parties' agreement with or without a preliminary hearing. However, the proposed procedure diverges from Rule 23 by authorizing the court to issue a *final* approval in specified circumstances. This can be achieved through a two-prong analysis, with the first prong comprising a categorical test and the second involving the rule of reason analysis. Under the first prong, the court utilizes certain pre-defined factors to decide whether to order a formal hearing.¹⁴⁵ Since the burden of persuasion lies with the settling parties, they must submit any requisite calculations and 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 will evolve into a streamlined process.

If the triggering factors are not found in the first prong, the court should conduct the rule of reason analysis which has been employed in various antitrust cases to interpret the federal Sherman Act¹⁴⁶ and state antitrust laws.¹⁴⁷ The court must balance anticompetitive harms and

¹⁴¹ *Id.*

¹⁴² *Id.* at 317.

¹⁴³ *Id.*

¹⁴⁴ *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 316–24 (3d Cir. 1998).

¹⁴⁵ For example, the court may set the threshold “Settlement Competition Index (SCI)” beyond which a formal hearing must be ordered. Opderbeck, *supra* note 97, at 1328–48. 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. 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, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *Activating Actavis*, 28 ANTITRUST 16, 18 (2013). Following this method, if the “otherwise unexplained” portion of the patentee’s payment exceeds a predetermined limit, a formal hearing may be ordered.

¹⁴⁶ *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.”).

¹⁴⁷ Molly Wilcox and Jason Yan, *Antitrust Violations*, 51 AM. CRIM. L. REV. 837, 869 (discussing that many state laws track the Sherman Act).

procompetitive benefits to determine whether the proposed agreement as a whole would unreasonably restrict competition in the relevant market.¹⁴⁸ If the court determines that the proposed agreement raises antitrust concerns, it must order a formal hearing.

Because the case being settled is a patent infringement action and thus is not bound by the *Actavis* decision, the court may freely consider the merits of the case in applying the rule of reason analysis. 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.”¹⁴⁹ 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.”¹⁵⁰ Additional factors that the court should consider include, in no specific order: the proposed market entry date of the generic;¹⁵¹ whether there are other companies that settled with respect to the same drug at issue;¹⁵² whether there are other agreements entered into by the same settling parties;¹⁵³ any other potentially anticompetitive provisions (e.g., no AG provision¹⁵⁴); the extent of antitrust injury to drug purchasers (e.g., the extent of overcharge¹⁵⁵); the brand-name company’s market power in a defined market;¹⁵⁶ the value of net considerations flowing from the brand-name company to the generic company;¹⁵⁷ and how other courts have treated similar settlements in the past.¹⁵⁸ With respect to the last factor,

¹⁴⁸ *Id.* at 840.

¹⁴⁹ Opderbeck, *supra* note 97, at 1336. *See also supra* note 92 and accompanying text.

¹⁵⁰ MANUAL, § 21.62, at 316.

¹⁵¹ *See* discussion *infra* Part IV.D.

¹⁵² *See* discussion *infra* Parts IV.A.–B .

¹⁵³ *See* discussion *infra* Parts IV.A., D.

¹⁵⁴ *See supra* note 86 and accompanying text.

¹⁵⁵ *See supra* notes 103–105 and accompanying text.

¹⁵⁶ “[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 97, at 1331 (quoting *Illinois Tool Works, Inc. v. Indep. Ink, Inc.* 547 U.S. 28, 43 (2006)).

¹⁵⁷ Edlin, *supra* note 145, 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.)

¹⁵⁸ *See* discussion *infra* Part IV.C (discussing the notion that court opinions create precedents).

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.”¹⁵⁹

iv. Parties’ Options After Having Their Agreement Approved or Disapproved Without a Formal Hearing

Under Rule 23, if the court finally approves a proposed settlement, an order of approval should include the court’s findings and reasonings.¹⁶⁰ An approved agreement is presumed legal, and both the court and the parties must abide by the approved settlement terms.¹⁶¹ If the court’s decision is appealed, the decision is reviewed under the abuse of discretion standard.¹⁶² “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.’”¹⁶³ However, “[w]hether an incorrect legal standard has been used is an issue of law to be reviewed *de novo*.”¹⁶⁴

If the court in the proposed procedure concludes after the two-prong analysis that the proposed agreement does not violate the antitrust laws, it may issue an official approval along with a detailed explanation of the court’s findings and reasons for its decision. The settling parties must submit the approved agreement to the FTC and the Antitrust Division of the United States

¹⁵⁹ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013).

¹⁶⁰ *MANUAL*, § 13.14, at 172.

¹⁶¹ *Klier v. Elf Atochem N. Am., Inc.*, 658 F.3d 468, 475–76 (5th Cir. 2011).

¹⁶² *See, e.g., In re Nutella Mktg. & Sales Practices Litig.*, Nos. 12-3456, 12-3457, 12-4629, 2014 U.S. App. LEXIS 18544, at *10 (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”).

¹⁶³ *In re Nutella*, 2014 U.S. App. LEXIS at *10 (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))).

¹⁶⁴ *In re Nutella*, 2014 U.S. App. LEXIS at *10 (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))).

Department of Justice pursuant to the current regulation.¹⁶⁵ Similar to Rule 23, a judicially approved agreement is presumptively legal, and the FTC must appeal instead of initiating an antitrust suit if it wishes to challenge the decision. The appellate court may review the district court's decision only under the abuse of discretion standard. The presumptive legality may be void, however, if the settling parties failed to disclose an undertaking 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 may 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; 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.

B. 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 arguments regarding the settlement terms.¹⁶⁶ For members who wish to object to the settlement, the notice instructs them to file written statements of their objections within a specified time and to notify the court if they also intend to appear at the fairness hearing.¹⁶⁷ Class counsel—attorneys representing a class—must communicate any proposed settlement terms to

¹⁶⁵ MMA, *supra* note 13, § 1112(c).

¹⁶⁶ MANUAL, § 21.632, at 321–22.

¹⁶⁷ *Id.* § 21.632, at 322.

class representatives¹⁶⁸ and ultimately to all class members.¹⁶⁹ Class counsel may convey information to class members in a variety of ways, for example by 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.¹⁷⁰ 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.”¹⁷¹

In the proposed procedure, the court should notify the FTC and members of the public before holding a formal hearing. The notice should also include descriptions of the proposed agreement, and instructions on how to file their objections within a specified time and on how to notify the court if they also intend to appear at the formal hearing. The notice need not include a complete copy of the agreement so long as it sufficiently describes all material terms of the proposed settlement. Public objectors may include wholesalers, retailers, insurance companies, and consumers, regardless of their potential status as direct or indirect purchasers.¹⁷² Those who fail to object during the specified time—including the FTC—forefeit their right to object, appeal or initiate an antitrust action on the basis of the approved agreement.

The court may instruct to provide notices in publications such as the Federal Register, magazines, newspapers, and trade journals.¹⁷³ It may also be appropriate to post notices on

¹⁶⁸ 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 LITIGATION INFORMATION (last visited on Nov. 4, 2014), <http://www.classactionlitigation.com/glossary.html>.

¹⁶⁹ MANUAL, § 21.641, at 323.

¹⁷⁰ *Id.* § 21.641, at 323–24.

¹⁷¹ *Id.* § 21.643, at 326.

¹⁷² The proposed procedure might raise an issue of standing with respect to objectors. This Comment proposes that any member of the public should be able to object, but if necessary, the proposed procedure may impose specific standing requirements.

¹⁷³ *See, e.g.*, MANUAL, § 21.311, at 287–88 (discussing various methods of distributing certification notices to unidentifiable class members after a reasonable effort).

websites or public places likely to be frequented by potential objectors.¹⁷⁴ The settling parties may initially bear the cost of preparing and distributing the notice and later share it with objectors in agreed-upon proportions. The court may appoint a public counsel similar to a class counsel who would be responsible for overseeing the notification procedure, communicating and coordinating with the objectors to consolidate similar arguments. If no objection is raised within the specified time period, the court must still hold a hearing with its advisor(s) playing the role of 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.”¹⁷⁵ At a Rule 23 fairness hearing, settling parties may “present witnesses, experts, and affidavits or declarations.” Objectors may also testify.¹⁷⁶ Objectors may act individually or on behalf of class members.¹⁷⁷ The court may set time limits on objectors’ arguments and refuse to hear the same objections more than once.¹⁷⁸ If objections are to be withdrawn, the court must approve the withdrawal.¹⁷⁹ If withdrawn objections result in modifications to the settlement terms, the withdrawal is considered as part of the settlement.¹⁸⁰ Even in the absence or scarcity of objections, the judge must still consider diverse interests of the class and requisite factors before reaching her decision as to the fairness, reasonableness, and adequacy of the settlement.¹⁸¹ Class counsels must protect the interests of the entire class regardless of the position taken by objectors or class representatives.¹⁸² The court may grant additional discovery if it is necessary for the

¹⁷⁴ *Id.* § 21.311, at 292.

¹⁷⁵ FED. R. CIV. P. 23(e)(2).

¹⁷⁶ MANUAL, § 21.634, at 322.

¹⁷⁷ *Id.* § 21.643, at 327.

¹⁷⁸ *Id.* § 21.634, at 322.

¹⁷⁹ FED. R. CIV. P. 23(e)(5); MANUAL, § 21.643, at 328.

¹⁸⁰ MANUAL, § 21.643, at 328.

¹⁸¹ *Id.* § 21.635, at 322–23.

¹⁸² *Id.* § 21.641, at 323–24.

objectors to demonstrate the inadequacy of the settlement.¹⁸³ However, the discovery should be limited and conditioned on a showing of need.¹⁸⁴ The court must also ensure that there is sufficient record of the basis and justification for the court's conclusion.¹⁸⁵ The court must explain the findings in writing in sufficient detail to class members and the appellate court.¹⁸⁶

At a formal hearing in the proposed procedure, the court may employ a burden-shifting approach in applying the rule of reason analysis:¹⁸⁷ the objectors must 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); 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 procompetitive effects to determine whether the settlement agreement is reasonable. The court should follow the general practice of Rule 23 regarding limited discovery, witnesses, experts, affidavits or declarations and withdrawal. The court must approve withdrawal of any objector,¹⁸⁸ and if withdrawn objections result in modifications to the settlement terms, the withdrawal is considered as part of the settlement.

iii. Parties' Options After the Formal Hearing

If the court approves an agreement in the proposed procedure, the parties to the agreement may begin acting immediately in accordance with the agreement. Only those who timely objected may appeal the decision. The agreement will be reviewed under a deferential standard, i.e., the

¹⁸³ *Id.* § 21.643, at 327–28.

¹⁸⁴ *Id.* § 21.643, at 328.

¹⁸⁵ *Id.* § 21.635, at 322–23.

¹⁸⁶ FED. R. CIV. P. 23(e)(2) [former FED. R. CIV. P. 23(e)(3)] advisory committee notes to 2003 Amendments, ¶ 1.

¹⁸⁷ James A. Keyte & Karen Lent, *Reasonable As A Matter of Law: The Evolving Role of the Court in Rule of Reason Cases*, 28 ANTITRUST ABA 62 (2014) (discussing how most courts employ a burden-shifting approach for antitrust claims that are not subject to per se rule or a 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).

¹⁸⁸ *See* discussion on objectors *infra* Part IV.C. **Error! Reference source not found.**

abuse of discretion standard as described above. 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 cannot be held liable in future antitrust suits or penalized for their actions during the appeal period in accordance with the agreement.

If the judge disapproves the agreement after the formal hearing, the settling parties may (1) continue to litigate the patent infringement case; (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 would not sue the defendant based on the product proposed in its ANDA. 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).

C. Additional Requirements of the Proposed Settlement Process

i. A Strict Timeline to Avoid Delaying the Settlement Process

Bona fide objectors in class actions can be beneficial as they assist the court in identifying areas of a settlement that need improvement.¹⁸⁹ On the other hand, objections delay final resolution of a settlement by requiring the court to consider their arguments.¹⁹⁰ This "holdup" becomes more severe when objectors appeal, which can take years.¹⁹¹ Appeals are costly to class counsel as well as to non-objecting class members because they are typically not entitled to

¹⁸⁹ MANUAL, § 21.643, at 326.

¹⁹⁰ *Id.*

¹⁹¹ Brian T. Fitzpatrick, *The End of Objector Blackmail?*, 62 VAND. L. REV. 1623, 1624 (2009).

payment “until the legal process has run its course.”¹⁹² 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.¹⁹³ 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.¹⁹⁴ The prospect of delay and financial loss has prompted many class counsels to pay objectors out of their own pockets to withdraw the appeals.¹⁹⁵ 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.¹⁹⁶ Attorneys who routinely seek out class actions and object on behalf of class members are called “professional objectors,”¹⁹⁷ of whom “[f]ederal courts are increasingly weary.”¹⁹⁸

Paragraph IV litigations are different from class actions in this regard, because monetary awards are typically not involved,¹⁹⁹ 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 ends up being rejected in the end. The defendant generic company might play along if it believes the later payout would outweigh the

¹⁹² Lopatka, *supra* note 121, at 865, 882.

¹⁹³ Lopatka, *supra* note 121, at 865, 878.

¹⁹⁴ MANUAL, § 21.643, at 326.

¹⁹⁵ Fitzpatrick, *supra* note 191, at 1624.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at 1624–25; *see also* Lopatka, *supra* note 121, at 865–66.

¹⁹⁸ O’Keefe v. Mercedes-Benz USA, L.L.C., 214 F.R.D. 266, 295 n.26 (E.D. Pa. 2003).

¹⁹⁹ Note, however, that filing a baseless 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 brand-name company because of defendant generic firm’s baseless challenge to the brand-name’s patent).

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 has pointed out a situation where 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.²⁰⁰ 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 that happens too early would result in a premature period of exclusivity that would expire pursuant to the forfeiture provision.²⁰¹ It would not be feasible to wait to file an ANDA against the weak patent until the strong patent 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.²⁰² A stay followed by a generic victory would allow the first-filing generic to retain its 180-day exclusivity period and to 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.

The proposed procedure should not serve as a substitute for a stay,²⁰³ and thus, it is

²⁰⁰ Herman, *supra* note 56, at 1789.

²⁰¹ 21 U.S.C. § 355(j)(5)(D).

²⁰² Herman, *supra* note 56, at 1789, 1808–1813 (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) (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 is set to expire.) 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) (The defendant's motion to stay the Paragraph IV litigation for about two years was denied.)).

²⁰³ According to an estimate, even a one-year delay in generic entry costs consumers about \$661 million per drug. Hemphill, *Aggregate Approach*, *supra* note 14, at n.85.

imperative to keep the proposed procedure on a strict timeline. Only in extraordinary circumstances should courts grant a request to extend any deadline. The aforementioned two-prong test²⁰⁴ and appointment of an expert advisor²⁰⁵ 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. Furthermore, settling parties must be prohibited from giving, lending, or promising valuable consideration to or for any person, to induce 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.

ii. Two Conditions Imposed on the Settling Parties

In order to encourage settling parties to negotiate in good faith, two conditions are imposed on them once they express their intent to settle: (1) the plaintiff 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.

²⁰⁴ See *supra* note 145 and accompanying text.

²⁰⁵ See discussion regarding expert advisor *supra* Part III.A.ii.

The first condition ensures that the plaintiff brand-name company utilizes the proposed procedure in good faith. As discussed above,²⁰⁶ brand-name companies benefit from staying 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 tactic 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.”²⁰⁷ 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.²⁰⁸ The purpose of this requirement is to protect the interest of non-party class members.²⁰⁹ 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

²⁰⁶ See discussion *supra* Part III.C. **Error! Reference source not found.**

²⁰⁷ 21 U.S.C. § 355 (j)(5)(B).

²⁰⁸ 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, § 21.61, at 309 n.948.

²⁰⁹ *Ingram v. Madison Square Garden Ctr., Inc.*, 482 F. Supp. 426 (S.D.N.Y. 1979). See also, *Malcolm v. Cities Serv. Co.*, 2 F.R.D. 405 (D. Del. 1942).

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.²¹⁰ This would result in dismissal of the action.²¹¹ Not only is such practice a waste of judicial resources, but it also exacerbates the power imbalance²¹² between the parties. Therefore, the second condition fosters bona fide challenges to brand name patents.

IV. The Advantages of the Proposed Judicial Approval Procedure

The following Subsections A through E will highlight certain aspects of the proposed procedure and discuss how they address the prevailing problems surrounding the current Hatch-Waxman settlements.

A. The Proposed Procedure Informs the Public and Allows Third Parties to Intervene Before Antitrust Injury Occurs

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.”²¹³ Paragraph IV settlements affect people’s right to healthcare,²¹⁴ yet not every injured person is entitled to recovery even when the federal and state statutes provide private causes of action for those who

²¹⁰ § 355 (j)(2)(A)(vii).

²¹¹ There has been at least one instance where the defendant’s conversion of its ANDA certification has resulted in a court dismissal. *See United Therapeutics Corp. v. Sandoz, Inc.*, 2014 U.S. Dist. LEXIS 121573 (D.N.J. Aug. 29, 2014) (“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.”)

²¹² *See* discussion *infra* Part IV.D.

²¹³ *Pearson v. Skydell*, 522 F.2d 171, 176–77 (5th Cir. 1975), rehearing denied 525 F.2d 1407, certiorari denied 425 U.S. 912 (internal citation omitted); *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.”).

²¹⁴ *See supra* note 98.

incurred anticompetitive injury.²¹⁵ 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.²¹⁶ This rule applies to the federal statutes²¹⁷ as well as many state statutes that do not specifically repeal the indirect purchaser rule.²¹⁸ 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.²¹⁹ Thus, indirect purchasers of pharmaceutical drugs often have no practical avenue to recover damages for overcharged 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 apply prospectively.²²⁰ 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,

²¹⁵ 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. Many state laws also provide similar remedies for private plaintiffs. See Kurtis A. Kemper, *Right of Retail Buyer of Price-Fixed Product to Sue Manufacturer on State Antitrust Claim*, 35 A.L.R.6TH 245, Part II.B. § 9 (2008).

²¹⁶ *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). See also Kemper, *supra* note 215, at Part I. § 2 (explaining that the indirect purchaser rule “generally bars actions by retail buyers against manufacturers of price-fixed products, subject to limited exceptions”).

²¹⁷ See, e.g., *Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d 1365, 1369 (S.D. Fla. 2001) (citing *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 130 (1969); *In re Beef Indus. Antitrust Litig.*, 600 F.2d 1148, 1168 (5th Cir. 1979)) (“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.”).

²¹⁸ 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].”).

²¹⁹ Some exceptions apply. For example in *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 368, 370 (D. Mass. 2004), retail drug store plaintiffs were allowed 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.

²²⁰ *In re Niaspan Antitrust Litig.*, No. 13-MD-2460, 2014 U.S. Dist. LEXIS 124818, at *55 (E.D. Pa. Sept. 5, 2014) ([T]he end-payor plaintiffs may not recover for any overcharges incurred before the Oregon and Rhode Island repealer statutes took effect.).

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.²²¹ 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.²²²

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. Individuals who were involved in 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.²²³ However, “publicly available information contains significant gaps.”²²⁴ 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.²²⁵ In light of *Actavis*, settlements of Paragraph IV lawsuits will likely become more complex to avoid an appearance of a large, unexplained reverse payment.²²⁶ It is questionable as to whether publicly available information is sufficient for private

²²¹ 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).

²²² *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 allow ‘an end run around the policies allowing only direct purchasers to recover.’”).

²²³ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 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 Securities and Exchange Commission filing).

²²⁴ Hemphill, *Aggregate Approach*, *supra* note 14, at 647.

²²⁵ *In re Lipitor Antitrust Litig.*, No. 12-CV-02389, 2014 U.S. Dist. LEXIS 127877, at *33–40 (D.N.J. Sept. 12, 2014).

²²⁶ See Amanda P. Reeves, *Muddying the Settlement Waters: Open Questions and unintended Consequences Following FTC v. Actavis*, 28 FALL ANTITRUST 9, 12 (2013) (“To eliminate as much risk [of antitrust lawsuit] as

parties to plead a cause of action that can survive a motion to dismiss or to recognize an anticompetitive scheme to begin with.

Since settling parties in Hatch-Waxman lawsuits are required to submit their agreements to the FTC,²²⁷ one might argue that the FTC is better positioned 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.²²⁸ But government agencies have limited resources and cannot satisfy the interests of individual purchasers. Furthermore, political climate could shift an agency's focus and resources to another issue at anytime. Most significantly, the FTC cannot always be proactive in its approach to consumer protection. Its enforcement actions could take place long after consumers have been injured.

The proposed approval procedure addresses these public concerns and prevents unnecessary injury in various ways. First, settling parties must submit their proposed agreement to the judge who must act as a “skeptical client” and “critically examine” the terms of the agreement for any unreasonable restriction on competition.²²⁹ Next, if the judge decides to hold a formal hearing, members of the public will have an opportunity to object to the proposed agreement and identify areas that need improvement. Any issues must be resolved before the agreement is approved. Third, the proposed procedure requires settling parties to disclose any undertakings that, “although seemingly separate, may have influenced the terms of the

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

²²⁷ MMA, *supra* note 13, § 1112(c).

²²⁸ José P. Sierra, *FTC reveals plans for Reverse Payment Hatch-Waxman*, 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.”). The FTC and the Department of Justice generally believe that any reverse payment settlements are presumptively unlawful under the Sherman Act. *See, e.g.*, Brief for the United States in Response to the Court’s Invitation at 21–27, *Ark. Carpenters Health & Welfare Fund v. Bayer AG* at 11, 604 F.3d 98 (2009) (No. 05-2851-cv(L)).

²²⁹ *See Lopatka, supra* note 121, at 889

settlement.”²³⁰ The public would have access to settling parties’ information less any privileged materials or work product. It would no longer be necessary for the injured parties to scour through public records to find fragmented information on a settlement years after it goes into effect. Fourth, the judge approving a settlement must provide his or her opinion in writing which would be available to the public.

B. The Proposed Procedure Deters Sham Litigations

Sometimes a brand-name company can completely block competition in a particular market through a series of settlement agreements with multiple ANDA filers.²³¹ Suppose a brand-name company has an extremely weak patent that is blocking competition in a lucrative market. As described above, a weak patent does not warrant its owner to exclude others from competition.²³² 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. Suppose further that a number of the subsequent filers 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. Because of the complexities and confidential nature of these agreements, antitrust

²³⁰ FED. R. CIV. P. 23(e)(2) [former FED. R. CIV. P. 23(e)(3)] advisory committee notes to 2003 Amendments, ¶ 2.

²³¹ 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, to have colluded with both the first Paragraph IV filer Actavis, Inc. and the subsequent filer Paddock to share in Solvay’s monopoly profits. Solvay agreed to pay the two filers in exchange for delaying market entry.).

²³² *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.”) (emphasis as original).

plaintiffs might be able to attack only some of them individually. The brand-name company might prevail on the individual actions, even if the settlement scheme as a whole is unlawful.

Because the proposed procedure would be imposed on first-filers and subsequent filers alike, it enables the court to identify an anticompetitive scheme before it comes to fruition. This is achieved by requiring disclosure of any agreement in connection with settling parties' proposed settlement agreement. 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."²³³ Likewise, the disclosure requirement in the proposed procedure forces the settling parties to put all potentially related transactions on the table, thereby allowing the judge to examine the parties' motives and identify valuable considerations. The parties may include with their disclosure explanations as to how certain side deals do or do not relate to the proposed agreement. If any of such side agreements signal an anticompetitive concern, the issue can be resolved before any long-term anticompetitive harm takes place. The disclosure requirement also obviates the need to speculate illegality and spares the settling parties from expensive discovery years after the settlement takes place.

C. The Proposed Procedure Increases Predictability and Protection for Settling Parties

The proposed procedure alleviates the concerns of settled parties that they might face antitrust liability years after their settlement takes place. The antitrust enforcement system is decentralized in the United States, and thus potential plaintiffs include the federal government,

²³³ MANUAL, § 21.631 at 319.

state governments, and aggrieved individuals. A federal antitrust action may be brought under two federal statutes: the Sherman Act and the Clayton Act.²³⁴ The FTC²³⁵ may initiate an antitrust action under the Sherman Act against parties for collusion (Section 1) or against a single party for engaging in monopoly (Section 2).²³⁶ 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.²³⁷ 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.²³⁸

For civil antitrust suits under the federal law, a cause of action must be commenced within four years of accrual.²³⁹ An antitrust cause of action accrues when a defendant commits an act that causes injury to the plaintiff.²⁴⁰ In the Hatch-Waxman context, this means that the statute of limitations begins to run when settling parties enter into an allegedly unlawful agreement. However, the statute of limitations 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.’”²⁴¹ The statute of

²³⁴ 15 U.S.C. §§ 1–7; 5 U.S.C. §§ 12–27; 29 U.S.C. §§ 52–53. This Comment assumes that the interstate commerce requirement of the federal statutes is satisfied.

²³⁵ 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). However, criminal prosecutions 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.” *Wilcox, supra* note 148, at n.8 (quoting Phillip E. Areeda & Herbert Hovenkamp, *Antitrust 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.

²³⁶ §§ 1–2.

²³⁷ § 15c.

²³⁸ § 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* discussion *supra* Part IV.A.

²³⁹ § 15b.

²⁴⁰ *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)).

²⁴¹ *In re Ciprofloxacin*, 261 F. Supp. 2d at 219 (citing *Crown, Cork & Seal Co., Inc. v. Parker*, 462 U.S. 345, 353-54 (1983) (citing *Am. Pipe & Constr. Co. v. Utah*, 414 U.S. 538, 554 (1974))).

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 intervene as plaintiffs in the pending action.”²⁴² 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,²⁴³ and many state laws provide remedies for private plaintiffs.²⁴⁴ State statutes of limitations vary, but some states hold that the limitation period begins when the plaintiff discovers the anticompetitive act as opposed to when the defendants settle. 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.”²⁴⁵

Some antitrust defendants have attempted to claim antitrust immunity under the Noerr-Pennington doctrine,²⁴⁶ but 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 *Noerr-Pennington* immunity.”²⁴⁷ Furthermore, it is not clear whether a consent judgment falls within the scope of Noerr-

²⁴² *Crown*, 462 U.S. at 354.

²⁴³ *Wilcox*, *supra* note 148, at 869.

²⁴⁴ *Kemper*, *supra* note 215, at Part II.B. § 9.

²⁴⁵ R.I. Gen. Laws Ann. § 6-36-23 (2014 West); *see also* N.J. Stat. Ann. § 56:9-14 (2014 West) (“Any action brought to enforce the provisions of this act shall be barred unless commenced within 4 years after the cause of action arose . . .”).

²⁴⁶ “The Noerr-Pennington doctrine 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.” *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 394 (D. Mass. 2013) (citing *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988)).

²⁴⁷ *Id.* at 395 (citing *Andrx Pharms., Inc. v. Biovail Int’l*, 256 F.3d 799, 818–19 (2001) and *In re Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 618, 634–36 (2000)).

Pennington.²⁴⁸ In *In re Nexium (Esomeprazole) Antitrust Litigation*, the defense was unsuccessful because “it [was] unclear whether the judge could be fairly said to have endorsed the terms of the settlement agreements.”²⁴⁹ On the other hand, there is an indication that sufficient judicial intervention might lead the court to conclude that a settlement was sanctioned by a judge. In *In re Effexor Antitrust Litigation*, the court deemed the payment arrangement as stipulated in the settlement agreement justified 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.²⁵⁰

The proposed procedure improves predictability and builds confidence in the legality of Paragraph IV settlement agreements in several ways. First, the proposed settlement procedure provides a limited window of opportunity for any party (including the FTC) to object to a proposed agreement. Those who fail to timely object forfeit their right to appeal or bring an antitrust action based on the agreement. Second, the court’s reasons for approval would be made publicly available to aid future Paragraph IV litigants in structuring their agreements if they wish to settle. Third, because courts’ approval or denial of proposed agreements would be published, precedents will develop over time, resulting in more consistent decisions nationwide. Fourth, once a court approves a settlement agreement, it is presumed legal. At the appellate level, the legality of an approved agreement is reviewable only under a deferential standard.

D. The Proposed Settlement Procedure Mitigates the Power Imbalance Between the Settling Parties

²⁴⁸ *Id.* (“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.”).

²⁴⁹ *See, e.g., id.* at 398.

²⁵⁰ *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 U.S. Dist. LEXIS 142206, at *37–40 (D.N.J. Oct. 6, 2014). Note, however, the opinion does not specifically address the Noerr-Pennington doctrine.

Under the Hatch-Waxman regime, there is currently an inherent power imbalance between brand-name companies and generic companies. This is because a Paragraph IV litigation occurs before the generic enters the market.²⁵¹ 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.”²⁵² 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.²⁵³ The power imbalance also affects settlement 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’s expected payout from winning the lawsuit.²⁵⁴ 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.²⁵⁵ *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.

Within the proposed settlement framework, courts are in a unique position to mitigate this imbalance and manage both parties’ interests. For example, the court may raise concerns when the generic company demands payment that is unreasonably high or market entry date that is too soon. This way, the court acts to protect the brand-name company’s need to recover its investment in research, which ensures continued development of new drugs. Furthermore, by allowing

²⁵¹ 21 U.S.C. § 355 (j)(2)(B).

²⁵² Opderbeck, *supra* note 97, at 1307.

²⁵³ Brief for the Intellectual Property Owners Association as Amicus Curiae Supporting Respondents at 24, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416) (“[F]or more than 90% of branded drug sales (measured in dollars), a generic challenger balancing upside gain under Hatch-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.”).

²⁵⁴ Reeves, *supra* note 226, at 12.

²⁵⁵ Fazio, *supra* note 84, at 14.

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.

E. The Proposed Procedure Likely Enhances Predictability Which in Turn Encourages Innovation

The current regulatory system 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.”²⁵⁶ 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,²⁵⁷ 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.²⁵⁸ A brand-name company may also take into account the likelihood of generics’ market entry,²⁵⁹ the cost of future litigations (including potential antitrust litigations), and the probability of successful settlement(s).²⁶⁰ If the occurrence of future antitrust litigation is so unpredictable, companies might overestimate the associated costs and shy away from particular research projects altogether.

²⁵⁶ Mylan Pharm., Inc. v. U.S. Food And Drug Admin., 454 F.3d 270, 272 (4th Cir. 2006) (quoting *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230 (4th Cir. 2002)).

²⁵⁷ Harper, *supra* note 20.

²⁵⁸ Brand-name companies are subject to additional financial strains. For example since 2011, Section 9008 of the Patient Protection and Affordable Care Act has imposed an annual fee on manufacturers and importers of “branded prescription drugs.” 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 (Oct. 15, 2014, 8:21 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. Furthermore, the Affordable Care Act provisions mandates drug manufacturers to provide 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.

²⁵⁹ Murat C. Mungan, *Reverse Payments, Perverse Incentives*, 27 Harv. J.L. & Tech. 1, 39 (2013).

²⁶⁰ *Id.*

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 the non-R&D costs. The overestimation is justifiable since the FTC interprets the *Actavis* decision to be a “significant victory for the Commission.”²⁶¹ Therefore, brand-name companies will likely factor in expected costs of antitrust litigations when determining drug prices, effectively shifting the costs to consumers.²⁶²

The proposed procedure would improve predictability as to the volume of future antitrust lawsuits, because settling parties can structure their agreements in conformity with precedents. Furthermore, since an approved agreement is presumed legal, the likelihood that settled companies would face antitrust liability diminishes significantly. Thus, brand-name companies would be encouraged to invest in R&D and less reluctant to lower drug prices.

One commentator on reverse payment settlements has proposed a model that demonstrates the effect of the shift in legality of reverse payment settlements.²⁶³ According to the model, switching from a regime that legalizes reverse payment settlements to a regime that illegalizes the settlements increases incentives for brand-name companies to develop stronger inventions rather than weaker inventions, therefore strengthening their patents.²⁶⁴ The model also shows that a move toward illegalization of reverse payment settlement deters generics from entering the market when the patent is strong.²⁶⁵ The proposed procedure does not illegalize reverse payment settlements, but makes it difficult for brand-name companies to rely on them. If this model

²⁶¹ Wright, *supra* note 3.

²⁶² Pamela J. Clements, *The Hatch-Waxman Act and the Conflict Between Antitrust Law & Patent Law*, 48 IDEA 381, 401 (2008).

²⁶³ Mungan, *supra* note 259 at 41–44.

²⁶⁴ *Id.* at 43–44.

²⁶⁵ *Id.* at 41–42.

accurately forecasts the behaviors of brand-name and generic companies, the proposed procedure would encourage strong innovation.

V. 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. The parties 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 anticipated antitrust lawsuits may cause brand-name companies to divert resources from R&D and shift costs to consumers. On the other hand, interested members of the public cannot intervene before Paragraph IV settlements are finalized and are unable to escape the effects of the settlement terms. Many of the consumers who are injured as a result of a Paragraph IV settlement have no legal recourse under the indirect purchaser rule, and even the ones 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 some of the problems surrounding the parties to Paragraph IV settlements. Most significantly, it provides a process through which settling parties can obtain judicial approval of their agreement. Once approved, an 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, settling parties 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 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 prevents 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 public welfare. A more preemptive and drastic approach is necessary and desirable.