IS DISGORGEMENT A PENALTY IN THE ANTITRUST-ENFORCEMENT REALM?:
EXPLORING MEDIATION AS THE FTC’S RESPONSE TO KOKESH IN THE
CONTEXT OF REVERSE PAYMENT SETTLEMENTS

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I. INTRODUCTION

In July 2012, the Federal Trade Commission (“FTC” or “the Commission”)—the federal administrative agency that enforces its legal authority to protect consumers from unfair, deceptive, or anticompetitive business practices—retracted its policy of limiting pursuit of disgorgement only to situations when clear violations of antitrust laws existed. Monetary relief in the form of disgorgement, requiring the wrongdoer to divest from wrongly obtained benefits, became an implied remedy that the FTC more readily sought through Section 13(b) of the Federal Trade Commission Act (“FTCA”), or 15 U.S.C. § 53. Section 13(b) grants the FTC authority to seek a temporary restraining order or preliminary injunction when the FTC believes that it is in the public’s best inter-

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’est to enjoin the person, partnership or corporation from violating a law enforced by the FTC.\textsuperscript{5} Despite Section 13(b) not expressly permitting the FTC to seek monetary relief, in many cases, the Commission has broadly construed the statute to include pursuit of this remedy.\textsuperscript{6} The Commission’s expansive reading of its Section 13(b) powers has led it to seek disgorgement relief more regularly in antitrust (or competition) cases in the last several years, which has garnered great debate with weighty opposition from manufacturers of brand name prescription drugs and other lobbies.\textsuperscript{7}

The scope of the FTC’s power to obtain disgorgement relief remains ambiguous. To support its position, the FTC relies on a string of cases in which numerous courts recognized such authority of the FTC in antitrust cases.\textsuperscript{8} Only a Supreme Court decision in the future will tell, but currently, the Supreme Court’s decision in \textit{Kokesh v. SEC} this past July may have reduced the FTC’s incentive to seek disgorgement past the five-year statute of limitations set forth in 28 U.S.C. § 2462.\textsuperscript{9} This statute presents a limitations period of five years on government enforcement actions seeking civil fines, penalties, or forfeitures.\textsuperscript{10} In \textit{Kokesh}, the Supreme Court barred the Securities Exchange Commission (“SEC”) from recovering disgorgement from the defendant.\textsuperscript{11} While \textit{Kokesh} and the statute of limitations provision in 28 U.S.C. § 2462 applies to disgorgement in the context of securities-enforcement actions,\textsuperscript{12} other language in the majority opinion leaves room to venture into whether the holding also applies to other federal administrative

\textsuperscript{5} \textit{Id.}

\textsuperscript{6} \textit{Id.; see also FTC v. Mylan Labs., Inc., 62 F. Supp. 2d 25, 36 (D.D.C. 1999)} (“It is true that the plain language of § 13(b) does not authorize the FTC to seek monetary remedies.”).

\textsuperscript{7} Dana A. Elfin, \textit{Should FTC Seek Disgorgement of Profits in Pay-for-Delay Cases?}, \textit{HEALTH CARE ON BLOOMBERG L.} (Apr. 18, 2016), https://bna.com/ftc-seek-disgorgement-n57982069953/ (explaining that opponents of the FTC’s broad use of the implied disgorgement authority believe that seeking this remedy should not be routine even after the FTC’s withdrawal of the 2003 policy statement).

\textsuperscript{8} \textit{See, e.g., FTC v. Bronson Partners, LLC, 654 F.3d 359 (2d Cir. 2011); FTC v. Gem Merchandising Corp., 87 F.3d 466 (11th Cir. 1996); FTC v. Cephalon, Inc., 100 F. Supp. 3d 433 (E.D. Pa. 2015); Mylan Labs., 62 F. Supp. 2d 25.}

\textsuperscript{9} \textit{Kokesh v. SEC, 137 S. Ct. 1635 (2017).}

\textsuperscript{10} 28 U.S.C. § 2462; \textit{see also THOMAS V. VAKERICS, ANTITRUST BASICS § 2.02} (Law Journal Press 2018) (“There is a five-year statute of limitations applicable to FTC civil penalty actions.”); FTC v. Lukens Steel Co., 454 F. Supp. 1182, 1185 n.2 (D.D.C. 1978) (noting that because 28 U.S.C. § 2462 applies to civil penalty actions, FTC requests for civil penalties relief must be brought “within five years from the date when the claim first accrued.”).

\textsuperscript{11} \textit{Kokesh, 137 S. Ct. at 1635.}

\textsuperscript{12} \textit{Id. at 1639.}
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agencies, such as the FTC, seeking disgorgement relief. Notwithstanding the FTC having sought and successfully obtained disgorgement as a remedy in a series of antitrust cases since 1999, the Commission must consider alternatives other than seeking court-ordered disgorgement in litigation procedures. Especially in the context of patent claims and investigating “pay-for-delay” or reverse payment settlements, where the brand drug manufacturer pays the generic drug company to delay the generic drug’s entry into the market, the FTC has an incentive to settle issues with branded drug companies bearing in mind the potential repercussions on the FTC after *Kokesh*. The brand drug manufacturer would also find it in its best interest to not have to expend litigation costs and time in addition to reserving the possibility of having to pay court-ordered disgorgement monies to the FTC. Thus, in connection with patent infringement and subsequent reverse payment settlement suits, seeking a mutually beneficial resolution through alternative dispute resolution (“ADR”) would be more beneficial to both parties than the alternative of seeking and defending against disgorgement payments in federal court.

This Note seeks to answer the following question: How can the FTC respond to the potential influence of *Kokesh* by utilizing mediation to settle with and recover monetary relief from brand drug companies? Part II of this Note discusses the FTC’s role in competition cases historically, as well as the Commission’s proac-

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13 *Id.* at 1644. (“The 5-year statute of limitations in § 2462 therefore applies when the SEC seeks disgorgement” (emphasis added)).


17 *See* Brenna E. Jenny, *Information Costs and Reverse Payment Settlements: Bridging the Gap Between the Courts and the Antitrust Agencies*, 30 *Santa Clara High Tech. L.J.* 231, 288 (2014) (pointing out that in 2007 alone, 2,896 patent cases were filed, and by 2011, there was a 40% uptick of patent cases from 2007).

tive pursuit of monetary remedies, primarily disgorgement relief. It also provides a general overview of the Hatch-Waxman Act and its influence on the rise of patent infringement litigation, which, in effect, resulted in the rise of “pay-for-delay” settlements between brand and generic drug companies. Part III dissects the Supreme Court’s decisions in FTC v. Actavis and Kokesh v. SEC along with their potential implications on or limitations to the FTC pursuing the disgorgement remedy in pay-for-delay settlements. Part III also provides a brief summary of the different methods of mediation. Lastly, Part IV of this Note proposes how brand drug companies and the FTC can better utilize dispute resolution—specifically in the context of patent infringement litigation—in light of Kokesh v. SEC and FTC v. Actavis. The Note will then review the types of mediation techniques. In patent infringement suits generally, including pay-for-delay cases, this Note proposes that greater weight be given to evaluative mediation techniques should the FTC and pharmaceutical companies engage in mediation proceedings.

II. BACKGROUND

A. The FTC’s Enforcement of Antitrust Matters and Pursuit of Monetary Remedies

Upon its passage in 1914, the FTCA bestowed the FTC with the power to lead the fight against businesses that profit at the expense of vulnerable consumers. The FTC has further been empowered to enforce antitrust laws under the Clayton Act, through which the Commission is able to challenge corporate mergers and acquisitions. For antitrust law violations in

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19 See In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006) (noting that the rise of reverse payment settlements was fostered by the environment created by the Hatch-Waxman Act).

20 FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013) (holding that reverse payment settlements are not per se illegal, and rather that courts should deliberate under the rule of reason to decide the legality of such settlements); Kokesh v. SEC, 137 S. Ct. 1635 (2017).

21 Kokesh, 137 S. Ct. at 1635; Actavis, 133 S. Ct. at 2223.


the pharmaceutical industry, however, the FTC acts pursuant to Section 5 of the FTCA to strike down unfair competition arising from transactions that may, for example, lead to horizontal restraints in the industry, namely reverse payment settlements. A reverse payment settlement exists when a patent-owning brand drug company agrees to compensate a generic drug manufacturer, and in exchange, the generic company agrees to delay its drug’s entry into the market. The FTC’s interpretation of the FTCA’s Section 13(b) coupled with the well-established principle that Section 13(b) allows the FTC to seek ancillary equitable relief and for courts to grant such led the Commission to increasingly pursue monetary remedies such as restitution and disgorgement.

Before the Commission more actively sought monetary relief in the pharmaceutical realm, it settled the government’s first anti-trust matter against pharmaceutical companies without monetary relief because the FTC “believed the public interest was satisfied with [the injunction] orders.” Nevertheless, the Commission made a point to pharmaceutical firms that, moving forward, it would not only enjoin pharmaceutical companies from engaging in anticompetitive conduct, but that it would also “consider its entire range of remedies . . . including possibly seeking disgorgement of illegally obtained profits.”

Thereafter, despite having sought disgorgement in only two cases between 1980 and 2002, the Commission issued a policy...
statement in 2003 that outlined more stringent standards the FTC should follow when it tried seeking monetary equitable remedies in antitrust cases brought pursuant to Section 13(b).\(^{31}\) Throughout the policy statement, the FTC emphasized that the monetary remedies of disgorgement and restitution are “equitable.”\(^{32}\) The Commission also supported that claim by referring to the Court historically having granted disgorgement or restitution in antitrust cases when “appropriate” and “necessary” by “depriving the violator of any of the benefits of illegal conduct.”\(^{33}\) The effect of the policy statement affirmed the FTC’s authority to pursue these monetary remedies, but only in “exceptional circumstances,” to which the Commission noted that it would not seek such remedies routinely.\(^{34}\)

In this policy statement, the FTC spelled out three specific factors that it would consider to determine whether to seek monetary equitable remedies in antitrust matters.\(^{35}\) The Commission stated that it would seek monetary equitable remedies when (1) “the underlying violation is clear;” (2) there is a “reasonable basis for calculating the amount of a remedial payment;” and (3) when the Commission anticipates that other remedies might fail to bring complete equitable relief or when the “monetary remedy may provide important additional benefits.”\(^{36}\) Thus, until 2012, the FTC carefully sought monetary remedies only in exceptional cases by employing a combination of prosecutorial discretion, precedent from case law, and the strict framework provided by the policy statement.\(^{37}\)

the two cases were *Hearst Trust* and *Mylan*); see, e.g., Compl., FTC v. Hearst Trust, No.1:01CV00734 (D.D.C. Apr. 4, 2001) (involving the FTC challenging the acquisition by Defendant Hearst because the corporation’s monopolization of the market came to existence after Defendant did not produce certain required documents prior to the merger for the FTC to review and analyze the proposed acquisition); Compl., FTC v. Mylan Labs, Inc., No.1:98CV03114 (D.D.C. Dec. 21, 1998) (involving “an alleged conspiracy to monopolize a market for two anti-anxiety drugs”).

\(^{31}\) *Policy Statement*, supra note 3.

\(^{32}\) Id. (“[A] case may be particularly appropriate for disgorgement when private actions likely will not remove the total unjust enrichment from a violation” . . . “[W]hen practical or legal difficulties are likely to preclude compensation for those injured by a violation in equity should be made whole, [the FTC] may seek restitution for them.”).

\(^{33}\) Id.; see also FTC v. Febre, 128 F.3d 530, 537 (7th Cir. 1997) (“Disgorgement to the United States Treasury does not transform compensatory damages into punitive damages.”).

\(^{34}\) *Policy Statement*, supra note 3; see also Ohlhausen, supra note 30.

\(^{35}\) *Policy Statement*, supra note 3.

\(^{36}\) Id.

\(^{37}\) Ohlhausen, supra note 30. The FTC only sought disgorgement in two cases—*Perrigo* and *Lundbeck*—between 2003 and 2012. See, e.g., Compl., FTC v. Perrigo Co., No.1:04CV01397
2012, the FTC withdrew the 2003 policy statement to turn instead to past judicial determinations of the Commission’s authority to seek disgorgement or restitution in competition cases. In doing this, the Commission abandoned its narrow framework and deemed that the policy statement “chilled [its] pursuit of monetary remedies,” and therefore seeking disgorgement (or restitution) should not only apply in “exceptional cases.” Aside from the second factor of demonstrating a “reasonable basis to calculate the remedial payment,” the Commission found that the remaining factors to help determine the granting of disgorgement or restitution posed as too burdensome to the Commission beyond the law already required. After the FTC’s withdrawal of the 2003 policy statement, there has been a surge in cases where the Commission has sought monetary equitable remedies. Where the Commission sought monetary remedies in merely two cases prior to the issuance of the policy statement and in two more cases from 2003 and 2012, the Commission employed its now more extensive equitable power after the policy withdrawal to pursue monetary relief in six competition cases from 2012 through 2017. Without the withdrawal statement stipulating guidelines to replace the framework of the 2003 policy statement, the FTC has simply been following a trend of broadly exercising its Section 13(b) authority derived from

38 Withdrawal Statement, supra note 1.
39 Id. (“[W]ile disgorgement and restitution are not appropriate in all cases, [the FTC] do[es] not believe they should apply only in ‘exceptional cases,’ as previously set out in the Policy Statement.”
40 Id.
41 Ohlhausen, supra note 30 (stating the FTC Commissioner views that the FTC should not have withdrawn the 2003 policy statement); see also Deborah L. Feinstein & Kelly C. Smith, Federal Trade Commission to Increasingly Seek Monetary Relief in Antitrust Matters, ARNOLD & PORTER LLP (Aug. 2012), https://files.arnoldporter.com/advisory-federal_trade_commission_to_increasingly_seek_monetary_relief_in_antitrust_matters.pdf.
42 Ohlhausen, supra note 30 (“Since 2012, the Commission has sought disgorgement four times. That is as many times as the FTC pursued such relief in the prior twenty years.”). After the Commissioner’s statement in 2016, the FTC requested disgorgement of wrongfully gained profits and other appropriate equitable monetary relief two more times in 2017. See FTC v. Allergan, et al., No. 17-cv-00312 (N.D. Cal. Jan. 23, 2017); FTC v. Shire Viropharma, Inc., No. 1:17-cv-00131 (D. Del. Feb. 6, 2017).
case law, leaving potential defendants and the courts with little insight as to how and when the Commission elects to obtain monetary equitable relief.\textsuperscript{43}

\textbf{B. The Hatch-Waxman Act}

Pertinent to the FTC’s involvement in antitrust law enforcement is the legislative act that substantially influenced the emergence of reverse payment settlements: the Drug Price Competition and Patent Term Restoration Act of 1984.\textsuperscript{44} More commonly known as the Hatch-Waxman Act (“the Act”), this was the pioneering legislative act that provided generic drug companies an easier avenue to enter generic versions of brand drugs into the market.\textsuperscript{45} The Act was intended to facilitate the entrance of generic drugs into the market by requiring generic drug manufacturers to submit an Abbreviated New Drug Application (“ANDA”).\textsuperscript{46} By “help[ing] generic drugs reach the market more quickly,”\textsuperscript{47} the Act allowed consumers to access a wider variety of drugs and gave

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\item\textsuperscript{43} Ohlhausen, \textit{supra} note 30 (stating that the withdrawal of the policy statement has not automatically led to the FTC seeking disgorgement in every competition case, but that “the factors that undergird the Commission’s decision making are unclear” and that “[t]he Commission disclaimed the three factors from the 2003 statement but offered nothing else in their place”).
\item\textsuperscript{44} Timothy A. Weil, \textit{Devising a Legislative Solution to the Reverse Payment Dilemma: How Congress Can Balance Competition, Innovation, and the Public Policy Favoring the Settlement of Disputes Without Litigation}, 55 \textit{St. Louis L.J.} 741, 742 (2011) (“Settlement agreements between brand-name drug manufacturers and generic firms have limited the type of generic competition the Hatch-Waxman Act was designed to encourage.”).
\item\textsuperscript{45} Gerald J. Mossinghoff, \textit{Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process}, 54 \textit{Food & Drug L.J.} 187, 188 (1999); see also Well, \textit{supra} note 44 (explaining that the Hatch-Waxman Act promotes competition by allowing generic drug manufacturers to challenge patents before they expire, which streamlines the process of generic products entering the market on a timely basis).
\item\textsuperscript{46} Allen M. Sokal & Bart A. Gerstenblith, \textit{The Hatch-Waxman Act: Encouraging Innovation and Generic Drug Competition}, \textit{Finnegan, Henderson, Farabow, Garrett & Dunner, LLP} (2010). \url{https://finnegan.com/en/insights/the-hatch-waxman-act-encouraging-innovation-and-generic-drug.html}. Congress also intended to restore lost time on patent life by extending the validity of patents, contingent on the brand drug companies’ completion of specific procedural requirements. The purpose of this patent life extension was to compensate brand drug companies for any delays that may have been caused during the FDA’s regulatory review periods, which include multiple phases.
\item\textsuperscript{47} Sokal & Gerstenblith, \textit{supra} note 46; see also Tracey Toll, \textit{Pharmaceutical Reverse Payment Settlement Agreements and a Proposal for Clarifying the Application of Antitrust Law Rule of Reason Analysis to These Agreements}, 15 \textit{Hous. J. Health L. & Pol’y} 281, 283 (2015).
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them the option to purchase less expensive versions of brand
drugs.48

Prior to the enactment of the Hatch-Waxman Act, the FDA
required both brand and generic drug manufacturers to perform
the same level of expensive research and development over an ex-
tended period of time49 in compliance with the New Drug Ap-
lication (“NDA”) to guarantee the safety and efficacy of their drugs.50
To make the process of entering generic drugs into the market
more efficient, the FDA required the generic manufacturer to sub-
mit an ANDA, which requires less data than an NDA.51 When fil-
ing this ANDA, the generic applicant must do so under one of four
certifications—paragraphs I, II, III, and IV certifications—which
read, “(1) that the drug has not been patented; (2) that the patent
has already expired; (3) the date on which the patent will expire,
and that the generic drug will not go on the market until that date
passes; and (4) that the patent is not infringed or is invalid,” re-
spectively.52 In addition to satisfying one of the four certifications,
the generic applicant must include a showing of bioequivalence be-
tween its generic product and the branded version of the drug,53
and must “notify the patent holder54 of the submission of the
ANDA.”55

While challenging a brand drug’s patent under paragraph I, II,
or III certifications is straightforward and uncomplicated,56 the ma-
majority of patent litigation in the United States stems from a paragraph IV certification, which states, “an applicant must certify in [its] opinion . . . and to the best of [its] knowledge [that the patent] is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted.”

This is because, unlike the other three certifications when filing an ANDA, the filing of an ANDA under paragraph IV “is a statutory act of patent infringement,” according to 35 U.S.C. § 271(e)(2).

Even if a generic company files an ANDA application under paragraph IV, thereby creating a presumption of patent infringement in violation of 35 U.S.C. § 271(e)(2)(A) on its face, pursuant to 21 U.S.C. § 355(j)(2)(B), the generic firm may also protect the validity of its ANDA application by providing proper and timely notice to each patent holder and the Secretary of Health and Human Services that the generic company filed an ANDA application with bioavailability or bioequivalence studies. This notice must also be supported with a detailed justification as to why the “patent is invalid or will not be infringed,” despite other potential similarities of the two drugs (e.g. chemical makeup). The ANDA applicant must fulfill each of these particularities under 21 U.S.C. § 355(j)(2)(B), should it attempt to defeat the branded company’s patent infringement claim. For example, if a generic company describes that generic drug X is primarily used only for neuropathic pain, whereas the branded drug X claims patents for uses other than neuropathic pain, the court may look more favora-

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59 Pensabene & Gregory, supra note 50, at 3; see also 35 U.S.C. § 271(e)(2) (2010) (stating that it is an outright act of patent infringement “[f]or a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of the drug . . . before the expiration of such patent.”)

60 CHISUM, supra note 56, at 1641; see also DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co., 62 F.3d 1397, (Fed. Cir. 1995) (“Under section 271(e)(2), . . . a generic drug manufacturer infringes when it files an ANDA to obtain FDA approval to market a generic drug product before the expiration of the drug patent.”).


62 Id.

63 Id.
bly upon the generic applicant’s claim and approve the ANDA. Consequently, the branded company may contend that although its drug does not possess a patent specifically for neuropathic pain, that patients still use it to heal their neuropathic pain and doctors prescribe the product for treatment of neuropathic pain. However, to this contention, the court will likely decide against such a claim by the brand drug manufacturer because such “proposed interpretation is inconsistent with both of the stated purposes of the Hatch-Waxman Act, and would confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to infer.”

Although it is well established that the very act of filing an ANDA under a paragraph IV certification constitutes patent infringement ripe for litigation, generic companies may believe that the incentives for filing under this certification will reap greater benefits for the company and therefore outweigh the risks and costs of litigation. One incentive for the first ANDA applicant to file its generic under paragraph IV is that if such applicant defeats the branded company’s infringement claim, that generic drug of the first-filer will have 180 days of exclusivity in the market, allowing it to only compete with the corresponding brand drug with-

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64 See ERIC E. BENSEN, PATENT LAW PERSPECTIVES § 3.7 (explaining the requirements of a Paragraph IV certified ANDA application under 21 U.S.C. § 355(j)(2)(B)); see also Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1355, 1356 (Fed. Cir. 2003). In this case, Warner-Lambert brought suit against Apotex for allegedly infringing its drug Neurontin having a neurodegenerative use that is patented. However, Apotex, having certified its generic gabapentin under Paragraph IV, claimed that its generic “does not include any indication for use in the treatment of either neurodegenerative or neurogenerative diseases” and thus the manufacture, sale, or use of its generic would not infringe on the patented use of Neurontin. The Court of Appeals read § 271(e)(2)(A) plainly, as did Apotex, and stated that the mere fact that physicians may prescribe gabapentin for neurodegenerative purposes, the FDA did not approve the safety and efficacy of gabapentin for neurodegenerative diseases. Therefore, Apotex did not infringe on the neurodegenerative patent of Neurontin and Warner-Lambert does not have a cause of action against Apotex. The Court of Appeals affirmed the District Court’s granting of summary judgment for Apotex.

65 BENSEN, supra note 64.

66 Id. at 14 (stating that such a narrow interpretation of 35 U.S.C. § 271(e)(2) would defeat the purpose of the Hatch-Waxman Act and allow branded companies to use the statute “as a sword against any competitor’s ANDA seeking approval to market an off-patent drug for an approved use not covered by the patent”).

67 Toll, supra note 47, at 288 (affirming that “[t]he filing of the paragraph IV certification is considered an act of patent infringement”).

68 Id. (arguing that the Hatch-Waxman Act encourages generic manufacturers to file an ANDA under a paragraph IV certification and be deemed the first generic applicant to do so “by providing a reward to the first generic manufacturer”).
out other generics in the market during the exclusivity period.\footnote{69} This exclusivity period begins on the first day the first ANDA applicant commercially markets the generic drug alongside the branded version.\footnote{70} Subsequently, the other incentive would be that the generic company has the opportunity to enter the market earlier than when the patent of the brand drug expires.\footnote{71} Henceforth, the first generic applicant’s benefits of a 180-day marketing exclusivity period and its earlier entrance into the market make it more appealing to generic manufacturers to file an ANDA under a paragraph IV certification.\footnote{72} Such advantages for the generic applicants, nonetheless, have raised concerns for brand drug manufacturers regarding their confidence in the strength of their respective patents and the more hurried loss of revenue, especially after the FDA authorizes the generic drug of the first ANDA applicant.\footnote{73}

\section{Discussion}

\subsection{The FTC’s Role in Antitrust Cases in the Context of “Pay-for-Delay” Settlements}

Understanding that brand companies risked losing the validity of patent on their respective drugs when the generic applicant challenges the patent holder under a paragraph IV certification in an attempt to commercialize the brand drug, brand drug manufacturers sought ways to avoid situations in which the court could invali-
date their patents, presumably because such patents were weak from its creation.\footnote{Hanks et al., supra note 53 (stating that “patents of questionable validity” are essentially being challenged by the new generic being certified under Paragraph IV).} One of the most controversial alternatives\footnote{Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, FED. TRADE COMM’N (2010), https://ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/10112payfordelayrpt.pdf (explaining that until the generic drug is launched on the date that the brand and generic firms agreed on through their reverse payment settlement, “the brand and generic share the benefits of the brand’s monopoly profits,” which results in consumers losing earlier opportunities to purchase generic drugs at prices “that can be as much as 90 percent less than brand prices”).} that brand companies explored was entering into “pay-for-delay” settlements with generic firms.\footnote{Fialkoff, supra note 72, at 524.}

These pay-for-delay settlements are perceived as peculiar,\footnote{Cook, supra note 77, at 419; Hanks et al., supra note 53.} for these types of transactions are contrary to most other conventional settlements where defendants pay plaintiffs in exchange for the plaintiff agreeing to cease the pursuit of the litigation. In an attempt to protect its questionable patent and instead of filing an infringement suit against the generic company, the branded manufacturer proposes to pay the generic manufacturer a large sum of money along with the assurance from the generic company that it will delay the entry of its generic product into the market.\footnote{Jon Leibowitz, How Settlements Make Strange Bedfellows: Or How the Federal Trade Commission Has Managed to Unite the Entire Pharmaceutical Industry (Sep. 29, 2006), https://www.ftc.gov/sites/default/files/documents/public_statements/how-settlements-make-strange-bedfellows-or-how-federal-trade-commission-has-managed-unite-entire/060929gphapubvers_0.pdf.} As a result of drug manufacturers from both sides engaging in these reverse payment settlements, brand drug companies have reaped large profits that exceed the amounts of money paid to generic manufacturers.\footnote{Cook, supra note 77, at 419; Hanks et al., supra note 53.} Meanwhile, the delaying of generic versions of costly brand drugs harm consumers,\footnote{Cook, supra note 77, at 419; Hanks et al., supra note 53.} along with the federal and...
state governments, and American businesses. The pay-for-delay settlements increase the costs of prescription drugs and allow for branded companies to keep the prices of their brand drugs excessively high for consumers that make up the vulnerable populace. Thus, according to the FTC as of 2010, these reverse payment settlements cost consumers $3.5 billion per year.

The arguably anticompetitive nature of pay-for-delay settlements remains contentious, but with the decision of FTC v. Actavis in 2013, the Supreme Court clarified that pay-for-delay settlements are not per se illegal. The majority held that reverse payment settlements must be examined according to the rule of reason analysis, subjecting drug companies to greater antitrust scrutiny. This decision holds true even when the transaction falls within the scope of the patent. Prior to this decision, there was a circuit split.

The Sixth Circuit Court of Appeals stated in In re Cardizem CD Antitrust Litigation that the reverse payment settlement between the brand and generic drug company involving the brand drug, Cardizem CD, and its generic equivalent is a “classic example of

81 Hanks et al., supra note 53; see also Cook, supra note 77 (stating that pay-for-delay settlements have depleted the United States’s health-insurance system by $35 billion (data as of June 23, 2009 by the FTC)).
82 McCaughan, supra note 76, at p. 3. Although the design of reverse payment settlements work in the favor of both brand and generic companies, consumers argue that they become the ones to fall victim to the anticompetitive nature of these settlements. While brand drug companies maintain their costly drug prices due to the generic version being kept out of the market until a later date, consumers are left with no choice but to purchase the brand drugs that are priced “higher than they would otherwise be.”
83 Fialkoff, supra note 72, at 524.
85 Id. (holding, consistent with prior case law in Cal. Dental Ass’n v. FTC, 526 U.S. 756 (1999), that the court does not “believe that reverse payment settlements . . . meet [the] criterion” for the application of the quick-look approach. In dissent, Chief Justice Roberts took the position that when a patent entitles the patentee to engage in precompetitive efforts by excluding others from the market, “the scope of the patent . . . forms the zone within which the patent holder may operate without facing antitrust liability.”).
86 Actavis, 133 S. Ct. at 2238 (rejecting the FTC’s argument that reverse payment settlements are illegal and finding instead that the FTC can challenge pay-for-delay settlements on a case-by-case basis on the grounds that they violate antitrust laws under the rule of reason illustrated in Actavis).
87 The circuits that took the position that reverse payment settlements are per se illegal were the Second, Third, and Sixth Circuits. The circuits that took the opposite position were the Seventh and Eleventh Circuits.
89 Id. at 902. Andrx Pharmaceuticals (“Andrx”) (later acquired by Allergan) was the potential drug manufacturer of the generic version of Cardizem CD. Andrx was the first to file an ANDA under a paragraph IV certification in 1995, asserting that its corresponding generic product did not infringe any patents that covered Cardizem CD. Thereafter, the brand drug manufac-
a *per se* illegal restraint of trade,” because the transaction was a “horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States.” The generic company, Andrx Pharmaceuticals (“Andrx”), agreed to delay the launch of its generic product, effectively postponing the entrance of other inexpensive generic competitors into the market. Meanwhile, the Eleventh Circuit, through the holding in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, took the position that not all reverse payment settlements are *per se* unlawful. The Eleventh Circuit distinguished settlements that resemble a company attempting to monopolize a market by paying off competitors from settlements, such as pay-for-delay settlements, as the only unacceptable version of these transactions. The Supreme Court in *Actavis* took the middle approach to these decisions and established that reverse payment settlements would be scrutinized under antitrust and patent laws in order to determine their legality under the unique circumstances of each settlement. Moreover, the Court expressed that it is necessary to examine the size of the settlement money paid to the generic company and whether such amount is justified.

90 *Id.* at 906, 908. The “*per se* approach . . . applies a ‘conclusive presumption’ of illegality to certain types of agreements.” See also Samuel N. Weinstein, *Rigged Results? Antitrust Lessons from Keyword Auctions*, 91 Tul. L. Rev. 629, 649, 688 (2017). The Second and Third Circuits also adopted the view of the Sixth Circuit regarding pay-for-delay settlements. See e.g., *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 210–11 (3d Cir. 2012) (explaining that the Sixth Circuit’s reasoning for viewing pay-for-delay settlements as illegal is also applicable to cases that do not involve “bottlenecking,” or “preventing other generic manufactures from entering the market by delaying the triggering of the first filer’s 180-day exclusivity period”); see also *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997) (holding that there are some transactions that “have such predictable and pernicious anticompetitive effect . . . that they are deemed unlawful *per se*” and that when a transaction is labeled as *per se* illegal, it is because the court is “confiden[ts] that the rule of reason will condemn it” (internal quotations omitted)).

91 *Cardizem CD Antitrust Litig.*, 332 F.3d at 907–08.

92 *Valley Drug Co. v. Geneva Pharm.*, Inc., 344 F.3d 1294, 1303–05 (11th Cir. 2003) (in which the Eleventh Circuit labeled agreements as *per se* violations of antitrust laws when they are “so obviously anticompetitive, or so unlikely to be pro-competitive” that they essentially “violate the Sherman Act without much more than an examination of the agreement itself and the relationships of the parties to the agreement.” However, the court opined that the focus should be on questioning the “competitive impact of the challenged restraint,” thus emphasizing the *purpose* underlying the antitrust issue and placing greater emphasis on the patent holder’s exclusionary right).

93 *Id.* at 1304 (noting that the instant case is not a case that “merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market”); see also Weinstein, *supra* note 90.

without adversely affecting competition in the market. The Supreme Court did not quickly reach the conclusion that all reverse payment settlements eliminate competition from the market and are therefore presumptively illegal per se, contrary to the FTC’s perspective. Nor did the Court argue that the patent holder’s exclusionary right permits reverse payment settlements to avoid deeper scrutiny under antitrust laws. Rather, it seems that moving forward, the Supreme Court encourages additional questions to be asked by the lower courts, such as whether the brand firm wielded greater market power over the generic company, if the brand firm is able to justify its large payment, and what the purpose of settling a patent dispute through reverse payment was instead of choosing another settlement scheme to utilize. To an extent, the Supreme Court integrated, but did not entirely accept the respective approaches to the issue made by the Sixth Circuit Court of Appeals and Eleventh Circuit Court of Appeals.

Post-Actavis, the FTC loosely interpreted its Section 13(b) authority due to the Commission withdrawing its policy statement in 2012. In its Actavis complaint, the FTC had requested the Supreme Court to grant injunctive relief as against the defendant

95 Id. at 2235–36. An example of when a reverse payment may be justified is when the payment “may amount to no more than a rough approximation for the litigation expenses saved through the settlement” and such “payment may reflect compensation for other services that the generic promised to perform.” Contrarily, “there are indications that patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market,” which signals the possibility that the brand lacks confidence in the validity of its patent. Such a payment may be a strong indicator that the patent holder is attempting to cause the generic to “abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.” See also id. at 2237. The Court looks at the following factors regarding the payment to determine whether the settlement is anticompetitive: “its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”

96 Id. at 2237. The FTC advocated for the Supreme Court to adopt a “quick look,” or abbreviated approach without inquiring more than perceiving the anticompetitive tendencies to be “sufficiently anticompetitive on their face.”

97 Id. at 2234 (rejecting the argument that the “patent-related factor,” that is, the patent holder’s right to exclude others, should not end the analysis and determine that such settlements are not per se illegal).

98 Id. at 2237 (pointing out that companies should not perceive settlements as “one size fits all,” but instead strategize other ways to settle patent disputes without risk of incurring antitrust liability. For instance, one different way of settling a patent dispute other than reverse payment is “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.”).


100 See Policy Statement, supra note 3; Withdrawal Statement, supra note 1.
drug manufacturers and “ancillary equitable relief to remedy the injury caused by Defendants’ violations.”101 The Actavis decision put pharmaceutical companies on alert that a heightened level of scrutiny under antitrust laws will be placed on determining the legality of reverse payment settlements.102 As for the FTC, aside from the Court expressly rejecting the Commission’s argument that the Court should apply the quick-look approach to conclude that these settlements are illegal per se,103 the holding provided no additional guidelines for the Commission to follow when seeking monetary equitable remedies in this realm of cases. However, four years after Actavis,104 the Supreme Court in Kokesh v. SEC105 tackled an issue regarding monetary relief in the context of securities law; yet the Court’s decision may also be applicable to antitrust law and guide the FTC in its pursuit of monetary remedies.106

B. Kokesh v. S.E.C.

After the Supreme Court decided in Gabelli v. S.E.C.107 that the five-year statute of limitations of 28 U.S.C. § 2462108 applied to instances where the Securities Exchange Commission (“SEC”) sought monetary penalties, the Court in Kokesh v. SEC109 was asked to answer a narrower question in connection with the same statute: Is the disgorgement remedy that the SEC routinely seeks synonymous to 28 U.S.C. § 2462’s definition of “civil penalty” and

104 Id.
106 Martens et al., supra note 16.
109 Kokesh, 137 S. Ct. at 1635. Kokesh involved the SEC bringing an enforcement action against Charles Kokesh in 2009 for violating multiple securities laws from 1995 to 2009. Along with the action, the SEC sought monetary penalties, disgorgement, and injunctive relief. The Supreme Court established that disgorgement is a penalty under § 2462, reversing the Tenth Circuit’s ruling. Therefore, because the SEC sought disgorgement after the five-year statute of limitations period expired, the Commission could not recover monies through the disgorgement remedy.
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therefore subject to the five-year statute of limitations.\footnote{110} Unlike the FTC, the SEC possessed express authority under a 1990 federal statute to seek monetary civil penalties in an action brought in a federal district court.\footnote{111} The Supreme Court ruled that when disgorgement is specifically “applied in SEC enforcement proceedings,” such monetary relief constitutes as a penalty sought within five years from when the alleged conduct occurs, pursuant to 28 U.S.C. § 2462.\footnote{112} Justice Sotomayor writing for the majority defined that the three hallmarks that indicate when certain remedies might constitute penalties are when the remedy (1) violates public laws, (2) is imposed for punitive purposes, and (3) does not compensate victims.\footnote{113}

The Court in \textit{Kokesh} does not address other federal administrative agencies.\footnote{114} However, the three hallmarks defined in \textit{Kokesh} strongly indicate that the decision may be applicable to the FTC when the Commission seeks disgorgement as a form of monetary relief in competition cases.\footnote{115} Applying the three hallmarks to the FTC, we first observe that by the FTC enforcing its authority over consumer fraud and competition cases through the FTCA, it generally works to serve the public interest.\footnote{116} Second, the dis-

\footnote{110} It is worth observing that though the Supreme Court answered the narrow question of whether disgorgement constitutes as a penalty subject to the five-year statute of limitations pursuant to 28 U.S.C. § 2462, the decision contains a footnote that “[n]othing in this opinion should be interpreted as an opinion on whether courts possess authority to order disgorgement in SEC enforcement proceedings or on whether courts have properly applied disgorgement principles in this context”; see also Andrew J. Morris, \textit{“Kokesh v. SEC”: Its Wide-Ranging (and Mostly Good) Implications for Disgorgement Actions}. WLF LEGAL PULSE (June 14, 2017), https://wlflegalpulse.com/2017/06/14/kokesh-v-sec-its-wide-ranging-and-mostly-good-implications-for-disgorgement-actions/#more-13315 (noting that the aforementioned footnote in the opinion “all but invites defendants to make a challenge” as to “whether the SEC has the authority to obtain disgorgement”).

\footnote{111} 15 U.S.C. § 77t(d) (2010).

\footnote{112} 28 U.S.C. § 2462.

\footnote{113} See \textit{Kokesh}, 137 S. Ct. at 1638 (“SEC disgorgement is imposed by the courts as a consequence for violating public laws . . . imposed for punitive purposes . . . is often not compensatory.”).

\footnote{114} \textit{Id.} at 1645.

\footnote{115} \textit{Id.} at 1643–44 (justifying through the three hallmarks why the disgorgement that the SEC seeks for securities law violations constitutes as a penalty for the purposes of 28 U.S.C. § 2462).

\footnote{116} See Hershey Chocolate Corp. v. Fed. Trade Comm’n, 121 F.2d 968, 971 (3d Cir. 1941) (“The making available to all competitors of commodities essential to open competition in the industry and thereby insuring a free and unobstructed flow of such commodities from manufacturer to consumer is certainly in the public interest.”); see also Moir v. Fed. Trade Comm’n, 12 F.2d 22, 28 (1st Cir. 1926) (stating that the very act of the FTC bringing suit was “sufficient proof” that it was brought in the public interest without requiring a specific finding of fact); Fed. Trade Comm’n v. Magui Publishers, 1991 U.S. Dist. LEXIS at *48 (C.D. Cal. 1991) (finding that
gorgement relief acts to deter future violations of the FTCA by the alleged wrongdoer.\textsuperscript{117} When a monetary remedy serves a punitive purpose, the relief is deemed a penalty.\textsuperscript{118} Lastly, when a monetary relief such as disgorgement is not compensatory, more often than not, such relief is considered a penalty.\textsuperscript{119} When the FTC or any other administrative agency collects disgorgement money from the defendant, the money is not only distributed to harmed consumers.\textsuperscript{120} Instead, the district court exercises discretion to distribute a certain amount of funds to the United States Treasury and issues the funds to the wronged victims when “they have not identified any statutory command to do so.”\textsuperscript{121} Upon obtaining disgorgement remedy, compensating the wronged consumers is secondary to dispersing funds to the Treasury.\textsuperscript{122}

Not surprisingly, after the Supreme Court’s ruling in \textit{Kokesh}, several law firms that commonly represent defendants expressed their opinions on how the Supreme Court’s recognition of the disgorgement remedy as to the SEC will play out when the FTC continues to seek the same remedy in its consumer protection and competition actions.\textsuperscript{123} Not only have defendants articulated the strong implications of the \textit{Kokesh} ruling on the FTC, but they have

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\textsuperscript{118} \textit{Kokesh}, 137 S. Ct. at 1638 (“The primary purpose of disgorgement orders is to deter violations of the securities laws by depriving violators of their ill-gotten gains.”).

\textsuperscript{119} See FTC v. Pantron I Corp., 33 F.3d 1088, 1103 n.34 (9th Cir. 1994) (stating that disgorgement of a defendant’s unjust enrichment or ill-gotten gains is appropriate when it is impossible to reimburse all of the consumers causally harmed by the defendant’s misrepresentations).

\textsuperscript{120} \textit{Kokesh}, 137 S. Ct. at 1644 (“Some disgorged funds are paid to victims; other funds are dispersed to the United States Treasury.”).

\textsuperscript{121} \textit{Id.}

\textsuperscript{122} \textit{Id.} at 1644 (identifying the disbursement of disgorged funds to victims as a “distinctly secondary goal” (quoting SEC v. Fischbach Corp., 133 F.3d 170, 175 (2d Cir. 1997)).

\textsuperscript{123} Benjamin Mundel & Lucas Croslow, \textit{How Kokesh Will Impact the FTC and Other Agencies}, Law360 (June 22, 2017, 10:28 AM), https://www.law360.com/articles/957090/how-kokesh-will-impact-the-ftc-and-other-agencies (arguing that the government would be “hard pressed to deny that the court’s ruling applies more broadly than SEC enforcement actions,” especially considering the SEC’s concession that if the court did indeed construe disgorgement to constitute as penalty subject to the five-year statute of limitations period, its decision should apply when the government seeks disgorgement in other contexts—specifically citing the FTC’s pursuit of monetary relief under the FTCA); \textit{see also} Martens et al., \textit{supra} note 16 (arguing that since 28 U.S.C. § 2462 does not only apply to enforcement actions by the SEC, but to actions by any government entity, \textit{Kokesh} could affect “all financial regulatory agency actions seeking disgorgement as a remedy for past misconduct” (emphasis added)).
also cited to *Kokesh* to argue against the FTC’s request for disgorgement relief.124

The Supreme Court distinguished a punitive remedy from an equitable remedy.125 In doing so, the *Kokesh* Court classified the SEC’s disgorgement relief as punitive rather than equitable.126 This is of chief significance to the argument that *Kokesh* may influence the FTC’s pursuit of monetary relief under Section 13(b) of the FTCA.127 In an amicus brief of *Kokesh*, the Washington Legal Foundation (“WLF” or “the Foundation”)128 defended the petitioner’s position that the disgorgement remedy was the same as “imposing a civil judgment because an individual has engaged in ‘misconduct’”129 and that the Tenth Circuit Court of Appeals also recognized that “disgorgement serves a deterrent purpose,”130 reinforcing the assertion that disgorgement is a penalty and therefore a punitive remedy. While the Tenth Circuit Court of Appeals accepted the SEC’s argument that disgorgement is equitable, or “remedial” because it “restores the status quo,” the Supreme Court took the position that “it is not clear that disgorgement . . . simply returns the defendant to the place he would have occupied had he not broken the law,” reason being that disgorging its ill-gotten gains may actually “leave the defendant worse off.”131 With the Supreme Court establishing that disgorgement is punitive (at least in the context of securities law for now), the FTC should not ignore that this definition of disgorgement may pollute the FTC’s long-

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124 Defendants have cited *Kokesh*, 137 S. Ct. 1635, to make arguments against the FTC’s pursuit of disgorgement beyond the five-year statute of limitations period, though this has been challenging because of the dicta in *Kokesh* that it applies to violations of securities law more generally. However, defendants have yet to cite to *Kokesh* in connection with a case involving a reverse payment settlement. See FTC v. J. William Enters., LLC, 283 F. Supp. 3d 1259, 1261 (M.D. Fla. 2017).

125 *Kokesh*, 137 S. Ct. at 1635.

126 *Id.*

127 Mundel & Croslaw, *supra* note 123 (“ . . . *Kokesh* casts doubt on the authority of agencies like the SEC and the FTC to seek disgorgement or restitution at all,” because both agencies have historically sought monetary remedies by arguing that they are “equitable” and “ancillary” to the district court’s equitable jurisdiction).


129 Brief for Washington Legal Foundation as Amicus Curiae Supporting Petitioner at 6, *Kokesh* v. SEC, 137 S. Ct. 1635 (No. 16-529), 2017 WL 3382304.

130 SEC v. *Kokesh*, 834 F.3d 1158, 1164 (10th Cir. 2016).

131 *Kokesh* v. SEC, 137 S. Ct. 1635, 1644–45 (2017) (demonstrating that disgorgement is a “punitive sanction”).
standing interpretation of disgorgement as an equitable remedy and should be on notice that its prospective disgorgement claims may be limited by the five-year statute of limitations.\textsuperscript{132}

Seeking out opportunities that would guarantee a quicker turnover of resolving patent disputes arising out of reverse payment settlements should sway the FTC to utilize ADR in the wake of \textit{Kokesh}.\textsuperscript{133} Despite being held outside of federal courts, administrative proceedings proved to be increasingly costly and prolonged.\textsuperscript{134} Further, Congress recognized that disputing parties did not appreciate the ambiguity of the administrative agencies’ authority, which would have made it harder for some parties to fully accept the outcome of certain agency decisions.\textsuperscript{135} In response to these practical concerns, Congress approved the passage of the original Administrative Dispute Resolution Act in 1990 ("ADR Act").\textsuperscript{136} Congress enacted the ADR Act upon observing that the private sector had successfully taken advantage of ADR processes for numerous years\textsuperscript{137} and thereby hoped that federal agencies would be encouraged to use “mediation, conciliation, arbitration, and other techniques for the prompt and informal resolution of disputes.”\textsuperscript{138} Six years later, President Bill Clinton signed into law the ADRA of 1996, which made many adjustments to the original statute,\textsuperscript{139} but retained the ADR Act’s primary purpose of encouraging and authorizing administrative agencies to implement ADR procedures within their respective agencies.\textsuperscript{140} In general, the

\textsuperscript{132} Mundel & Croslow, \textit{supra} note 123.
\textsuperscript{133} \textit{Kokesh}, 137 S. Ct. at 1635.
\textsuperscript{135} 136 \textit{CONG. REC.} H3152, 1990 WL 74946 (daily ed. June 5, 1990) (statement of Rep. Frank) (noting that employing ADR to settle administrative disputes would “lead to more creative, efficient, and sensible outcomes that foster stability” and the “use of common sense procedures in appropriate cases”).
\textsuperscript{137} ADR Act § 2. See also 136 \textit{CONG. REC.} H3152, 1990 WL 74946 (daily ed. June 5, 1990) (statement of Rep. Frank) (noting that the use of ADR in the private sector has resulted in quicker decisions from “less expensive and less contentious” procedures).
\textsuperscript{138} See ADR Act at preface.
\textsuperscript{139} See 5 U.S.C. § 574 (1996). One of the significant changes from the ADR Act to the ADRA of 1996 was the strengthening of the confidentiality provisions, which provides guidance on how dispute resolution communications should be kept confidential and exempt from the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 (1967).
\textsuperscript{140} See Key ADR Statutes, INTERAGENCY ALT. DISPUTE RESOLUTION WORKING GRP., https://www.adr.gov/adrguide/04-statutes.html (last visited Nov. 9, 2017).
ADRA has been especially helpful with resolving disputes concerning government contracts, the workplace, and federal law and regulation enforcement.\textsuperscript{141} The FTC should address the discord surrounding reverse payment settlements and the potential time constraint on disgorgement claims with brand drug companies in less adversarial settings.\textsuperscript{142}

C. Mediation: Facilitative and Evaluative

There are primarily two types of mediation: facilitative and evaluative.\textsuperscript{143} In regards to facilitative mediation, the mediator “does not take an actual position, as would a judge, arbitrator, or neutral expert.”\textsuperscript{144} Although the facilitative mediator may give other general “opinions, assertions, challenges, and actions,”\textsuperscript{145} the chief distinguishing factor of a facilitative from an evaluative mediator is that the former must not chime in with his or her own “opinion on the merits or damages due to a party”\textsuperscript{146} and therefore predict how the court might decide in the event the parties fail to settle in mediation. For some, facilitative mediation can be seen as the standard style of mediation that fuels the process of “captur[ing] the parties’ insights, imagination, and ideas [for the purpose of helping them] identify and shape their preferred outcomes” (emphasis added).\textsuperscript{147}

On the other hand, mediators who employ evaluative techniques “give advice, assess arguments, and express their own opin-

\textsuperscript{141} Jacob A. Stein \& Glenn A. Mitchell, Administrative Law § 33.06 (2017).
\textsuperscript{143} See Roberts, \textit{supra} note 22. The establishment of the vocabulary “facilitative” and “evaluative” to describe different forms of mediation is credited to Leonard Riskin from 1994 and 1996.
\textsuperscript{144} E. Patrick McDermott \& Ruth Obar, “What’s Going On” in Mediation: An Empirical Analysis of the Influence of a Mediator’s Style of Party Satisfaction and Monetary Benefit, 9 Harv. Negot. L. Rev. 75, 82–83 (2004) (suggesting that the facilitative mediator has the role of “reframing; structuring of the bargaining agenda; probing of assessments and positions; challenging proposals; urging parties to obtain additional resources or information; suggesting possible resolutions; and reality testing or checking”).
\textsuperscript{145} \textit{Id.} at 83.
\textsuperscript{146} \textit{Id.}
\textsuperscript{147} Joshua R. Schwartz, Laymen Cannot Lawyer, but is Mediation the Practice of Law?, 20 Cardozo L. Rev. 1715, 1718 (1999).
ions about the disputing parties’ claims,” in effect, resembling a quasi-attorney. The mediator, however, cannot play the part of an attorney and establish an attorney-client relationship with either party, but the mediator may restrict his or her role to continue a dialogue between the parties to reach their respective desired outcomes.

IV. PROPOSAL

A. Alternative Dispute Resolution: Evaluative Mediation

Considering the Supreme Court’s decisions of Actavis and Kokesh, the FTC should turn to ADR when seeking disgorgement for the purposes of tackling antitrust matters involving reverse payment settlements. There has been a growing acceptance and use of ADR by attorneys in connection with patent litigation. Focusing on only litigating patent cases would waste judicial resources and flood the court system with the ever-increasing patent disputes filed in courts. Patent attorneys recognize the benefits of mediation and exhibit a preference for mediation over more binding ADR mechanisms, such as arbitration. Mediation also proves to

148 Roberts, supra note 22. See also Blackman & McNeill, supra note 18, at n.26 (observing that mediators who apply the evaluative mediation style “evaluate” and “provide feedback” on the parties’ assertions).

149 See ROBERT C. LARNER & THOMAS SMITH, 3A OHIO JUR. 3D ALTERNATIVE DISPUTE RESOLUTION § 116 (2017) (“[T]he mediator, when acting as mediator, is not engaged in the practice of law.”).


151 Quinn, Jr., supra note 18, at 80 (noting that evidence from survey, empirical evidence, and overall trends have demonstrated patent attorneys’ increasing interest in and reliance on ADR techniques); see also Mitchell Smith, Mediation as an Alternative to Litigation in Patent Infringement Disputes, 11 ADR BULL. 6 (2009), available at https://epublications.bond.edu.au/cgi/viewcontent.cgi?article=1481&context=adr.

152 Quinn, Jr., supra note 18, at 84. Note that the argument for settlement over litigation is one of the justifications that the Eleventh Circuit Court of Appeals used regarding patent disputes of reverse payment settlement agreements between a patent holder and a generic drug company; see Valley Drug Co., 344 F.3d 1294. Even the Sixth Circuit Court of Appeals position is in conformity with the Eleventh Circuit to an extent, as demonstrated in ARO Corp. v. Allied Witan Co., 531 F.2d 1368 (6th Cir. 1976). See also Smith, supra note 151. Studies show that patent litigation, through the trial stage, results in about $2 million for each party and that the projected expenses will only increase (by up to 15%) every year. Moreover, regarding the waste of judicial resources by litigating instead of settling patent disputes, it is important to recognize that while parties, on appeal, usually are required to re-argue the interpretation, mediation does not have this result.

153 Quinn, Jr., supra note 18, at 99 (noting that mediation must be completely confidential).
be more flexible than arbitration and allows the parties to have full control over the process with the mediator—a neutral party—facilitating the conversation between the two parties to help the parties reach a resolution, if possible and desired. Moreover, the costs associated with mediation tend to be less than those of litigation, where arbitration expenses can amount to litigation costs. Therefore, for antitrust issues as well—pay-for-delay settlements or patent infringement claims in general—mediation with a heavier focus on evaluative characteristics would be more appropriate.

B. Mediation Between the FTC and Brand Drug Manufacturers

The idea that the FTC should utilize mediation to pursue obtaining disgorgement remedies from a brand drug manufacturer in the “shadow of the law” is not so far-reaching. An administrative agency has discretion to use a dispute resolution program to help resolve issues in connection with its agency pursuant to the Administrative Dispute Resolution Act of 1996 (“ADRA of

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154 Id. at 95; see Jonathan M. Hyman, Slip-sliding Into Mediation: Can Lawyers Mediate Their Clients’ Problems?, 5 CLINICAL L. REV. 47, 58 (1998) (describing mediation as an agreement that considers the interests of the parties during the process of solving the problem in an efficient and effective way by integrating the opinions of the mediator); see also Leonard J. Frankel et al., Why Cases Settle—Why Cases Don’t Settle, FRANKEL, RUBIN, KLEIN, DUBIN, SIEGEL & PAYNE, P.C., http://frankelrubin.com/why-cases-settle-why-cases-dont-settle/ (last visited Jan. 27, 2018) (explaining that situations sometimes arise in which a party is not willing to compromise because it intends to approach the mediation as a means to state reasons as to why it would succeed in court over its opponent. The intent of such parties is not to settle the case or to settle the case only on their conditions).

155 Thomas J. Stipanowich & J. Ryan Lamare, Living With ADR: Evolving Perceptions and Use of Mediation, Arbitration, and Conflict Management in Fortune 1,000 Corporations, 19 HARV. NEGOT. L. REV. 1, 1718 (2014) (“Relatively few [respondents] expressed concerns about the costliness or complexity of arbitration, although, tellingly, such concerns were more often expressed about arbitration than about mediation.”); see also Quinn, Jr., supra note 18, at 95 (“While arbitration can offer significant cost savings, some estimates indicate that arbitration can also cost nearly as much as litigation.”).

156 Roberts, supra note 22, at 195 (explaining that patent law experts in patent infringement disputes and reverse payment settlements are able “to ask appropriate questions, guide the parties in a reasonable direction, and help the parties realistically reevaluate their claims”); see also Stephen P. Anway, Mediation in Copyright Disputes: From Compromise Created Incentives to Incentive Created Compromises, 18 OHIO ST. J. ON DISP. RESOL. 439, 444 (2003) (attributing the growing prevalence of evaluative mediation to the increase in lawyers and former judges acting as mediators).

1996”).158 Though the ADRA of 1996 does not mandate agencies to implement ADR procedures, the ADRA encourages agencies to consider other methods to resolve conflicts outside of litigation.159

Despite federal agencies providing individuals and businesses the option to resolve disputes earlier on through multiple ADR methods, it does not seem to be as common for an administrative agency itself to participate as a party in mediation.160 The FTC has been a party in a court-ordered mediation against a corporation.161 The existence of at least one known case where the FTC was a party to mediation162 furthers the proposal for the Commission to rely not only on the district courts to grant disgorgement, but to take advantage of dispute resolution opportunities. Moreover, since there may have been more mediation proceedings that the FTC participated in, yet undisclosed to the public due to the confidential nature of mediation, the FTC should be largely compelled to seek mediation opportunities preemptively to address the ambiguity that Actavis and Kokesh left behind.163

159 See 5 U.S.C. § 572(a) (1996) (“An agency may use a dispute resolution proceeding for the resolution of an issue in controversy that relates to an administrative program, if the parties agree to such a proceeding” (emphasis added)).
160 These situations are probably less common because, for the most part, mediations remain confidential. Although each jurisdiction has its own confidentiality rules, the overall rule is that records and communications from mediations are to remain confidential as between the parties, their respective counsels (if applicable), and the mediator. See Uniform Mediation Act (“UMA”) of 2003, 2003 Neb. Laws 255 (2003). See also Rachel Ehrlich et al., How Confidential are Mediation Communications? You Might Be Surprised, A.B.A., n.2 (2016), https://www.americanbar.org/content/dam/aba/administrative/litigation/materials/2016_insurance_coverage_litigation_communications_final_paper.authcheckdam.pdf (stating that as of January 2016, the following jurisdictions adopted the UMA: Hawaii, Illinois, Idaho, Iowa, Nebraska, New Jersey, Ohio, South Dakota, Utah, Vermont, Washington, Washington D.C.). See also Mediation Act, Unif. Law Comm’n, http://www.uniformlaws.org/Act.aspx?title=Mediation%20Act (last visited Nov. 28, 2017). The Uniform Mediation Act has also been introduced in 2017 to Massachusetts and New York through bills HB 49 and SB 1017, respectively.
C. Appointing the Appropriate Neutral Party as the Mediator

Before rounding up the parties—one or more representatives each from the FTC and the brand drug company with their respective counsel—a qualified mediator must be appointed to oversee and facilitate negotiations and convey conversations from one party to the other. Because patent claims in general—and more specifically patent infringement claims resulting from paragraph IV certifications—are extremely complex issues, designating a mediator who emphasizes evaluative techniques and has a background in patent law would be advantageous in helping reach a mutual agreement between the FTC and the brand drug firm. Furthermore, a mediator who largely recognizes the evaluative style of mediation and has experience with patent law may increase the likelihood of both parties feeling understood. A currently practicing patent attorney who generally defends pharmaceutical manufacturers, namely brands, will not qualify as a neutral and unbiased party because he or she may be less discerning with his or her opinions as a mediator apart from a defense patent attorney. As the District Court of New Jersey in FTC v. Wyndham assigned a mediator who had experience and possessed expert knowledge in antitrust matters (among many others) while serving as a federal judge, for cases in connection with pay-for-delay settlements, the district court should appoint a mediator who was formerly a federal judge; an attorney from the FTC, the Department of Justice’s (“DOJ”) Antitrust Division, or the like; or a private sector patent attorney with experience in advocating for either plaintiffs or defendants.

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164 Wyndham Worldwide Corp., 10 F. Supp. 3d 602; see also Mediation Order, supra note 161. The Court set Hon. Garrett E. Brown, Jr. (Ret.) in his capacity as a mediator (or “neutral”) from JAMS (formerly Judicial Arbitration and Mediation Services, Inc.).

165 See Smith, supra note 151.

166 Id.

167 Smith, supra note 151; see also Roberts, supra note 22, at 195 (stating that because the focus of evaluative mediation is on the “legal rights of the parties,” mediators of this type “evaluate the merits of each party’s claim” without hostilities of the court setting).


170 Roberts, supra note 22, at 195 (pointing out that evaluative mediators are expected to possess a background and experience in law, along with expertise in the subject matter of the dispute, because “[s]uch knowledge is necessary in order to ask appropriate questions, guide the parties in a reasonable direction, and help the parties realistically reevaluate their claims.”).
D. The Mediation Process with Heightened Focus on Evaluative Methods

Once each party voluntarily agrees to commit to and participate in mediation, and an eligible mediator has been assigned, the assigned mediator should first consider the desired results of the mediation from the perspectives of the FTC and the brand drug company.\footnote{See Fast Track Mediation, Internal Revenue Serv., https://www.irs.gov/compliance/appeals/fast-track-mediation (last visited Jan. 31, 2018) (explaining that once an individual agrees to mediate with the Internal Revenue Service (“IRS”) to resolve a collection dispute, the IRS requires the contacted individual to submit a statement in writing that details the individual’s position (position statement)); see also Effective Position Statements, Equal Employment Opportunity Comm’n, https://www.eeoc.gov/employers/position_statements.cfm (last visited Jan. 31, 2018) (showing the contrast at the EEOC from the IRS: if a party files a discrimination complaint (the charging party) with the Equal Employment Opportunity Commission (“EEOC”), the EEOC requires the charging party to provide a position statement).} The FTC, within the narrow category of reverse payment settlements, would seek disgorgement from the drug company immediately after a claim for the disgorgement action accrues and the FTC subsequently files a complaint\footnote{See Gabelli, 568 U.S. 442, supra note 107 (“In common parlance a right accrues when it comes into existence. The standard rule is that a claim accrues when the plaintiff has a complete and present cause of action”) (internal quotations omitted).} to a district court; the FTC must bring this action within five years of the defendant’s alleged wrongdoing.\footnote{Requesting disgorgement to the court is important because despite triggering the five-year statute of limitations, the FTC’s submission of the claim will signal to the brand drug company that it is committing its pursuit of the remedy. Otherwise, the five-year statute of limitations will not start to run if the FTC wishes to proceed to mediation without commencing an action for the monetary remedy, and the brand drug company will feel a disconnect between the FTC’s sincerity in obtaining disgorgement and its confidence in the mediation process.} As for the brand drug company, if it has less confidence in successfully defending its position at trial, the company will be inclined to be more lenient with the disgorgement amount being negotiated. Demonstrating a greater disposition to reach a settlement, the drug company’s attitude may be influenced in part by the company wanting current and even future shareholders to look favorably upon the brand.\footnote{Agreeing to pay disgorgement to the other party (here, the FTC) is not equivalent to acknowledging a loss, as would be the case after the court’s judgment at trial.}

The dialogue will then continue between the parties with the mediator facilitating the process, but should the mediation slow down—possibly due to the parties resisting compromise at both ends or either end—the mediator should employ evaluative-focused methods of mediation. The mediator can “evaluate the merits of the case” by “calibrating [the parties’] expectations if they
were either too high or too low” or by “advising the lawyers where they need to focus their time and energy” should the case proceed to trial. The mediator, while maintaining his or her unbiased position, has the ability to calculate an estimation of either parties’ potential win or loss at trial. When the mediator also possesses a corporate background, he or she may “suggest creative business solutions that might otherwise be overlooked.” The solution may be as simple as the brand company re-negotiating the reverse payments to the generic firm to mitigate antitrust concerns and instead directing the difference to the FTC. To warrant the possibility that evaluative-focused mediators of these patent-antitrust disputes may cross the fine line between providing their opinions on the merits of the case and forcing their views onto the parties, an objective survey should be given to the parties at the close of the mediation whether or not a settlement results.

While this Note upholds the distinction between facilitative and evaluative mediation, the labels are less important than the experience and style of the mediator. Indeed, studies demonstrate that parties that experienced a settlement through the use of the mediator’s facilitative style have expressed higher satisfaction with the process. Regardless of the model used, the mediator should consider whether the disputing parties desire a just outcome based on “disputant satisfaction” or “substantive quality” of facilitative and evaluative mediation. Jeffrey Stempel posits, “Disputant satisfaction is an important factor for measuring mediation but so is the substantive quality of outcomes.” However, patent disputes are starkly contrasted from, for instance, divorce cases, where more emotions are involved and thus, quicker resolu-

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176 See Anway, supra note 156, at 459.
177 Id.
178 See Paula M. Young, Take it or Leave it. Lump it or Grieve it: Designing Mediator Complaint Systems That Protect Mediators, Unhappy Parties, Attorneys, Courts, the Process, and the Field, 21 OHIO ST. J. ON DISP. RESOL. 721, n.229 (2006) (noting that there is potential for mediators to become coercive because they are “largely unregulated” and “few courts operate rigorous monitoring systems”).
179 Barry Edwards, Renovating the Multi-Door Courthouse: Designing Trial Court Dispute Resolution Systems to Improve Results and Control Costs, 18 HARV. NEGOT. L. REV. 281, 330 (2013).
180 McDermott & Ruth Obar, supra note 144, at 77–78.
182 Id. at 375.
tion and disputant satisfaction may be of higher interest to the parties. Furthermore, one facet of facilitative mediation to be mindful of is that many of the professionals who promote and apply facilitative mediation styles are not attorneys.\textsuperscript{183} Having an attorney, or a professional with a legal background, to integrate evaluative mediation techniques to resolve patent disputes would present more favorable outcomes for the parties.\textsuperscript{184} \textit{Kokesh} suggests that agencies like the FTC should contemplate alternatives to litigation like mediation that will ensure a higher probability of obtaining disgorgement or other fees.\textsuperscript{185} Though there is a preference for legal professionals who are experienced in patent law and antitrust law to serve as mediators for evaluative-type mediation for such matters, the emphasized basic qualifications of a mediator are impartiality in assessing the information provided by the parties and competence in leading the parties to settle the issue by self-determination.\textsuperscript{186}

V. Conclusion

Mediation in the context of patent law must be stressed and encouraged. Patent cases that are filed and litigated in court continue to overwhelm the court system,\textsuperscript{187} and the intricacies of patent law still remain complex and costs associated with these cases are on the rise.\textsuperscript{188}

Whether reverse payment settlements are anticompetitive or \textit{per se} illegal depends on the specific facts and circumstances of the patent dispute.\textsuperscript{189} Though brand drug and generic manufacturers

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\item \textsuperscript{183} See Jeffrey W. Stempel, \textit{The Inevitability of the Eclectic: Liberating ADR from Ideology}, 2000 J. Disp. Resol. 247, 249–50 (2000) (“[A] significant percentage of the facilitative mediation community is composed of nonlawyers, many of whom appear to have a generalized aversion to things legal or litigation like.”).
\item \textsuperscript{184} \textit{Smith}, supra note 151 (asserting that “an evaluative approach to the mediation process may be most suitable” for patent disputes).
\item \textsuperscript{185} \textit{Kokesh} v. SEC, 137 S. Ct. 1635 (2017); see also Martens et al., \textit{supra} note 16.
\item \textsuperscript{186} See Colatrella, \textit{supra} note 168, at 714.
\item \textsuperscript{187} See Jenny, \textit{supra} note 17; see also Bradley D. Riel, \textit{A Correlation Between the State of the US Economy and Patent Litigation Activity}, 92 J. Pat. & Trademark Off. Soc’y 71, 101 (2010) (noting that, despite some exceptions, overall studies show that annually, the number of patent cases filed trends upward; also, regardless of fluctuations in the U.S. economy, patent cases substantially flood the district courts (over the appellate courts)).
\item \textsuperscript{188} Jenny, \textit{supra} note 17, at 39. To demonstrate the complexity of patent law, District Court Judge Patti Saris stated, “Patent litigation is like the neurosurgery of litigation: it is hard scientifically and it is hard legally.”
\item \textsuperscript{189} FTC v. Actavis, Inc., 133 S. Ct. 2223, 2235 (2013).
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may have intended to resolve paragraph IV patent infringement suits in an efficient manner through the reverse payment methodology, there is no doubt that there is great concern for drug companies’ ill-gotten gains obtained at the expense of consumers’ losses.

Looking forward after the Supreme Court’s clear-cut interpretation of disgorgement in *Kokesh*, the FTC in particular should be fueled to advocate for mediation with brand drug manufacturers. The Commission would find more opportunities to collect ill-gotten gains from brand drug companies in the context of reverse payment settlements before the expiration of the statute of limitations found in 28 U.S.C. § 2462. With the expected increase in patent disputes filed in district court in the coming years and the potential for the Supreme Court’s current construction of disgorgement rolling over into the realm of antitrust-enforcement, the FTC faces intensified uncertainty about what the established law will be when the Supreme Court or Congress addresses this inquiry. Distinguishable from restitution and compensation, if the FTC demands disgorged funds from the brand manufacturer for unjustly profiting from a reverse payment settlement, this increase in reward to the Commission is better characterized as a penalty. By orienting its focus on pursuing disgorgement relief now, the FTC can develop and continue to sharpen an enhanced model of mediation as applied to antitrust-enforcement cases and patent disputes.

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192 See 1 DONALD S. CHISUM, CHISUM ON PATENTS § 20.03 (2017). This scenario between the FTC and a brand drug company is in stark contrast from a case that involves a party infringing another party’s patent; see, e.g., Beatrice Foods Co. v. New England Printing & Lithographing Co., 923 F.2d 1576 (Fed. Cir. 1991) (thereby causing damages in lost profit). In such a situation, “enhanced damages” to relieve the patent holder would not constitute a penalty, but compensation.