“PAY-FOR-DELAY” SETTLEMENTS
POST-ACTAVIS: WHY MEDIATION CAN
TACKLE THE “UNREASONABLE”
ANTITRUST SETTLEMENTS

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I. INTRODUCTION

Intellectual property has long been a balancing act between incentivizing innovation and protecting consumers. The pharmaceutical industry relies on patent policy in order to innovate through new drug development as well as to profit from its initial investment. However, the potential high profitability of drug innovation has brought about a possible antitrust dilemma: when do subsequent cost-saving generic drugs become another barrier for public health? “Reverse payment” settlements, also known as “pay-for-delay” settlements, in the pharmaceutical industry illustrate this problem in intellectual property policy.1 Reverse payment settlements comprise an agreement between brand name pharmaceutical manufacturers and generic manufacturers, commonly including the generic manufacturers’ agreement to delay market entry of a generic drug.2 While reverse payment settlements are not always linked with inappropriate delays in generic drug entry and other cash and cash-less litigation settlement terms, the public policy issues associated with numerous reverse payment settlements have led the Federal Trade Commission to go up in arms to confront this concern in the United States.3

The Federal Trade Commission has not been the only agency examining pharmaceutical reverse settlements; international regulatory enforcers have also been increasingly scrutinizing “pay-for-delay” settlements. For example, in July 2014, the European Commission fined Servier $449 million USD for its antitrust settlements

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2 Id. at 1557.

3 Id. at 1561–62.
“abusing its dominance” to prevent generic versions of its blockbuster blood pressure medication perindopril from appearing on the market. Other countries have also begun the regulatory process of claiming antitrust liability against these types of pharmaceutical settlements.

In the United States, following a circuit split, the Supreme Court decided Federal Trade Commission v. Actavis in June 2013, holding that reverse payment settlements may potentially have antitrust liability if the settlements are designed to delay competition between a brand-name pharmaceutical company and a generic manufacturer. Justice Breyer illustrated the majority’s reasoning for its conclusion: (1) reverse payment settlements have “significant” anticompetitive effects; (2) the anticompetitive effects can be unjustified; (3) based on the size and breadth of some of the settlements, the party making the settlements can likely suppress competition; (4) because “it is normally not necessary to litigate patent validity to answer the antitrust question,” there is not as high an administrative burden; and (5) antitrust liability resulting from “large, unjustified” reverse payments does not discourage parties from entering into legitimate settlements. The resulting Supreme Court’s ruling may encourage increased future litigation, as brand-name pharmaceutical companies are no longer incentivized to reach a Paragraph IV settlement with generic manufacturers due to antitrust liability. However, increased litigation expends resources and time, especially due to the complex technical issues inherent in the claim. Therefore, an alternative dispute resolution should be employed to resolve the standards of the Supreme Court and the inefficiencies of litigation.

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5 See Global Convergence on ‘Pay-for-Delay’ Settlements, Bristows (Oct. 16, 2014), http://www.bristows.com/articles/global-convergence-on-pay-for-delay-settlements (detailing Canada, Brazil, Australia, India and France as recent international enforcers scrutinizing pharmaceutical reverse payments).


7 Id. at 2236–37.

8 Paragraph IV refers to certifications in the Hatch-Waxman Act that a generic drug does not infringe the patent rights of a brand-name drug or that a brand-name drug’s patent rights are invalid. See infra Section II.A.
Mediation is an alternate dispute resolution that can balance court efficiency and the potentially anticompetitive reverse payments. Even in patent disputes, mediation can provide a neutral assessment of the chances of success in litigation, and serve as a reality check between lawyers and their clients. Mediators can also reduce the pressure on court dockets because they can be skilled in the field of patents and provide informed critique on both the strengths and weaknesses of the brand name and generic drugs suit. Skilled mediators also have a better and faster learning curve than judges and juries. Analyzing patents and antitrust liability takes into account the balance between consumers and companies by “maintaining the competitive structure of existing markets against benefits to consumers by permitting the intellectual property rights system to provide an incentive for research toward new and improved products.”

This Note discusses the benefits that mediation can have on the reverse payment settlement and antitrust debate, and how it can satisfy the “rule of reason” requirement post-Actavis. Accordingly, Section II discusses the legislative history and policy of the Hatch-Waxman Act. It elaborates on the pioneer drug development process and how the combination of legislation and the inherent nature of drug development resulted in “pay-for-delay” settlements. Section III discusses majority and dissenting opinions in the landmark Supreme Court case FTC v. Actavis as well as the circuit split decisions that led up to the Court’s ultimate ruling and its implications. This section also analyzes the subsequent cases and the different interpretations from the district courts. Section IV discusses mediation as a means to resolve the debate of antitrust liability and reverse payment settlements between brand name pharmaceutical companies and generic manufacturers. The Conclusion discusses mediation’s utility in resolving the antitrust tendencies between generic drug and brand-name drug manufacturers.

10 See Jane Player, Vive la Resolution!, INTELL. PROP. MAG. 55, 56 (2013).
II. BACKGROUND

A. The Hatch-Waxman Act and Policy

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act, in order to combat high drug costs by providing regulatory and financial incentives to grant higher access to affordable generic versions of brand-name pharmaceutical drugs.\textsuperscript{13} The Hatch-Waxman Act has two goals: (1) strengthening the patent awarded to pioneer drug developers and (2) easing the way to bring generic drugs to market and providing consumers to cheaper, yet equally efficacious and safe drugs.\textsuperscript{14} Generic drugs typically cost thirty to eighty percent less than their brand-name bioequivalents and therefore save consumers billions of dollars each year.\textsuperscript{15} The two goals of the Act are accomplished through (1) ensuring the correct patent term of a pioneer drug despite a lengthy FDA process, and (2) abbreviating the generic drug process.\textsuperscript{16}

The Hatch-Waxman Act provides the regulation framework for pharmaceutical companies to obtain approval for marketing pharmaceutical compounds in the United States.\textsuperscript{17} Brand name pharmaceutical companies must first submit a New Drug Application (“NDA”) to the Food and Drug Administration (“FDA”) and complete the requisite scientific testing to establish the safety and effectiveness of the new drug prior to release and marketing in the United States.\textsuperscript{18} The Hatch-Waxman Act also attempts to address regulatory delays with NDAs by allowing an extension of exclusivity for up to five years, for a total period of fourteen years.\textsuperscript{19}

Once the FDA has approved the brand-name drug, generic manufacturers can then seek to obtain approval for marketing a
bioequivalent generic compound by filing an Abbreviated New Drug Application ("ANDA") to the FDA. In contrast, a generic manufacturer is not subject to patent liability for regulatory approval. Therefore, a generic drug can market and compete once the pioneer drug patent has expired but without the high research cost for regulatory approval required of the pioneer drug.

Within the ANDA application, the FDA requires generic drug manufacturers to certify that the generic is a bioequivalent and contains the same active ingredients as the brand-name drug. The certifications for early generic approval must confirm one of the following: (1) no patent rights exist; (2) the patent rights have expired; (3) the generic drug will not be marketed until the patent rights expired; or (4) the generic does not infringe or that the brand-name drug patents are invalid or unenforceable. Most notably, in the ANDA application is the "Paragraph IV" certification that verifies that the generic drug does not infringe on the brand-name drug or that patents on the brand-name drug are invalid or unenforceable and therefore bring about patent infringement litigation. All the patents that a generic manufacturer certifies against are located in the "Orange Book," an FDA resource.

Therefore, the Hatch-Waxman Act provides the means to question USPTO approved, yet potentially invalid, weak patents. Through the FDA’s approval of ANDA applications and certifications, particularly in Paragraph IV certifications, generic manufacturers can dispute the novelty and validity of brand-name drugs and drug-making processes. These contentions lead to litigation regarding patent invalidity and infringement claims.

The Hatch-Waxman Act also galvanizes generic manufacturers to be the first-to-file an ANDA. By filing an ANDA with Paragraph IV certification, first-to-file generic manufacturers can receive a 180-day exclusive right to market their generic drug over other generic manufacturers. Generic manufacturers estimate

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22 See supra note 21 and accompanying text.
23 Id.
24 Id. at § 355(j)(2)(A)(vii)(IV).
25 The “Orange Book” is formally known as “Approved Drug Products with Therapeutic Equivalents.”
26 See, e.g., Bayer AG v. Pharm. Research Corp., 212 F.3d 1241 (Fed. Cir. 2000) (holding that the patent in question was not infringed by the generic company’s ANDA).
that this 180-day period generates anywhere between sixty and eighty percent of any singular generic drug.\textsuperscript{28} Since the majority of a generic manufacturer’s profits from a generic drug are from the 180-day exclusivity period prior to other generics entering the market to lower prices, the Hatch-Waxman Act incentivizes generic manufacturers not only to be the first-to-file but also motivates settlements.\textsuperscript{29}

In fact, despite the Hatch-Waxman drafters’ original intent to encourage generic companies to bring suit to invalidate sham patents,\textsuperscript{30} studies have shown that a generic manufacturer can justify a litigation challenge against a brand-name patent even if it believes it has a low chance of success.\textsuperscript{31} This is in large part because Paragraph IV filers are exempted from damages for infringement as long as the generic manufacturer has not begun to market the generic drug.\textsuperscript{32}

While brand name pharmaceutical companies had previously coped with litigation against their pioneer drugs by delaying early resolution, Congress amended the Hatch-Waxman Act in 2003 by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 to address this delaying tactic.\textsuperscript{33} Following the amendment, the Paragraph IV ANDA filer is allowed to bring declaratory judgment for non-infringement or invalidity under 28 U.S.C. § 2201 against the patent owner if no infringement action is taken within forty-five days of notice.\textsuperscript{34} Regardless of the drug patent’s validity, these amendments have not stifled the brand-name companies efforts to extend their patent monopoly; however another way they have extended their exclusivity is through reverse payment settlements.


\textsuperscript{29} See Hemphill, \textit{supra} note 1, at 1588–94.


\textsuperscript{31} \textit{Id.} at 14–15.


\textsuperscript{34} \textit{Id.}
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B. Economics of Creating a Pioneer Drug: Determining a Valid Settlement

The United States spent approximately $329 billion dollars on prescription medicine in 2013.\textsuperscript{35} The incentive for maintaining drug exclusivity and its corresponding high sinking costs has long been rationalized by the lengthy drug discovery and development process. Brand name pharmaceutical companies contend that development of a new drug potentially costs $500 to $800 million to develop with only 30\% making a good return.\textsuperscript{36} The research and development (“R&D”) of pioneer drugs is typically a long process from start to approval and while the productivity has not improved significantly, developmental costs have escalated.\textsuperscript{37} R&D is conducted in a linear, or stepwise manner.\textsuperscript{38} The process to take a compound or molecule from early research to approved product takes approximately $1 billion USD.\textsuperscript{39} This amount is heightened because of the highly fragmented, or siloed, drug discovery process; brand-name companies fail to learn from the mistakes of others due to their need to protect their own intellectual property.\textsuperscript{40}

Marketing decisions have also influenced the actions of brand name companies to cope with the increased number of generic drugs being brought to market.\textsuperscript{41} Generally there are two types of marketing strategies for R&D: (1) blockbuster model and (2) spe-


\textsuperscript{37} See IMS HEALTH, supra note 35, at 32.


\textsuperscript{39} Id. This number includes the cost of producing compounds that failed along the discovery process.

\textsuperscript{40} Id.

\textsuperscript{41} The industry has been noted to spending twice as much on marketing as on R&D with “only one tenth of drug sale profits” cycling back into R&D. See Medicins Sans Frontieres, MSF Campaign for Access to Essential Medicines: Briefing Note (Nov. 2004), http://www.accessmed-msf.org/documents/MexicoR&Dbriefing.pdf.
cialist model.\textsuperscript{42} The brand-name pharmaceutical companies have largely shifted to the more costly specialist model and to creating specific disease subtype medications rather than to generating mass-market blockbusters.\textsuperscript{43} This specialization leads to higher developmental costs for the brand-name medication, although it limits inter-brand-name competition and fewer “me-too” drugs on the market due to the difficulty of formulating these distinctive drugs.\textsuperscript{44}

The rapid introduction of generic drugs to the market decreases the profitability of a brand-name drug. Generics are dispensed ninety-four percent of the time where a generic form is available.\textsuperscript{45} Generic drug usage has garnered such intensive use because of motivations such as coverage by an insurance plan as well as affordable co-payments with public coverage.\textsuperscript{46} State laws have also contributed to the widespread usage of generic drugs; some states allow automatic substitution of generic drugs unless the physician as written ‘dispensed as written’ on the prescription.\textsuperscript{47} The pro-generic drug attitude from commercial sectors and state law has resulted in at least eighty percent of dispensed prescriptions within the United States being dispensed as generics.\textsuperscript{48} Furthermore, within the first year of generic markets, it captures “90 percent of branded sales and that prices drop[ping to] 85 percent with multiple generics on the market.”\textsuperscript{49}

Another economic driving force for brand-name pharmaceutical companies fighting the entrance of a generic bioequivalent is the “patent cliff.”\textsuperscript{50} The patent expiration impact has represented

\textsuperscript{43} Id. at 16–17.
\textsuperscript{44} Id. at 15. Me-too medications are drugs that are similar to on-the-market drugs with minor differences.
\textsuperscript{47} Id.
\textsuperscript{48} IMS Health, supra note 44, at 26.
\textsuperscript{50} A “patent cliff” refers to a sudden drop in sales in a group of “blockbuster” drug. (A blockbuster drug is defined as any pioneer drug that exceeds global sales of $1 billion dollars per
an approximately $127 billion loss globally due to a shift in generics.\footnote{The Global Use of Medicines: Outlook Through 2016, IMS Health 3 (2012), \url{http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Global%20Use%20of%20Meds%202011/Medicines_Outlook_Through_2016_Report.pdf}.} This global loss of revenue has led brand-name pharmaceutical companies to protect their existing patents through processes such as evergreening and reverse payment settlements.\footnote{Pharmaceutical evergreening, also known as creating “me-too” drugs, refers to the brand name companies taking out new drug patents by slightly modifying existing drug formulations. Evergreening has offset generic competition and other cost-lowering policies. A study in 2002 showed that 68% of total new chemical entities marketed in the last twenty-five years were “me-too” products that demonstrated little to no therapeutic benefit; see generally Trouiller P et al., Drug development for neglected diseases: a deficient market and a public-health policy failure, 359 Lancet 2188 (2002).} Consequently, the potential exorbitant costs of developing an innovative drug coupled with the ease in which generic drugs are formulated and brought to market following the Hatch-Waxman Act have laid the foundation for reverse payment settlements to flourish.

\section*{C. Advent of “Pay-for-Delay” or Reverse Payment Settlements}

“Pay-for-delay” settlements, also known as reverse settlements, occur in the pharmaceutical industry when the patent holder and alleged infringer come to an agreement regarding a Paragraph IV certification. Whereas most patent infringement cases would involve the patent infringer compensating the patent holder, the “reverse” is true in settlements between the brand-name and generic companies. In this case, the brand-name company agrees to provide compensation to the generic company, or alleged infringer, who in turn agrees to delay the marketing of a generic drug.\footnote{See Christopher M. Holman, Do Reverse Payment Settlements Violate the Antitrust Laws?, 23 Santa Clara Computer & High Tech. L.J. 489, 494 (2007).} Reverse payment settlements have generally involved four types of agreements: “(1) amount of reverse payment; (2) length of generic marketing restriction; (3) retention of generic market exclusivity; and (4) ancillary licenses.”\footnote{See David W. Opderbeck, Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation, 98 Geo. L.J. 1303, 1308 (2010).} Many blockbuster drugs such as Cipro or Lipitor have had either exclusive or partial mone-
tary settlements with generic companies. These settlements also can contain set delays to generic entries, which can potentially allow blockbuster producers to reap billions of dollars from consumers with a one-year delay. Settlements also allow the generic company to retain their 180-day exclusivity period even after reaching a settlement due to a loophole within the Hatch-Waxman Act when it defined the “failure to market” provision. The ancillary licensing agreements can also contribute to a portion of the reverse payment. These types of agreements could include the generic company agreeing to license some of its generic drugs to the brand-name company. As the Federal Trade Commission scrutinized these types of agreements as anti-trust, the subsequent litigation resulted in circuit splits regarding the standard of judgment for reverse payment settlements.

III. SUPREME COURT’S “RULE OF REASON” TEST RULING IN FTC V. ACTAVIS

A. Background of Case

The circuit splits were finally resolved in 2013 when the Supreme Court addressed reverse payment settlements in the landmark case FTC v. Actavis. The case involved “Androgel,” a prescription gel formulation to treat male hypogonadism or low testosterone levels, that was originally developed by a Belgian pharmaceutical company, Besins Healthcare, S.A. Besins Healthcare subsequently entered into a licensing agreement with Solvay Pharmaceuticals to distribute Androgel through Solvay in the United States following FDA approval. Solvay filed an NDA

56 See id. at 650.
58 See Holman, supra note 53, at 498.
60 Id. at 1373.
with the FDA to market Androgel in 1999; the FDA approved the application in 2000. 61

Following FDA approval, Solvay also filed and obtained a patent with the Patent and Trademark Office in 2003. 62 Androgel’s patent is issued under Patent Number 6,503,894, and expires in August 2020. 63 Under the Hatch-Waxman Act, the FDA is required to grant drug manufacturers three years of drug exclusivity for an NDA with an active ingredient that has previously been approved by the FDA and also still encompasses important clinical investigations. 64 Because Solvay’s NDA provided these important clinical investigations regarding testosterone, the active ingredient in Androgel, the FDA granted Solvay drug exclusivity for three years. 65 This drug exclusivity proved extremely profitable for Solvay as U.S. sales of Androgel resulted in a profit of more than $1.8 billion dollars between 2000 and 2007. 66

In May 2003, two generic drug manufacturers, Actavis, Inc. (formerly known as Watson Pharmaceuticals) and Paddock Laboratories, Inc., filed an ANDA with the FDA in order to market a generic formulation of Androgel. 67 In the ANDA, the generic manufacturers certified the generic’s bioequivalency to the brand-name Androgel and also Paragraph IV, stating that the generic drug would not infringe on Solvay’s issued patent because Solvay’s patent was overly broad and therefore invalid. 68 In response, Solvay filed a patent infringement suit against Actavis and Paddock, which prompted the thirty-month waiting period before the FDA could approve an ANDA. 69

Despite Solvay, Actavis, and Paddock engaging in litigation, no decision was made prior to the end of the thirty-month waiting period in 2006; the FDA approved Actavis’ ANDA to begin the manufacturing and selling of a generic version of Androgel. 70 However, no generic version of Androgel was ultimately sold because of the settlement reached following the FDA’s approval.

61 Id.
62 Id.
65 See In re AndroGel Antitrust Litig., 687 F. Supp. 2d at 1373.
66 Id.
67 See Watson Pharm. Inc., 677 F.3d at 1304. Note that due to Actavis filing its ANDA first, only Actavis would be eligible for the first filer benefit of 180 day generic drug exclusivity.
68 Id.
70 Id. at 1304.
With a potential loss of $125 million per year in profit following a grant for summary judgment regarding their patent’s invalidity, Solvay offered Actavis and Paddock a settlement. One part of the settlement would be for delayed entry of generic Androgel until August 2015. In exchange for the delayed entry of the generic Androgel, Solvay agreed to give settlement amounts from AndroGel profits. Actavis would receive between $19 and $30 million of Solvay's AndroGel's profits per year until September 2015, because it was the first generic filer. Paddock would receive $10 million per year for six years.

Consequently, the FTC filed an action against the pay-to-delay settlement reached by Solvay and the generic manufacturers due to antitrust violations. The FTC stated that pay-for-delay “agreements deny patients the benefit of competition between branded and generic pharmaceuticals, and ultimately deny consumers hundreds of millions of dollars a year.” Although Solvay asserted that the settlement payment agreements were compensation for “other services” that the generics agreed to perform, the FTC countered this argument that the payments were solely to compensate the generics for their agreement not to compete until 2015.

In 2010, the FTC filed suit against Solvay and all the generic manufacturers for their settlement in the U.S. District Court for the Northern District of Georgia. The FTC’s complaint claimed that the respondents’ settlement violated federal antitrust laws through their unlawful agreement to share Solvay’s monopoly-gained profits, abandonment of their patent infringement challenges, and refraining from selling cost-saving generic drugs to compete with AndroGel for nine years.

The District Court dismissed the FTC’s case; the court held that the FTC’s allegations did not invoke antitrust law because the case belonged in the realm of patents. The Eleventh Circuit af-
firmed the District Court’s decision on appeal, holding that “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”81 The Eleventh Circuit acknowledged that normally when one company pays another company to stay out of the market those actions incur federal antitrust violations.82 However, due to the inherent exclusionary rights granted to patent holders, the appellate court reasons that reverse payment settlements in patent litigation are “atypical.”83 The Supreme Court granted the FTC’s writ of certiorari in order to resolve the competing standards of the federal courts when adjudicating reverse payment settlements and antitrust challenges.84 In order to determine the legality of the Actavis settlement agreement, the Court had three possible standards of antitrust review derived from circuit splits: (1) per se illegality, (2) scope of the patent test, and (3) the rule of reason analysis.85

B. Circuit Split: Per Se Illegality

Regarding antitrust violations, the Supreme Court has held that “only unreasonable restraints on trade”86 violate Section 1 of the Sherman Antitrust Act. Of these restraints, a subset with “predictable and pernicious anticompetitive effect[s]” is deemed unreasonable and unlawful per se.87 The first reverse settlement case decided in the federal appellate court was brought forward in the U.S. Court of Appeals for the District of Columbia and held that these types of settlements are per se violations of federal antitrust laws.88 In Andrx Pharmaceuticals Inc. v. Biovail Corp. International, the settlement was between first generic ANDA filer Andrx Pharmaceuticals and patent holder Hoescht-Marion Roussel, Inc. for the prescription drug Cardizem CD.89 Similar to Actavis, Hoescht-Marion Roussel sued for patent infringement following Andrx’s filing its

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81 See Watson Pharm., Inc., 677 F.3d at 1312.
82 Id. at 1307.
83 Id. at 1307.
85 See Section IIIB–D.
87 Id.
89 Id. at 799.
ANDA to the FDA. When the thirty-month waiting period ran through, Andrx and Hoescht-Marion Rousselle entered into a settlement agreement requiring Hoescht-Marion to pay Andrx $10 million in quarterly payments to delay generic drug marketing of Cardizem CD. The D.C. Circuit held that the Andrx and Hoescht-Marion Rousselle’s settlement agreement could “reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions;” the settlement agreement payments served as prima facie evidence as an illegal, noncompeting agreement.

Following the D.C. Circuit decision, the Sixth Circuit also heard arguments regarding the reverse settlement agreement between Andrx and Hoescht-Marion Roussell. Rather than being brought forward by the FTC, the case was brought forward by direct and indirect purchasers of the prescription medication Cardizem CD; these purchasers alleged that they suffered antitrust injury due to unnecessarily inflated drug prices due to the purposeful delay for a competitive generic alternative on the market.

Emphasizing the concern of reverse payment settlements that allow manufacturers to pay other manufacturers not to compete, the Sixth Circuit held that the Cardizem CD reverse settlement agreement was “a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade.” Though the D.C. Circuit Court and Sixth Circuit opted for a per se illegality of reverse payment settlements, they remained the outliers as other federal courts have opted not to hold these settlements presumptively invalid and to use a more lenient test.

C. Circuit Split: Scope of the Patent Test

The majority of federal courts have analyzed reverse payment settlements with the “scope of the patent test” when determining

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90 Id. at 803.
91 Id.
92 See id. at 813.
93 See In re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003).
94 Id. at 903–04.
95 Id. at 908.
whether the settlement violates federal antitrust law.\textsuperscript{96} The scope of the patent test presumes the legality of reverse payment settlements due to the inherent exclusionary rights of the patent holder; this includes excluding others from the market.\textsuperscript{97} Therefore, a reverse payment settlement is presumptively valid so long as its actions do not fall out of the scope of the patent holder’s rights and protections of a monopoly.\textsuperscript{98}

Prior to \textit{Actavis}, the Eleventh Circuit considered the validity of reverse payment settlements in three noteworthy cases: \textit{Valley Drug Co. v. Geneva Pharmaceuticals},\textsuperscript{99} \textit{Schering-Plough Corp. v. Federal Trade Commission},\textsuperscript{100} and \textit{Federal Trade Commission v. Watson Pharmaceuticals, Inc.}\textsuperscript{101}

Decided in 2003, \textit{Valley Drug Co. v. Geneva Pharmaceuticals Inc.} regarded two settlement agreements where the brand name manufacturer agreed to pay the generic manufacturers $30 million to delay their generic drug sale until after the brand name’s patent term had run.\textsuperscript{102} Though the patent in question was later found invalid,\textsuperscript{103} the Eleventh Circuit reasoned that patents give brand-name manufacturers the right to exclude competitors from the market.\textsuperscript{104} The case was subsequently remanded to determine whether any part of the agreement exceeded the scope of the protections afforded to patent holders.\textsuperscript{105} Only those agreements that exceeded the scope of the patent would be subject to antitrust scrutiny.\textsuperscript{106}

In 2005, the Eleventh Circuit decided a noteworthy case, \textit{Schering-Plough Corp v. Federal Trade Commission}. The FTC filed a complaint alleging antitrust violations regarding a settlement agreement between brand-name manufacturer, Schering-Plough, and a generic manufacturer, Upsher-Smith Laboratories, regarding the sale and marketing of hypertension (high blood pres-
sure) drug K-Dur 20.107 The defendants appealed the FTC’s determination of the settlement’s antitrust violation during an administrative proceeding to the Eleventh Circuit.108 The Eleventh Circuit rejected the FTC’s finding that Schering-Plough’s $60 million payment to Upsher-Smith was an exchange solely for market entry delay; the settlement payment was found to be only for licenses that Schering-Plough had obtained during the agreement to market five Upsher-Smith products.109 Because those payments were not found related to delayed market entry outside the scope of the patent, the Eleventh Circuit held that no antitrust violation had occurred with the settlement agreement.110

*Federal Trade Commission v. Watson Pharmaceuticals, Inc.* is the precursor to *Federal Trade Commission v. Actavis*. The Eleventh Circuit articulates that reverse payment settlements, “absent sham litigation or fraud in obtaining the patent,” need only determine whether the actions exceeded the scope of the patent.111

Resulting from these three cases, the Eleventh Circuit’s scope of the patent standard examines: “(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed the scope; and (3) the resulting anticompetitive effects.”112 However, because the scope of the patent test examines the wide-spectrum of monopolistic rights that a patent holder has, this test can be viewed as affording irrefutable validity to reverse payment settlements.113

The Second Circuit also heard *In re Tamoxifen Citrate Antitrust Litigation*114 regarding reverse settlement payments in 2006. The reverse settlement payment in question regarded the brand-name manufacturer making a payment of $21 million to the generic manufacturer in exchange for the generic manufacturer to request

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107 Schering-Plough Co., 402 F.3d 1056 (11th Cir. 2005).
108 Id. at 1061.
109 Id. at 1069–71.
110 Id. at 1071.
111 See FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1304 (11th Cir. 2012).
112 See Schering-Plough Co., 402 F.3d at 1066; Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003).
113 See Valley Drug Co., 344 F.3d at 1304 (“A patent grants its owner the lawful right to exclude others. This exclusionary right is granted to allow the patentee to exploit whatever degree of market power it might gain thereby as an incentive to induce investment in innovation and the public disclosure of inventions. The exclusionary right cannot be exploited in every way—patentees cannot pool their patents and fix the prices at which licensees will sell the patented article, for example—but a patentee can choose to exclude everyone from producing the patented article or can choose to be the sole supplier itself . . . .” (citations omitted)).
114 In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 186 (2d Cir. 2006).
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that the district court vacate its decision that the brand name patent for Tamoxifen was invalid.\(^\text{115}\) Even knowing that the district court had initially held that the patent for Tamoxifen was invalid, the Second Circuit applied a presumption of patent validity as used in the Eleventh Circuit; absent a patent obtained by fraud, “no injury to the market cognizable exist[s] under antitrust law, as long as competition is restrained within the scope of the patent.”\(^\text{116}\) However, the Second Circuit noted that “the less sound the patent . . . and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder.”\(^\text{117}\)

The Federal Circuit also adopted the “scope of the patent test” when adjudicating *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.\(^\text{118}\) This reverse payment settlement involved brand-name manufacturer, Bayer, and generic manufacturer, Barr Laboratories, regarding antibiotic Ciprofloxacin. In exchange for dropping the Paragraph IV certification of invalidity, Bayer agreed to pay Barr $398.1 million over several years, with an initial payment of $49.1 million. Using the scope of the patent test, the Federal Circuit reasoned “settlement of patent claims by agreement between the parties—including exchange of consideration—rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition.”\(^\text{119}\)

D. Rule of Reason Analysis

1. Result of *FTC v. Actavis*

   Instead of a strict *per se* illegality or a more lenient “scope of the patent” test, the Supreme Court opted for a middle ground that held in *Federal Trade Commission v. Actavis* that reverse payment settlements “can sometimes violate antitrust laws.”\(^\text{120}\) In Breyer’s majority five to three opinion, the Court stated that patent law policy and “precompetitive antitrust policies” must be considered to determine the “scope of the patent monopoly” and antitrust liabil-

\(^{115}\) *Id.* at 190.

\(^{116}\) *Id.* at 212–13.

\(^{117}\) *Id.* at 211.

\(^{118}\) See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008).

\(^{119}\) *Id.* at 1333 (citing Standard Oil Co. v. United States, 283 U.S. 163, 171 (1931)).

The Court also rejected the FTC’s stance of a per se antitrust rule against reverse payment settlements. Instead, the Court mandated a modified “rule of reason” analysis for lower courts when analyzing whether a reverse payment settlements incurs antitrust liability.

Under the “rule of reason” test, courts consider factors to determine whether the “questioned practice imposes an unreasonable restraint on competition.” These factors would include: “relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.” The antitrust plaintiff bears the initial burden to establish market power and anticompetitive effect. If the antitrust defendant can rebut this assertion through a pro-competitive objective, the burden falls back on the plaintiff to establish that this objective can be met without the antitrust action.

2. The Dissent’s “Scope of the Patent” Test

The dissent argued that the Solvay settlement did not incur antitrust liability because the settlement “conduct . . . did not exceed the scope of the patent.” Because no fraudulent or sham litigation had been alleged, the dissent stated that Solvay’s payments to generic companies did not violate antitrust laws.

The dissent also focused on the majority’s assumption that a settlement by the brand-name pharmaceutical company demonstrated that the patent holder doubted the strength or validity of the patent. The dissent argues that patent holders may simply be risk-adverse or unwilling to engage in a lengthy litigation process.

Another argument by the dissent is that under the majority’s reasoning, all patent settlements would then be subject to rule of

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121 Id. at 2231.
122 Id. at 2237.
123 Id. at 2236.
126 Id. (citing Nat’l Soc’y of Prof’l Eng’rs v. United States, 435 U.S. 679 (1978)).
127 Id. (citing Bhan v. NME Hosps., Inc., 929 F.2d 1404, 1413 (9th Cir. 1991)).
129 “Sham litigation” refers to suits “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.” Prof’l Real Estate Inv’r, Inc. v. Columbia Pictures Indus., 508 U.S. 49, 60 (1993).
130 See Actavis, Inc., 133 U.S. at 2244–45.
131 Id.
reason.\textsuperscript{132} The result would decrease judicial efficiency and increase litigation costs and burdens on the court system.\textsuperscript{133}

E. Implications of Actavis

The Supreme Court’s ruling of \textit{Actavis} took a middle ground; it neither established a \textit{per se} illegality in “pay-for-delay” settlement agreements, nor did it utilize the unassailable “scope of the patent” test to establish the legality of “pay-for-delay” settlement agreements.\textsuperscript{134} The Court noted that anticompetitive settlements would be dependent on “its size, its scale in relation to the payer’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”\textsuperscript{135} Furthermore, the Court left questions open regarding what a “reasonable” settlement would be and how to consider non-monetary reverse payment settlements.\textsuperscript{136}

The ever-increasing advent of generic drugs on the market due to the Hatch-Waxman Act have led brand-name manufacturers to make reverse payment settlements with generic manufacturers to extend the profitability and recoupment period of their drugs. As the population ages and more medications are brought to market, this friction between drug manufacturers and the FTC is therefore unlikely to resolve naturally. What results following \textit{Actavis} is whether or not brand-name companies would be willing to offer settlements to generic manufacturers when settlements result in the high likelihood that will later face antitrust scrutiny and addi-

\textsuperscript{132} \textit{Id.} at 2245.
\textsuperscript{133} \textit{Id.} at 2243.
\textsuperscript{134} Despite this, both the FTC and the pharmaceutical industry interpreted the ruling as a win. \textit{Compare} Prepared Statement of Federal Trade Commission before the U.S. House of Representatives Committee on the Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law, (Nov. 15, 2013) (“The Supreme Court’s decision in \textit{Actavis} was an important victory for consumers and a vindication of basic antitrust and free market principles . . . Because of the \textit{Actavis} decision, [the FTC is] in a much stronger position to protect consumers from anticompetitive drug-patent settlements that result in higher drug costs.) with \textit{PhRMA Statement on Supreme Court Ruling in Patent Settlement Case}, PhRMA (June 17, 2013), http://www.phrma.org/phrma-statement-on-supreme-court-ruling-in-patent-settlement-case (“We are pleased that the Court unanimously rejected the FTC’s position that patent settlement agreements between innovator and generic pharmaceutical companies should be viewed as presumptively unlawful under the antitrust laws.”).
\textsuperscript{135} See \textit{Actavis, Inc.}, 133 U.S. at 2237.
\textsuperscript{136} See generally \textit{id.}
tional expensive litigation due to the ambiguity of the Supreme Court ruling.

F. Post-Actavis Decisions

Though the Supreme Court addressed reverse payment settlements, its Opinion still has an ambiguity that needs to be resolved. The majority’s Opinion leaves open to the district courts the interpretation of “large and unexplained” payments. The lack of direction and guidance has resulted in the district courts’ split, especially regarding whether Actavis’ antitrust settlements apply only to ones that involve cash or ones that are not limited monetarily.137

Two noteworthy cases post-Actavis illustrate a way to evaluate antitrust in settlements between drug manufacturers. In In re Lipitor Antitrust Litigation, the “pay-for-delay” settlement was between Pfizer and Ranbaxy over Lipitor, Pfizer’s blockbuster cholesterol-lowering drug. As part of the settlement, Pfizer provided financial compensation, including:

(a) Pfizer’s ‘sweetheart’ agreement to dismiss damages claims likely worth hundreds of millions of dollars in Accupril II litigation in exchange for a token “pretexual” payment of $1 million; and
(b) the right to market generic Lipitor in at least eleven foreign markets outside the United States.138

This agreement was in exchange for Ranbaxy to (a) delay generic entry; (b) not relinquish its first-to-file 180-day exclusivity period; (c) not challenge the validity of Lipitor’s process patents that were allegedly delaying generic entry; and (d) not contest the reissuance of one of Lipitor’s patents that had been declared invalid.139 Judge Peter Sheridan held that in applying Actavis to the case at hand, “the non-monetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the

139 See id. at *59.
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ACTAVIS factors such as whether it is ‘large’ once the subtraction of legal fees and other services provided by generics occurs.”140 Because the complaint did not provide a reliable estimate of items such as the damages through a lost profits analysis, the Court dismissed the antitrust allegations regarding the settlement.141

In In re Effexor XR Antitrust Litigation, the alleged “pay-for-delay” settlement was between Wyeth and Teva for anti-depressant medication, Effexor XR. Teva agreed to delay generic entry for two years in exchange for Wyeth to not market a brand-name authorized generic version of Effexor XR.142 The plaintiffs erred by only “vague[ly] and amorphous[ly]”143 valuing the no authorized generic part of the agreement; the plaintiff should have valued the entire agreement.144 The Court’s analysis for valuing a settlement involves the following:

(a) valuing any consideration flowing from the patentee to the claimed infringer, which may be made over time and may take forms other than cash; (b) deducting from the payment the patent holder’s avoided litigation costs; and (c) deducting from the payment the value of goods, services, or other consideration provided by the claimed infringer to the patent holder as part of the same transaction (or linked transactions). The resulting net payment is “otherwise unexplained.”145

Due to the plaintiff’s failure to reasonable value the settlement, Judge Sheridan also dismissed the claim.

The district courts have clearly split along the spectrum regarding monetary and non-monetary compensations in “pay-for-delay” settlements. Only the Third Circuit has recently heard and decided a case regarding these types of settlements.146 In King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp., SmithKline Beecham Corp. d/b/a GlaxoSmithKline agreed to waive its right to manufacture an “authorized generic” of the brand-name drug Lamictal in their settlement agreement.147 The Third Circuit held that the alleged annual $2 billion market for an authorized generic of Lamictal could fall under Actavis’ “large, un-

140 See id. at *62.
141 See id. at *70.
143 Id. at *69.
144 See id. at *70.
145 Id. at *70–71.
147 See id. at 5.
explained” payments. However, the district court did not divulge any of the legitimate justifications that the defendant may have had that would establish lawfulness under the standard of the rule of reason; therefore, the Third Circuit remanded the proceedings. Due to the lack of guidance of the court’s guidance as well as the FTC’s determination to litigate “pay-for-delay” settlements, brand-name pharmaceutical manufacturers may decide to litigate claims rather than settle against generic manufacturers in order to avoid increased litigation after a settlement. Nevertheless, based on the Actavis opinion and the resulting court interpretations, I believe that mediation can be a tool to both prevent an overflow of litigation as well as stymie antitrust settlements.

IV. MEDIATION AS A TOOL

Mediation is an alternative dispute resolution technique that has been developing in the United States since the 1970s. Congress later formalized the process through ADR Act of 1998 where it “required every district court to devise and implement an ADR program that compels all civil litigants to consider the use of ADR and which provides them with at least one ADR process.” Due to high cost and lengthy litigation, alternative dispute resolutions such as mediation are increasing in the field of intellectual property. On average, patent infringement cases cost about $2.6 million dollars in litigation, with approximately $1.49 million dollars incurred during discovery. Mediation could potentially save 80 percent of that cost. Time, in particular, is an incredibly sensitive factor because patents themselves are inherently time-sensitive; expedient settlements can provide a resolution before a patent term has run and therefore also before the patent becomes obsolete potentially during the litigation process. Even without a pre-existing

148 Id. at 5–7.
149 Id. at 58.
151 Id. at 7.
152 See Player, supra note 10, at 55–56.
mediation contract, mediation should generally require less time to resolve than litigation, and even arbitration, due to the lack of procedural requirements to move forward. Mediation allows parties to achieve goals such as: “certainty, closure, economic security, avoidance of legal precedent, avoidance of future litigation, fairness, respect, understanding, or institutional change.”

Mediation settlements are also highly respected by the courts as “a consensual resolution [that is] achieved based on full information and honest negotiation between well-represented and evenly balanced parties.” Courts find that employing well-matched mediators also assures that “the proceedings [are] free of collusion and undue pressure.” Therefore using mediation could be a useful tool to resolve the incentive to litigate that has been created after Actavis.

A. Problems Post-Actavis

Brand name manufacturers and generic manufacturers have long used settlement negotiations to enter into agreements following a Paragraph IV filing; however, after Actavis, these companies will have to constantly be aware of antitrust liability. Though the Supreme Court did not use the per se illegality standard preferred by the FTC in Actavis, the Court’s rejection of the “scope of the patent” test has strengthened the FTC’s resolve to pursue settlements between brand-name and generic drug manufacturers. Their determination to pursue and challenge all of these types of settlements could hinder future reasonable negotiations between manufacturers because of the high chance of facing antitrust litigation following negotiations.

Due to this increased risk, which introduces a high probability of re-litigation, manufacturers may no longer be as willing to enter into any agreement; Actavis would seem to have a chilling effect on settlements. This incentive to litigate to create the benefit of a

155 Id.
158 D’Amato v. Deutsche Bank, 236 F.3d 78, 5 (2d Cir. 2001).
159 Id. at 5.
binding decision to prevent re-litigation not only would increase the burden on the courts but also increases the time and resources expended as each generic drug attempts to come to market.\textsuperscript{161}

B. Technical and Complex Patent Litigation

Litigation may appear to be the best avenue following \textit{Actavis} due to its creation of a final, binding judgment. However, the inherent nature of patent litigation makes this a lengthy, complex issue. Patent litigation is expensive because of “(1) heavy reliance upon expert witness testimony during trial; (2) extensive discovery of documents; (3) a significant number of pretrial depositions; and (4) the inevitable disputes regarding the discovery process that must be resolved by the court.”\textsuperscript{162} The high costs and lengthy procedure of litigation are exacerbated by the time and costs needed to explain technical patents to lay jurors and judges.\textsuperscript{163} Jurors are not usually prepared for the technical knowledge involved in patent claims.\textsuperscript{164} Therefore, both brand name and generic litigants would be required to use resources and time to inform jurors properly about the relevant processes or molecules necessary to decide the issue. Because both litigants would present the facts with their own biases rather than a neutral representation, a jury decision be-

\textsuperscript{161} See David A. Allgeyer, \textit{In Search of Lower Cost Resolution: Using Arbitration to Resolve Patent Disputes}, 12 \textit{CONFLICT MGMT.} 1, 9 (2007) (citing AIPLA’s 2005 economic survey “report[ing] that the typical cost of patent infringement litigation for matters with claims under $25 million averaged over $2 million – with the average in some larger cities coming closer to $3 million. The survey found that costs of discovery alone in cases of that size average $1.6 million”). \textit{See also} AIPLA 2013 Report of the Economic Survey (2013), http://library.constantcontact.com/download/getfile/1109295819134-177/AIPLA+2013+Survey+Press+Summary\_pages.pdf (reporting that patent infringement with amounts in controversy over $25 million will spend on average $3.6 million by the end of discovery and $5.9 million through the trial). \textit{See also} Emery G. Lee III & Thomas E. Willging, \textit{Litigation Costs in Civil Cases: Multivariate Analysis, Report to the Judicial Advisory Committee on Civil Rules} (Mar. 2010) (reporting that Intellectual Property litigation “costs almost 62% higher, all else equal, that [other civil litigation cases]”).

\textsuperscript{162} See Allgeyer, \textit{supra} note 156, at 9.


\textsuperscript{164} See Tran, \textit{supra} note 11, at 316.
comes increasingly uncertain especially as patents become more intricate.\footnote{Id. at 316.}

Judges also may have some difficulty with the technical complexity of patent infringement litigation that require more expenditure of resources and time. Although federal district court judges are entrusted to grapple with determining whether a settlement is too large and unreasonable, many of the judges themselves do not have formal science or mathematical backgrounds that are required to understand technically complex patents with ease.\footnote{Id. at 317.} Unjust verdicts also contribute to higher costs from errors due to potential lack of understanding.\footnote{See Thomas D. Barton & James M. Cooper, The United States Patent and Trademark Office Symposium on Trends in Alternative Dispute Resolution Concerning Intellectual Property Rights Litigation: Symposium Introduction: Advancing Intellectual Property Goals Through Prevention and Alternative Dispute Resolution, 43 CAL. W. INT'L L.J. 5, 14 (2012).} The difficulty of these patent infringement cases culminates in high expenditures of resources and time with an unknown result. While the results of \textit{Actavis} may overcome the original settlement intentions to avoid litigation, mediation can be a useful device to prevent over-litigation within the courts.

\section*{C. Patent Dispute Resolution}

Brand name and generic manufacturers should instead look to mediation as a potential solution to face antitrust risk rather than litigation. The United States Patent and Trademark Office notes:

[The] historically healthy matching of IP enforcement problems with traditional adjudicatory procedures is under strain. IP problems are becoming more complex, dynamic and jurisdictionally uncontainable. Yet the [general court] procedures traditionally employed by the law to deal with these problems may no longer be nimble enough to keep up with those stronger challenges.\footnote{Id. at 10.}

Mediation is more flexible and can tailor solutions for both parties based on their interests. Furthermore, mediation can avoid the high costs and time consumed during litigation. Even though some
discovery would have to occur pre-mediation and mediation also has its own costs, the overall savings are still substantial.\textsuperscript{169}

Another benefit of mediation is the fact that a mediator, or even mediators, is a third party. A third party can provide neutral perspectives that can evaluate and facilitate the process so that the parties’ interests and disputes are addressed. Mediation can also provide the benefit of an expert mediator well versed in the related subject matter of intellectual property. These expert IP mediators would “have strong mediation skills, experience mediating patent cases, and a thorough understanding of patent law and patent litigation.”\textsuperscript{170} Using these skills, an expert mediator can perform fact and reality checks for both parties as well as reasonably explain potential alterations to a settlement proposal.\textsuperscript{171} Tailoring a specialized mediator to the particularity of intellectual property and the resulting antitrust liability can be a beneficial cost-saving and effective method to resolve this issue. Currently, patent mediation has been used to resolve disputes ranging from buying and selling patents and patent licenses to patent infringement.\textsuperscript{172} The flexibility of choosing a mediator as well as the mediators expertise lends credence to mediation’s ability to resolve complex patent disputes.

Arbitration is another dispute resolution process that could also feasibly resolve the Hatch-Waxman dilemma. Generally, patent arbitration is considered more cost-effective and timely than litigation.\textsuperscript{173} At least one study has shown, however, while increased timeliness was found in arbitration, costs were not necessarily limited by arbitration.\textsuperscript{174} Nonetheless, arbitration gives parties the flexibility to determine factors such as: the number of arbitrators and their specialties, motion and procedural rules allowed, the number of hearings, time limits, and types of awards.\textsuperscript{175} The arbitration award is also final and binding with limited grounds for court review.\textsuperscript{176}

\textsuperscript{169} See Danny Ciraco, Forget the Mechanics and Bring in the Gardeners, 9 U. BALT. INTELL. PROP. L.J. 47, 70 (2000) (noting that mediation’s overall less formal procedures of discovery and related costs allow clients to save about eighty percent of the cost of litigation).

\textsuperscript{170} See International Institute for Conflict Prevention and Resolution, supra note 9, at 11.

\textsuperscript{171} Id. at 12.


\textsuperscript{174} Id.

\textsuperscript{175} See Agris, supra note 172, at 63.

\textsuperscript{176} Id.
While arbitration may appear to provide a dispute resolution process that incorporates both the flexibility of mediation and the process of litigation, its finality and confidentiality may work against its favor. Patent claim construction is reviewed *de novo* by the U.S. Court of Appeals for the Federal Circuit. This results in high reversal rates in litigation. The binding and finality of arbitration decisions would likely bar either party from revisiting a potentially devastating decision. Mediation’s process is more flexible than arbitration yet timely and cost-effective to allow for subsequent litigation if necessary.

D. *Mediation between Brand Name and Generic Manufacturers*

While the pharmaceutical industry may not have necessarily needed mediators to facilitate negotiations of their previous settlement agreements between brand name and generic manufacturers, the drug manufacturers could benefit from a neutral, expert mediator as an evaluator post-*Actavis*. Despite the temptation for brand-name manufacturers to turn to litigation, the outcome of patent litigation is still not a guarantee and there are high risks coupled with high costs and lengthy procedure. Mediation does not require a settlement outcome and, should litigation still occur, having had mediation can focus and address issues in a more direct and clear method for the court’s judges and jurors. With a more directed focus, an unjust decision may be less likely and would therefore still be cost-effective.

When presented with a Paragraph IV Certification issue, the court should therefore mandate a neutral mediator(s) with intellectual property experience. The neutral mediator can provide an informed, neutral evaluation of the issue of infringement and en-

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178 Id.

179 See Tran, *supra* note 11, at 316.

forceability at hand. While *Actavis* has not provided solid guidelines, a mediator “can give the parties a good idea what the court is thinking: he understands what issues are hot, how the court has decided previous cases.” Therefore, the mediator can pay special attention and provide reality checks to proposals for cash settlements and valuations of risk-analyses that have been deemed factors when analyzing a settlement for antitrust liability.

The type of mediation employed should be a combination of facilitative and evaluative mediation. Because of the special skill-set and understanding of the technical facets of patents, the mediator can provide more persuasive formal or informal proposals to the parties regarding the dispute’s outcome. Through the evaluative process, the mediator can point out weaknesses of either parties’ arguments and either move forward a reasonable settlement discussion or allow litigation to go forward. Through his or her determination, the mediator can also evaluate potential settlement amounts with antitrust experts to take into account current trends and tendencies of the courts. Therefore, the knowledge and skill-sets that a mediator possesses can still encourage settlement while addressing the antitrust risk that can harm the consumer.

V. Conclusion

The ambiguity of the Supreme Court’s decision post-*Actavis* seems to advocate for increased litigation between drug manufacturers to create a binding judgment. However, while litigation for future Paragraph IV controversies may seem like a tempting option to create that final, binding judgment, especially when future antitrust litigation seems inevitable, brand name and generic manufacturers should consider the benefits of mediation with those with an expertise in intellectual property. Neutral, expert mediators will be able to understand Intellectual Property industry norms and practices more quickly and cost-effectively than average judges and jurors, who generally may have a much steeper learning curve. Furthermore these mediators will be able to evaluate early on valuations of potential settlement proposals as well as reality checks for both brand name and generic manufacturers. The use of effective mediation can allow brand name and generic manufacturers to settle patent infringement disputes while also providing a bar to an

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181 See Tran, *supra* note 11, at 320.
182 Id. (quoting interview with James Amend).
antitrust settlement in order to provide benefits for the public. Using evaluative mediation techniques and economic analysis, mediators can guide the drug manufacturers to reasonable agreements. Mediation can be a method to allow continued advanced research and development for innovative drugs while also promoting public health and welfare.