FTC v. Watson Pharmaceuticals: 677 F.3D 1298 (11th Cir. 2012)

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FTC V. WATSON PHARMACEUTICALS
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I. INTRODUCTION

*FTC v. Watson Pharmaceuticals* is an appeal from a ruling by the Northern District Court of Georgia dismissing the Federal Trade Commission’s (FTC) lawsuit for failure to state a claim upon which relief can be granted, pursuant to Federal Rules of Civil Procedure Rule 12(b)(6).¹ The FTC alleged in its amended complaint that these reverse payment settlement agreements were unlawful agreements not to compete in violation of the Federal Trade Commission Act.² The FTC argued that these reverse payment agreements fell outside of the safe harbor of the Eleventh Circuit’s precedent because these agreements exceeded the potential exclusionary scope of the patent.³ Nevertheless, the United States Court of Appeals for the Eleventh Circuit declined to extend its rule to encompass a determination about the underlying patent litigation and reaffirmed its past precedent that a reverse payment settlement agreement will be valid if its anticompetitive effects fall within the scope of the exclusionary potential of the patent at issue; and that the determination of the extent of the potential exclusionary scope of the patent shall be made at the time the reverse payment settlement agreement was executed.⁴

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³ Watson, 677 F.3d at 1306.
⁴ Id. at 1308, 1312.
II. SUBJECT OPINION

A. Risk-Reward Benefit of Pharmaceutical Development and Reverse Payment Agreements

The Eleventh Circuit began with a discussion of the risks that a pharmaceutical manufacturer undertakes when attempting to develop a new drug.\(^5\) Only one in every 5,000 medicines tested is ever approved for patient use, and according to some estimates, developing a new drug can take anywhere between ten and fifteen years and cost upwards of $1.3 billion dollars.\(^6\) The court summarized the drug development and approval process with the maxim, “no risk, no reward and more risk, more reward.”\(^7\) Based on these substantial risks, the court surmised that many patent-holding companies are inclined to settle lawsuits “in order to preserve their patents and keep monopoly profits flowing” as opposed to “rolling the dice and risking their monopoly profits in the infamously costly and notoriously unpredictable process of patent litigation.”\(^8\)

Before addressing the opposing party’s arguments, the court noted that the type of settlement at issue here is known as a “pay for delay” or a “reverse payment” agreement.\(^9\) In a reverse payment agreement, “a patent holder pays the allegedly infringing generic drug company to delay entering the market until a specified date, thereby protecting the patent monopoly against a judgment that the patent is invalid or would not be infringed by the generic competitor.”\(^10\)

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5. Id. at 1300.
7. Id. (internal quotation marks omitted).
8. Id. at 1300-01.
9. Watson, 677 F.3d at 1301.
10. Id.
B. The FTC’s Arguments

The Federal Trade Commission brought this lawsuit against four drug manufacturers: the patent holder, Solvay Pharmaceuticals, Inc., and three generic manufacturers, Watson Pharmaceuticals, Inc., Paddock Laboratories, Inc., and Par Pharmaceutical Companies, Inc. In its complaint, the FTC alleged that the reverse payment settlements between the holder of the patent and two generic manufacturers were unfair restraints on trade in violation of the Sherman Act Section 45. Additionally, the FTC claimed the reverse payments were tools manufacturers used to ensure that a patent is not judged invalid or to avoid a ruling that the generic manufacturers would not infringe a patent. The court mentioned “the key allegation in the FTC’s complaint [was] that [Solvay Pharmaceuticals] was ‘not likely to prevail’ in the infringement actions that it brought against the generic manufacturers and then settled.” The FTC complained, in its view, the reverse payments unlawfully protected a monopoly and should therefore not be protected from antitrust attack. Lastly, the FTC asserted that generic drug companies are willing to settle their lawsuits because the patent holder can continue to reap monopoly profits that it will share with the generic manufacturer. This monopoly profit sharing strategy will often lead to greater profits than the individual profits the drug companies could make by competing against each other. The FTC claimed this was a “win-win” for the drug companies and it estimated that “reverse

11. Id. at 1305.
12. Id. at 1301.
13. Id.
14. Id. Specifically, the FTC alleged that the generic products “contained ingredients that the patent did not cover, or amounts of ingredients outside the amounts covered by the patent.” See Brief of Plaintiff-Appellant Federal Trade Commission at 38 FTC v. Watson Pharma., Inc., 677 F.3d 1298 (11th Cir. 2012) (No. 10-12729), 2010 WL 5064779 at *38.
15. Watson, 677 F.3d at 1301.
16. Id.
17. Id.
payment settlements cost consumers about $3.5 billion per year in the form of higher drug prices.”

C. Drug Companies’ Arguments

In defense of the alleged antitrust violation, the drug companies contended that reverse payment settlements are simply another tool that a patent holder is entitled to use in order to protect and maintain the exclusionary rights of its patent. Further, punishing a patent holder for paying a competitor to remain out of the market would cut against the grain of what patents are designed specifically to do; that is, exclude competition during the life of the patent. Lastly, they argued that public policy disfavored the infringement of patent holders’ rights because infringement “weakened incentives for investing in drug development, which would reduce the number of life-saving or life-enhancing innovations that benefit consumers.”

D. Process of Introducing New and Generic Pharmaceutical Drugs into the Market

After discussing each party’s legal arguments, the court delved into the issue of how drugs are introduced into the market. In order to sell a new drug in the United States, a manufacturer must first gain the approval of the Food and Drug Administration (FDA). A manufacturer seeking to sell a pioneer drug, which has never been approved by the FDA, must submit a New Drug Application (NDA). The NDA must contain all of the relevant information about the new drug, “including its chemical composition, full reports of investigations about its safety and efficacy, and descriptions of its production, packaging, and

18. Id. at 1301-02.
19. Id. at 1301.
20. Id.
21. Watson, 677 F.3d at 1301.
23. Watson, 677 F.3d at 1302.
24. Id.
labeling language.” An NDA applicant must also provide the FDA with the patent number and the expiration date of any patent that protects the new drug. Once the FDA approves an NDA, the drug, along with its chemical composition and relevant facts, is published in a book called “Approved Drug Products with Therapeutic Equivalence and Evaluations,” commonly known as the “Orange Book.”

However, if a drug company is applying to the FDA to sell a generic version of a pioneer drug, the drug company only needs to file an Abbreviated New Drug Application (ANDA). When a generic drug manufacturer files an ANDA, it is allowed to “piggyback” on the safety and efficacy studies performed by the pioneer drug manufacturer. When a drug company files an ANDA, it must submit one of the following four paragraph certifications that:

(I) no patent information for the brand name drug has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a specifically identified date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

If the generic manufacturer submits an ANDA with a paragraph IV certification, the applicant must send notice to the patent holder that the patent listed in the Orange Book is either invalid or will not be infringed by the applicant’s generic drug. “The patent holder then has 45 days to file an infringement lawsuit against the ANDA applicant,” and “[i]f the suit is timely filed, the FDA stays the ANDA approval process for 30 months to allow the parties or a

25. Id. (citing 21 U.S.C. § 355(b) (internal quotations omitted)).
26. Id. (citing 21 U.S.C. § 355(b) (internal quotations omitted)).
27. Id.
28. Id.
29. Watson, 677 F.3d at 1302.
30. Id. at 1303 (citing 21 U.S.C. § 355(j)(2)(A)(vii) (internal quotations omitted)).
31. Id.
court to resolve the infringement dispute. If a court decides that the patent is invalid or will not be infringed, the FDA’s approval of the ANDA becomes effective on the date that the court enters its judgment. Federal law encourages ANDA applications by allowing the first ANDA applicant making a paragraph IV certification that is approved by the FDA, a 180-day exclusivity period during which the FDA will not approve other ANDA applications. This gives the generic manufacturer a 180-day head start to compete with the pioneer drug—something the court noted was “a significant incentive for generic manufacturers to challenge weak or narrow drug patents.”

E. Facts

After concluding its statutory analysis, the court reviewed the specific facts of this case. It discussed the relationship among the four drug manufacturers and the details of the particular reverse payment settlement agreements that led to the lawsuit. Besins Healthcare, S.A., (Besins) developed the prescription drug AndroGel, a gel that releases synthetic testosterone into a patient’s bloodstream. “In August 1995, Besins granted Solvay Pharmaceuticals, Inc. [(Solvay)] a license to sell AndroGel in the United States and agreed to provide a commercial supply of the drug if the FDA approved it for sale.” Solvay filed an NDA for AndroGel in April 1999, which was approved in February 2000,

32. Id.
33. Id.
34. 21 U.S.C. § 355(j)(5)(B)(iv)(I) (“Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.”).
35. Watson, 677 F.3d at 1303.
36. Id. (citing Valley Drug Co. v. Geneva Pharms., Inc., 344 F.2d 1294, 1298 (11th Cir. 2003)).
37. Id.
38. Id. at 1303-06.
39. Id. at 1303-04.
40. Id.
and began marketing and selling the drug with great success.\textsuperscript{41} Solvay generated revenue in excess of $1.8 billion dollars from the sale of AndroGel between 2000 and 2007, revenue that far exceeded the cost of developing the drug.\textsuperscript{42}

Shortly after the FDA approved AndroGel for sale, Solvay filed a patent application with the United States Patent and Trademark Office (USPTO) on August 30, 2000.\textsuperscript{43} The USPTO granted Solvay’s patent application for the drug on January 7, 2003, and awarded Patent Number 6,503,894 jointly to Solvay and Besins.\textsuperscript{44} Solvay properly submitted its granted patent information to the FDA to be included in the Orange Book.\textsuperscript{45} Two drug manufacturers, Watson Pharmaceuticals, Inc. (Watson) and Paddock Laboratories, Inc. (Paddock), quickly developed generic versions of AndroGel and submitted ANDAs to the FDA in May 2003.\textsuperscript{46} Watson was the first to file its ANDA, entitling it to the 180-day exclusivity period, though both companies made paragraph IV certifications claiming that their generic AndroGel products did not infringe Solvay’s patent or that Solvay’s patent was invalid.\textsuperscript{47} Solvay timely filed its infringement lawsuit against Watson and Paddock triggering the 30-month stay of the FDA’s approval process for Watson’s and Paddock’s generic versions of AndroGel.\textsuperscript{48} The stay was set to expire in January 2006.\textsuperscript{49}

In order to spread the risks and costs of litigation, Paddock partnered with Par Pharmaceutical Companies, Inc. (Par).\textsuperscript{50} Par agreed to share the costs of the litigation in exchange for a portion of the profits from Paddock’s generic AndroGel if it were to be approved by the FDA.\textsuperscript{51} In January 2006, when the 30-month stay

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\begin{itemize}
\item 41. Watson, 677 F.3d at 1304.
\item 42. Id.
\item 44. Watson, 677 F.3d at 1304.
\item 45. Id.
\item 46. Id.
\item 47. Id.
\item 48. Id.
\item 49. Id.
\item 50. Watson, 677 F.3d at 1304.
\item 51. Id.
\end{itemize}
elapsed, the FDA approved Watson’s and Paddock’s ANDA applications.\textsuperscript{52} Meanwhile, the parties to the infringement litigation were awaiting disposition of opposing summary judgment motions as to the validity of Solvay’s patent, which meant that Solvay was facing the possibility of losing its monopoly on the AndroGel market.\textsuperscript{53} Watson estimated that its generic AndroGel could cut sales of branded AndroGel by 90% and cut Solvay’s profits by $125 million per year.\textsuperscript{54} However, before the district court could rule on the dual motions for summary judgment, the parties resolved their dispute with multiple settlement agreements.\textsuperscript{55} The terms of the agreements were as follows: (1) Watson, Par, and Paddock agreed not to sell AndroGel until August 31, 2015, unless another manufacturer launched a generic version before then; (2) Watson agreed to promote AndroGel to urologists; (3) Par agreed to promote it to primary care doctors; (4) Par “agreed to serve as a backup manufacturer for branded AndroGel but assigned that part of the agreement to Paddock”; (5) “Solvay agreed to pay Par/Paddock $10 million per year for six years and an additional $2 million per year for the backup manufacturing assistance”; and (6) “Solvay also agreed to share some of its AndroGel profits with Watson through September 2015, projecting those payments [to] be between $19 million and $30 million.”\textsuperscript{56}

After finalizing the settlement agreements, the four manufacturers stipulated to a dismissal of the patent infringement action that was pending in the district court awaiting a ruling on the dual motions for summary judgment.\textsuperscript{57} After the settlement agreements were reported to the FTC as required by law,\textsuperscript{58} the FTC filed an antitrust lawsuit against the four manufacturers claiming a

\textsuperscript{52} Id.
\textsuperscript{53} Id.
\textsuperscript{54} Id. at 1305.
\textsuperscript{55} Id.
\textsuperscript{56} Watson, 677 F.3d at 1305.
\textsuperscript{57} Id.
violation of 15 U.S.C. § 45(a)(1) which banned “unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce.” The court reiterated that the lynchpin of the FTC’s complaint was the allegation that “Solvay was not likely to prevail” in the underlying patent infringement action, and thus, Watson and Par/Paddock would not have been barred from entering the AndroGel market by Solvay’s patent. The four defendants moved to dismiss the complaint under Rule 12(b)(6), arguing that Eleventh Circuit precedent “immunize[d] reverse payment settlements from antitrust attack unless a settlement imposes an exclusion greater than that contained in the patent at issue.” The district court agreed with the defendants and granted the motion to dismiss, concluding that the FTC did not allege that the settlements exceeded the scope of Solvay’s patent. Appealing to the Eleventh Circuit, the FTC reiterated that Solvay was not likely to prevail in the infringement actions; thus, the parties should not have been allowed to enter into the settlement agreements.

1. Legal Standard of Review

The Eleventh Circuit began its legal discussion by noting that it reviews de novo a district court’s grant of a motion to dismiss under Rule 12(b)(6). Since the appeal arose from a dismissal under Rule 12(b)(6), all of the factual allegations in the complaint were accepted as true for the purposes of review.

59. Watson, 677 F.3d at 1305.
60. Id.
61. Id. at 1306.
62. Id.
63. Id.
64. Id.
65. Watson, 677 F.3d at 1303.
2. Precedential Cases


The Eleventh Circuit has had several chances to examine the merits of reverse payment agreements, and it began its analysis with its seminal case Valley Drug Co. v. Geneva Pharmaceuticals, Inc.⁶⁶ In Valley Drug, the court reasoned reverse payment settlements present an atypical case, specifically because ownership of a patent means the patent holder has a “lawful right to exclude others” from the market.⁶⁷ Therefore, “the agreements do not necessarily decrease the level of competition in the market.”⁶⁸ In deciding Valley Drug, the court noted that the antitrust implications of a reverse payment settlement must be judged against the “potential exclusionary power” of the patent “as of the time that the settlement was executed.”⁶⁹ The holding in Valley Drug did not exempt reverse payment agreements from antitrust scrutiny.⁷⁰ To wit, the court in Valley Drug held “that parties to a reverse payment settlement should be immune from antitrust liability if the anticompetitive effects of their settlement fall ‘within the scope of the exclusionary potential of the patent.”⁷¹

b. Schering-Plough Corp. v. FTC

After discussing Valley Drug, the court discussed another precedential case, Schering-Plough Corp. v. FTC.⁷² In Schering-Plough, the court reiterated that a patent holder’s right to “cripple competition” made the traditional analysis of an antitrust claim improper when evaluating a reverse payment agreement.⁷³ The

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⁶⁶. Id. at 1306 (citing Valley Drug, 344 F.3d at 1294).
⁶⁷. Id. at 1307.
⁶⁸. Id.
⁶⁹. Id. at 1308 (emphasis added).
⁷⁰. Id.
⁷¹. Watson, 677 F.3d at 1309 (citing Valley Drug, 344 F.3d at 1311). See Schering-Plough Corp. v. FTC., 402 F.3d 1056 (11th Cir. 2005).
⁷². Id.
⁷³. Id. at 1309-10.
proper analysis, "requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."\textsuperscript{74} This court stated that the "essence" of the three-prong analysis is an evaluation of whether the settlement agreements go beyond the scope of the exclusionary potential of the patent.\textsuperscript{75} In \textit{Schering-Plough}, the FTC argued that the defendant "had agreed to pay too much money to settle the case and that the generic companies had agreed to stay off the market for too long."\textsuperscript{76} In rejecting these arguments, the court in \textit{Schering-Plough} emphasized that "the general policy of the law is to favor settlement of litigation."\textsuperscript{77} Further, in light of the cost and complexity of patent litigation,\textsuperscript{78} it should be up to the patent holder to determine the value of its case.

c. Andrx Pharmaceuticals Inc. v. Elan Corp.

Lastly, the court looked to \textit{Andrx Pharmaceuticals, Inc. v. Elan Corp.}\textsuperscript{79} In \textit{Andrx}, the court ruled that plaintiffs had properly pleaded an antitrust claim because the generic manufacturer had agreed to \textit{never} enter the market for that particular drug.\textsuperscript{80} The generic manufacturer in \textit{Andrx} was also allowed to retain its 180-day exclusivity period, despite having no intention to ever market the drug.\textsuperscript{81} Allowing the generic manufacturer in this case to retain the exclusivity period would have acted like a "cork in a bottle" because all other generics would have been blocked from the market.\textsuperscript{82}

\textsuperscript{74} \textit{Id.} at 1310 (citing \textit{Schering-Plough}, 402 F.3d at 1066).
\textsuperscript{75} \textit{Id.}
\textsuperscript{76} \textit{Id.}
\textsuperscript{77} \textit{Watson}, 677 F.3d at 1310-11 (internal quotations omitted).
\textsuperscript{78} \textit{Id.} at 1311.
\textsuperscript{79} \textit{Id.} See \textit{Andrx Pharma., Inc. v. Elan Corp.}, 421 F.3d 1227 (11th Cir. 2005).
\textsuperscript{80} \textit{Id.}
\textsuperscript{81} \textit{Id.}
\textsuperscript{82} \textit{Id.} Other generics would be blocked because the 180-day exclusivity period does not begin to toll until the first ANDA applicant begins commercial marketing of the drug. \textit{See} 21 U.S.C. § 355(j)(5)(B)(iv)(I). Since the generic in
3. Discussion of FTC v. Watson Pharmaceuticals and Affirmation of the District Court’s Ruling

The FTC argued its allegation that Solvay was unlikely to prevail in an infringement action sufficiently stated an antitrust claim “because a patent has no exclusionary potential if its holder is not likely to win the underlying infringement suit.” According to the FTC, if the patent has no exclusionary potential, then any reverse payment settlement excludes too much competition from the market. The FTC urged the Eleventh Circuit to adopt “a rule that an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date.” The Eleventh Circuit declined to re-write its rule and rejected the FTC’s argument because such a rule “equates a likely result . . . with an actual result.” The court held that an antitrust claim cannot be based on the likelihood of a successful infringement action because “likely” includes the possibility of a 51% chance one-way, and a 49% chance the other way. Thus, the court stated, “giving the word its plain meaning, as many as 49 out of 100 times that an infringement claim is ‘likely’ to fail, it actually will succeed and keep the competitor out of the market.” The Eleventh Circuit again repeated that its “decisions focus on the potential exclusionary effect of the patent, not the likely exclusionary effect.”

Further, the court noted that parties often settle a lawsuit to minimize the overall cost of litigation and avoid the possibility of

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Andrx never intended to market the drug, the exclusivity period would have never begun to toll. *Watson*, 677 F.3d at 1311.

83. *Watson*, 677 F.3d at 1312 (emphasis omitted).
84. *Id.*
85. *Id.*
86. *Id.*
87. *Id.*
88. *Id.*
89. *Watson*, 677 F.3d at 1313 (emphasis added).
losing. The court went so far as to note that when both parties have a substantial chance of winning or losing, as would be the case where the probabilities are split 49%-51%, then it is reasonable for the parties to settle. Another reason the court rejected the FTC's argument was based on the fact that parties will be more willing to settle a lawsuit when hundreds of millions of dollars of lost profits are at stake. "[E]ven a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement" if it risked losing millions in profits. Further, the chances of succeeding in patent litigation "rarely exceed seventy percent."

The court also stated that it did not want to make an "after-the-fact" calculation about whether a patent holder would have been likely to succeed if the lawsuit had not been settled. Such after-the-fact calculations would place a heavy burden upon the parties and the courts because making these calculations would undo many of the benefits that a settlement provides, namely avoiding discovery and litigation costs. Moreover, this retroactive examination is likely to be unreliable.

The court also rejected the FTC's argument because Congress has given appellate jurisdiction over patent cases to the Federal Circuit, and the court felt that it "and the other non-specialized circuit courts have no expertise or experience in [patent matters]." The court felt that it would be ill-equipped to make judgments about the merits of a patent infringement claim, which is tantamount to what each appellate court would be forced to do. Such judgments would be in conflict with Congress' decision to

90. Id. The court made a somewhat humorous analogy when it said, "a party likely to win might not want to play the odds for the same reason that one likely to survive a game of Russian Roulette might not want to take a turn." Id.
91. Id.
92. Id.
93. Id.
94. Id.
95. Watson, 677 F.3d at 1313.
96. Id. at 1314.
97. Id.
98. Id. at 1314-15.
99. Id. at 1315.
have all appeals involving patent cases decided by the Federal Circuit.\textsuperscript{100}

Lastly, the court rejected the FTC’s argument that drug manufacturers would rather band together to maintain monopoly profits than compete with each other.\textsuperscript{101} In rejecting this argument, the court reasoned that there are many potential generic manufacturers that will not be bound by the terms of the reverse payment agreement, and may challenge drug patents that are vulnerable.\textsuperscript{102} The court mentioned that there is no way the patent holder will be able to pay every generic manufacturer who makes a paragraph IV certification in its ANDA application.\textsuperscript{103} The court closed its opinion by emphasizing that “what the FTC propose[d was] that we attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment.”\textsuperscript{104} The FTC was essentially asking that a court determine the outcome of a patent case underlying an antitrust case about the settlement of a patent case, a task that the court deemed a “turducken” task.\textsuperscript{105}

\section*{III. Future Implications}

In \textit{FTC v. Watson Pharmaceuticals}, the Eleventh Circuit reemphasized its position that a reverse payment settlement is not contrary to public policy when it does not exceed the potential exclusionary scope of the patent or patents at issue. Other Circuits have considered reverse payment agreements, and multiple opinions have developed as to how these agreements should be

\begin{itemize}
  \item \textsuperscript{100} \textit{Id.} at 1315.
  \item \textsuperscript{101} \textit{Watson}, 677 F.3d at 1315.
  \item \textsuperscript{102} \textit{Id.}
  \item \textsuperscript{103} \textit{Id.}
  \item \textsuperscript{104} \textit{Id.}
  \item \textsuperscript{105} \textit{Watson}, 677 F.3d at 1315. A turducken is a roast dish consisting of a boned chicken inside a boned duck, which is then placed inside a partially boned turkey. \textit{Turducken Definition}, OXFORD DICTIONARIES, http://oxforddictionaries.com/definition/english/turducken (last visited Feb. 28, 2013). The court used this metaphor to illustrate the complexity of situation the FTC was asking the court to undertake when analyzing the reverse payment settlement agreement. \textit{Watson}, 677 F.3d at 1315.
judged. Such diversity of opinion has led the Supreme Court to accept this case for review. The Supreme Court should adopt a holding substantially similar to that of the Eleventh Circuit in an attempt to enhance judicial economy and to protect a pharmaceutical company’s expectation interest. A pharmaceutical company can rely on this bright-line rule, thereby increasing the likelihood that the company will re-invest its profits into other life-saving or life-enhancing research.

A. A Spectrum of Analysis Among the Circuits

A variety of positions have developed in the Circuit Courts, creating a spectrum of analysis regarding reverse payment agreements. At one end of the spectrum, the Eleventh and Second Circuits essentially presume validity of these agreements, looking only to “whether the exclusionary effects of the agreement exceed the scope of the patent’s protection.” The Third Circuit sits in the middle of the spectrum and employs a “quick look” rule of reason analysis based on Congressional statements about the availability of low cost generic drugs during the passage of the Hatch-Watchman Act. Finally, at the opposite end of the spectrum, the Sixth Circuit has gone as far as to say that reverse payment agreements are per se unlawful as “horizontal market allocation agreement[s]” in violation of § 1 of the Sherman Act. Since these drastically different positions on the subject are irreconcilable, the Supreme Court will have to provide its guidance. The Supreme Court’s trend of late has been to move

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109. In re Cardizem CD Antitrust Litigation, 332 F.3d 896, 899 (6th Cir. 2003). The Ninth Circuit has also weighed in, albeit briefly, on the issue of reverse payment settlement agreements when it upheld, without undergoing its own analysis, a district court’s determination that the agreements are per se violations of Section 1 of the Sherman Act. Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc., 552 F.3d 1033, 1042 (9th Cir. 2009).
toward a rule of reason analysis when judging an antitrust claim.\textsuperscript{110} How the Court chooses to deal with the inherent tension between competition and the right to exclude competition will be interesting. Below, this article provides an argument for why the Supreme Court should adopt a rule substantially similar to the same rule adopted by the Eleventh Circuit.

\textbf{B. The Court Should Adopt an Approach Substantially Similar to the Eleventh Circuit's}

The Eleventh Circuit's approach to reverse payment agreements is well-reasoned and takes into account the realities of patents and patent litigation. In doing so, the Eleventh Circuit offers a bright-line rule for patentees: agreements that are within the exclusionary potential of the patent are valid. Given the exclusionary nature of patents and the complexity of patent and antitrust litigation, the Supreme Court should adopt an approach substantially similar to this bright-line rule with a single caveat; the FTC may pursue litigation if it has actual evidence that the patent holder had knowledge that its patent was invalid or would be ruled invalid. It is unclear what type of evidence would be necessary for this determination because any evidence would have to be present before the FTC could enter the discovery phase of litigation—perhaps a statement made in public by a manufacturer's CEO or President about the potential invalidity of its patent would be sufficient. While this type of situation would be exceedingly rare, it would leave open the possibility for the FTC to challenge a reverse payment settlement agreement.

Bright-line rules as a whole are beneficial because they foster consistency throughout the courts and because they alert parties to what is allowed and what is not in the eyes of the law. The Supreme Court has stated that one of the benefits of a bright-line rule is that the rule can provide "clear and unequivocal" guidelines

\footnotesize{\textsuperscript{110} See, e.g., Leegin Creative Leather Prods. v. PSKS, Inc., 551 U.S. 887, 882 (2007); Texaco Inc. v. Dagher, 547 U.S. 1, 5 (2006); State Oil Co. v. Khan, 522 U.S. 3, 10 (1997).}
for handling specific situations. Additionally, the Second Circuit has noted that one of the benefits of a bright line rule is that it is “relatively easy for district courts to apply and avoids protracted litigation and discovery.” However, a bright line rule in this instance could allow a brand name manufacturer to unfairly protect a revenue stream; even if the manufacturer has actual knowledge of a patent’s invalidity.

This small caveat does not remove the substantial benefits that a bright line rule provides in regard to reverse payment agreements used to settle patent infringement litigation. Bright line rules are especially beneficial in the context of pharmaceutical patent litigation due to the high cost of developing a new, FDA-approved drug. In its judicial opinion, the Eleventh Circuit began by noting the high costs that pharmaceutical companies incur when trying to develop a new drug for the market, citing some statistics that show that developing a new drug takes between ten and fifteen years and can cost more than $1.3 billion. That $1.3 billion is, however, only one estimate. Another estimate has large pharmaceutical companies spending $50 billion per year in collective research and development in attempting to discover and develop a new drug, raising the cost for a pharmaceutical company to bring each new drug to the market to around $1.8 billion.

The cost that a pharmaceutical company undertakes in developing a new drug dictates the necessity of applying a bright line rule to reverse payment settlements. The adoption of this rule will give a pharmaceutical manufacturer the assurance that its drug will be protected, at least to the extent that the patent itself

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111. Arizona v. Roberson, 486 U.S. 675, 682 (1988) (discussing the benefits of having a bright line rule in regard to a suspect in custody’s request to speak with counsel before speaking with the police).


113. Watson, 677 F.3d at 1300 (citing Dicket, Orszog & Tyson, supra note 6 at 369, n.10.).

excludes competition. If a pharmaceutical manufacturer has the assurance that its profit-making drug will continue to be profitable, the pharmaceutical manufacturer will re-invest its profits into the research and development of other drugs. These new drugs have the potential to be unprofitable, costing the manufacturer millions, if not billions, of dollars in research and development costs.

In this case, the FTC argued that reverse payment settlements cost consumers about $3.5 billion per year.\textsuperscript{115} However, without the assurances that a manufacturer would be able to protect its profits, perhaps the manufacturer would be less likely to re-invest its money, fearing insolvency if its gold mine patent was ruled invalid.\textsuperscript{116} The pharmaceutical manufacturers in this case essentially made this argument when they claimed that the erosion of patent rights would weaken the incentives for investing in new drug development.\textsuperscript{117} The FTC also argued that reverse payment settlements are against public policy because they protect a drug manufacturer's monopoly rights.\textsuperscript{118} On the contrary, the ruling protects the public interest because it allows pharmaceutical manufacturers to re-invest their profits, knowing that their revenue stream is protected. In the long run, the re-investment of profits can lead to the further development of other lifesaving drugs.

\textbf{IV. CONCLUSION}

This was a test case for the FTC in which it was trying to get the Eleventh Circuit to extend its rule for determining the validity of a reverse payment settlement agreement to include a court's determination of how the underlying patent infringement lawsuit would hypothetically be decided.\textsuperscript{119} The Eleventh Circuit decided not to extend its rule regarding reverse payment settlement agreements and affirmed its previous rule that a reverse payment settlement agreement is valid if (1) "its anticompetitive effects fall within the scope of the exclusionary potential of the patent at

\begin{itemize}
\item 115. \textit{Watson}, 677 F.3d at 1301-02.
\item 116. \textit{ld.} at 1302.
\item 117. \textit{ld.} at 1301.
\item 118. \textit{ld.}
\item 119. \textit{ld.} at 1312.
\end{itemize}
issue” and (2) the determination of the extent of the potential exclusionary scope of the patent shall be made at the time the reverse payment settlement agreement was executed. The Eleventh Circuit’s opinion is one of a number of differing views among the Courts of Appeals. The Supreme Court has granted certiorari in this case to unify the analysis relating to reverse payment agreements. The Court should adopt a position substantially similar to the Eleventh Circuit’s because it provides the benefit of being attached to a bright line rule. As discussed above, bright line rules are beneficial generally because they provide predictability and are easy for district courts to apply to a variety of situations. Furthermore, bright line rules are especially beneficial in the pharmaceutical patent context because they allow a pharmaceutical manufacturer to maximize its profits and re-invest those profits into the development of new technology.

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120. Id. at 1308, 1312.

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