

No. 08-1129

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRTEENTH CIRCUIT**

FEDERAL TRADE COMMISSION,

Plaintiff-Appellant,

v.

NORTON PHARMACEUTICALS,

Defendant-Appellee.

**On appeal from the United States District Court
for the District of Mason**

BRIEF FOR THE APPELLEE

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QUESTIONS PRESENTED

- I. Whether the district court correctly held that the settlement of a patent infringement litigation, including a “reverse payment” in excess of a generic’s attorneys’ fees, that permits a generic’s market entry two years prior to the expiration of the patent, is not “per se” illegal.

- II. Whether the district court correctly held that the settlement, which permits generic entry two years prior to the expiration of the patent, is lawful under a “rule of reason” analysis that focuses solely on whether the settlement terms fall within the scope of the patent, absent evidence of a sham.

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PRELIMINARY STATEMENT

Two pharmaceutical companies, Norton Pharmaceuticals (“Norton”) and QuikClone Laboratories (“QuikClone”), settled a patent infringement suit Norton brought against QuikClone. On April 14, 2007, the Federal Trade Commission (“F.T.C.”) sought a permanent injunction to invalidate the settlement. The F.T.C. and Norton made cross-motions for summary judgment. On October 30, 2008, the United States District Court for the District of Mason denied the F.T.C.’s motion for summary judgment, declining to find the settlement agreement “per se” illegal. Further, the court granted Norton’s motion for summary judgment, finding the settlement to be lawful under a “rule of reason” analysis that focuses solely on whether the settlement terms fall within the scope of the patent, absent evidence of a sham. The F.T.C. now appeals the district court’s decision.

STATEMENT OF FACTS

Introduction

Norton Pharmaceuticals (“Norton”) manufactures and sells Logotor, a patented medicinal palliative for logorrhea. (R. 1, R. 2). QuikClone Laboratories (“QuikClone”) is the generic drug manufacturer of Quiescence, a generic version of Logotor. (R. 1, R. 5, R. 7). On March 1, 2005, QuikClone submitted to the F.D.A. an Abbreviated New Drug Application (“ANDA”) for approval to market Quiescence. (R. 7). On the same day, QuikClone also filed a “Paragraph IV” certification, indicating QuikClone’s intention to begin marketing Quiescence with the F.D.A.’s approval, despite Norton’s patent on Logotor. (R. 5, R. 7). On April 14, 2005, Norton sued QuikClone for patent infringement. (R. 7). Before the district court issued a ruling on the patent litigation, Norton and QuikClone settled the case with a “win-win” compromise, and the infringement suit was dismissed. (R. 7, R. 8, R. 9).

In accordance with the Medicare Prescription Drug Improvement and Modernization Act of 2003, the parties submitted their settlement to the Federal Trade Commission (“F.T.C.”) and the Department of Justice. (R. 9). The F.T.C. then sought a permanent injunction to prevent the settlement, alleging that it violated § 1 of the Sherman Act, 15 U.S.C. § 1. (R. 1, R. 9).

Norton Pharmaceuticals and QuikClone Laboratories

Norton is a brand-name pharmaceutical manufacturer that sells a wide variety of prescription and over-the-counter drugs. (R. 2). Norton’s three patented “blockbuster products,” from which more than half of its revenues derive, are Nogaine for weight control, HeartStart for anti-coronary disease, and Logotor for logorrhea. (R. 2, R. 3, R. 4). Still, Norton is “best known” for Logotor, and the drug’s ability to “control all symptoms of logorrhea.” (R. 1, R. 2).

QuikClone is a generic drug manufacturer that seeks to market its own logorrhea treatment, Quiescence, a generic version and bioequivalent of, Norton’s patented Logotor. (R. 1, R. 5, R. 7).

Logorrhea and Norton’s Patented Logotor

Logorrhea is a mental disease of excessive wordiness, also known as “diarrhea of the mouth.” (R. 1, R. 3). By 1999, the disease had infected universities and legislatures in “epidemic proportions.” (R. 2, R. 3). For example, in 2004, Mason Senator Hubert Hornblower was investigating a bridge collapse in Mason and was expected to interview a key witness. (R. 3). Senator Hornblower spent so much time asking his first question that his witness could not answer, and further discussion was not permitted because the time limit had expired. (R. 3). This incident significantly affected his re-election campaign and he was suddenly trailing in the polls. (R. 3). Soon thereafter, Senator Hornblower announced that he suffered from logorrhea and required a two-week regimen to keep his disease under control. (R. 3, R. 4).

Experts have estimated that as many as 10-15 million other Americans like Senator Hornblower also suffer from logorrhea, resulting in \$1.5 billion of annual deadweight loss. (R. 3, R. 4). In essence, logorrhea is no longer viewed as a mere affectation or personality quirk. (R. 2).

Fortunately, Norton's scientists had researched and developed Logotor as a medicinal palliative for logorrhea. (R. 1). Studies have shown that when taken daily and over a long period of time, Logotor is effective in controlling "all symptoms of logorrhea." (R. 2, R. 3, R. 4).

After demonstrating Logotor's safety and effectiveness in controlling the symptoms of logorrhea, Norton obtained F.D.A. approval of its New Drug Application ("NDA") for Logotor, authorizing the prescription sale of the drug. (R. 2, R. 5). Norton's extensive research and development, at costs of over \$800 million, also enabled Norton to secure a patent for Logotor. (R. 2). The patent on Logotor is valid until January 1, 2014. (R. 2, R. 7, R. 10, R. 11). Norton identified this patent to the F.D.A., which listed it in the publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." (R. 5).

The most commonly prescribed dosage of Logotor is a 20 milligram tablet for \$1. (R. 4, R. 12). For the "seriously verbose," Logotor40 is available for \$1.50. (R. 4). According to a government expert, there is a possibility that following the duration of Norton's patent, the price of a 20 milligram Logotor tablet could be 50 cents, or lower. (R. 12).

Nevertheless, Norton's patent on Logotor remains valid until 2014, and the publicity surrounding Senator Hornblower's affliction with logorrhea gave Logotor's sales and public awareness an "enormous boost." (R. 3, R. 4, R. 7). In particular, after Senator Hornblower actively endorsed Logotor with a public service message, many major insurers began to reimburse for Logotor, and its sales soared to \$1 billion in 2006. (R. 4).

In addition to Logotor, Norton has patented a drug named Blogotor to control the prosequer equivalent of logorrhea: blogorrhea. (R. 4). Norton plans to combine Logotor and Blogotor to control both diseases with a single tablet called STFU. (R. 4). Norton anticipates marketing STFU in 2012. (R. 5).

QuikClone's "Paragraph IV" Certification

On March 1, 2005, in an attempt to copy Norton's innovator drug Logotor, QuikClone sought F.D.A. approval of its generic alternative, Quiescence, by submitting an Abbreviated New Drug Application ("ANDA"). (R. 5, R. 7). Ordinarily, QuikClone would need to show only that Quiescence was a "bioequivalent" of the brand-name, patented Logotor to obtain F.D.A. approval. (R. 5). However, QuikClone's situation is different because Logotor is protected by a patent, and as such, Norton has a legal monopoly on the sale of Logotor. (R. 9). Consequently, QuikClone is prohibited from simply marketing Quiescence upon F.D.A. approval. (R. 6).

Nevertheless, QuikClone did not want to wait until Norton's patent on Logotor expired; indeed, on March 1, 2005, QuikClone infringed Norton's patent by submitting a "Paragraph IV" certification. (R. 6). In submitting its "Paragraph IV" certification, QuikClone claimed that Norton's patent on Logotor was invalid, or alternatively, that QuikClone did not infringe the patent. (R. 6, R. 7). Despite QuikClone's allegations, its "Paragraph IV" certification was still an act of infringement on Norton's patent. (R. 6).

Following the expiration of Norton's patent, as the first to file an ANDA and "Paragraph IV" certification, but "subject to the resolution of the patent litigation," QuikClone could receive six months of generic exclusivity to market Quiescence. (R. 6, R. 7).

The Patent Infringement Suit and the Parties' Impasse

On April 14, 2005, in response to QuikClone's infringement of Norton's patent, Norton sued for patent infringement in the State of Madison. (R. 7). Following discovery, both parties filed cross-motions for summary judgment. (R. 7). Both parties maintained that their respective positions were strong, and indeed, had "reasonable good faith arguments in support of their positions." (R. 8, R. 12).

Specifically, Norton vigorously defended its "clearly valid" patent and asserted that QuikClone had infringed it. (R. 8). Norton's counsel estimated that Norton had a 70% chance of successfully "prevailing on all issues if the case proceeded to judgment." (R. 8, R. 12). Moreover, according to Norton, QuikClone's attempt to enter the market before Norton's patent expired in 2014 was "highway robbery." (R. 8). Still, Norton was willing to allow QuikClone to enter the market on January 1, 2012, two years before Norton's patent expired, and when Norton estimated it would start marketing STFU to consumers. (R. 8, R. 10).

As for QuikClone, it continued to protest Norton's patent validity, or alternatively, deny any infringement on Norton's patent. (R. 8). QuikClone also maintained that its chance of success on at least one of its claim was 60%. (R. 8). QuikClone further insisted that it needed to market Quiescence by January 1, 2010 in order to produce some cash flow to satisfy its lenders. (R. 8). Thus, the parties were at a "seeming impasse." (R. 8).

The Parties' Settlement

At this "seeming impasse," the parties agreed to a "win-win" compromise. (R. 8, R. 9). Specifically, Norton agreed to allow QuikClone to begin marketing Quiescence on January 1, 2012 "without objection from Norton" even though Norton's patent on Logotor would not expire until two years later on January 1, 2014. (R. 7).

The parties attempted to settle without any payment from Norton to QuikClone, but according to witnesses from both parties, this was “impossible” because both parties maintained that their positions were strong and had “good faith arguments.” (R. 8, R. 12).

Accordingly, the settlement provided that Norton would pay QuikClone \$150 million “for attorney fees and various opportunity costs attendant to settlement,” though concededly, QuikClone’s fees and costs were no more than \$2 million. (R. 7, R. 8). The payment also includes “the after-tax profits QuikClone might stand to realize from entry in 2010 rather than 2012.” (R. 8). The F.T.C. seeks to invalidate the parties’ mutually agreeable settlement. (R. 9).

District Court’s Decision

On October 30, 2008, the Honorable Sterling Prattle rejected the F.T.C.’s position that a “settlement involving reverse payments by a monopoly patent holder in excess of a generic challenger’s fees is per se illegal,” and denied the F.T.C.’s summary judgment motion. (R. 11, R. 13). Judge Prattle recognized that “an agreement that allows competition within the scope of the patent may actually be procompetitive” and a “hard and fast” “per se” rule prohibiting “reverse payments” in excess of a generic’s attorneys’ fees “would be too extreme.” (R. 10, R. 11).

Having rejected the F.T.C.’s position that the parties’ agreement is “per se” illegal, Judge Prattle also favored Norton’s position that a settlement such as Norton’s and QuikClone’s is lawful if it falls within the “scope” or “exclusionary zone” of the patent, and is not a sham. (R. 11, R. 12). Judge Prattle ruled that those criteria are satisfied in this case, as the F.T.C. also concedes. (R. 12). Judge Prattle also declined to determine the validity and enforceability of Norton’s patent because such an inquiry would be too imprecise, and would effectively defeat the purpose of a good faith settlement. (R. 12). Accordingly, the court granted Norton’s motion for summary judgment. (R. 12).

STANDARD OF REVIEW

The “identification of governing legal standards and their application to the facts found” is a question of law, which appellate courts review *de novo*. See *F.T.C. v. Ind. Fed. of Dentists*, 476 U.S. 447, 455 (1986). As such, this Court should review *de novo* the district court’s denial of the F.T.C.’s motion for summary judgment on the issue of the applicability of a “per se” rule. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Cipro I), 544 F.3d 1323, 1330 (Fed. Cir. 2008). Likewise, this Court should review *de novo* the district court’s grant of Norton’s motion for summary judgment on the issue of the applicability of the specified “rule of reason” analysis. See *id.*

SUMMARY OF ARGUMENT

“Per se” illegality is inapplicable for a patent infringement litigation settlement in the context of the Hatch-Waxman Act because no pattern or experience demonstrates that such an agreement is obviously or manifestly anti-competitive. Furthermore, the pro-competitive effects of such an agreement, and the long-standing policies of favoring settlement and pharmaceutical innovation further highlight the inappropriateness of “per se” illegality. Therefore, the district court correctly held that the settlement agreement between Norton and QuikClone, including a “reverse payment” in excess of QuikClone’s attorneys’ fees, is not “per se” illegal.

In addition, as a result of the settlement, Norton did not receive any competitive advantage beyond that granted to it by its presumptively valid patent on Logotor. In fact, the settlement allowed QuikClone to enter the market with its generic version of Logotor, Quiescence, two years prior to the expiration of Norton’s patent. As such, the agreement fell well within the scope of the patent. Furthermore, this Court should not temper the exclusionary zone of the patent on the basis of the parties’ subjective evaluations of the patent litigation because such an approach would be too uncertain, and would discourage settlement and innovation. Thus, the district court also correctly held that the settlement between Norton and QuikClone is lawful under a “rule of reason” analysis that focuses solely on whether the settlement terms fall within the scope of the patent, absent evidence of a sham.

ARGUMENT

- I. THE DISTRICT COURT CORRECTLY HELD THAT THE SETTLEMENT OF A PATENT INFRINGEMENT LITIGATION, INCLUDING A “REVERSE PAYMENT” IN EXCESS OF A GENERIC’S ATTORNEYS’ FEES, THAT PERMITS A GENERIC’S MARKET ENTRY TWO YEARS PRIOR TO THE EXPIRATION OF THE PATENT, IS NOT “PER SE” ILLEGAL.

An antitrust inquiry ultimately aims to “form a judgment with respect to the competitive significance” of restraints on trade, condemning only those that are “unreasonable.” *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997); *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1063 (11th Cir. 2005); *see also Cal. Dental Assoc. v. F.T.C.*, 526 U.S. 756, 779-80 (1999) (“the essential [antitrust] inquiry is . . . whether or not the challenged restraint enhances competition.”); *Nat’l Coll. Athletic Ass’n v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 104 (1984) (“criterion . . . in judging the validity of a restraint on trade is its impact on competition.”). In forming this judgment, a court may find a restraint to be unreasonable because it is categorically “per se” unreasonable or because it violates the “Rule of Reason.” *Ind. Fed’n of Dentists*, 476 U.S. at 457; *see also Capital Imaging Assoc., P.C. v. Mohawk Valley Med. Assoc., Inc.*, 996 F.2d 537, 542 (2d Cir. 2003) (explaining that a plaintiff must show an “agreement constituted an unreasonable restraint of trade either per se or under the rule of reason”). However, most courts reject a “per se” rule and “presumptively apply a ‘rule of reason’ analysis” *Cipro I*, 544 F.3d at 1331; *see also Khan*, 522 U.S. at 10 (“most antitrust claims are analyzed under a ‘rule of reason[.]’ . . .”).

Indeed, “[t]he area of per se illegality is carefully limited.” *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 178 (1965); *see also In re Ciprofloxacin Hydrochloride Antitrust Litig. (Cipro II)*, 261 F. Supp. 2d 188, 232 (E.D.N.Y. 2003) (“a majority of cases fall outside these narrow, carefully demarcated categories held to be illegal per se.”).

More specifically, a “per se” rule is inapplicable unless “experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it.” *In re Cardizem CD Antitrust Litig.* (Cardizem I), 332 F.3d 896, 906 (6th Cir. 2003); *see also Broad. Music Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 19-20 (1979) (“[O]nly after considerable experience with certain business relationships [will] courts classify them as *per se* violations”); *Cipro II*, 261 F. Supp. 2d at 232 (explaining that certain categories of restraints like horizontal price-fixing, market divisions, tying and group boycotts are “per se” illegal only because they “reflect judicial experience with a particular type of conduct under the rule of reason”). As such, the “per se” rule is invoked only “where a defendant’s actions are so plainly harmful to competition and so obviously lacking in any redeeming pro-competitive values that they are ‘conclusively presumed illegal without further examination.’” *Capital Imaging*, 996 F.2d at 542; *see also In re Tamoxifen Citrate Antitrust Litig.* (Tamoxifen), 466 F.3d 187, 202 n.13 (2d Cir. 2006) (explaining that unless conduct has “such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit” a “per se” rule is inappropriate). In any event, once a “per se” rule broadly condemns an entire category of restraints, any individual antitrust inquiry no longer considers the actual effect of a particular restraint. Accordingly, a recognized cost of the “per se” rule is condemning certain pro-competitive agreements, within that category, that the “rule of reason” would allow. *See Cardizem I*, 332 F.3d at 907 n.11; *In re Terazosin Hydrochloride Antitrust Litig.* (Terzaosin), 352 F. Supp. 2d 1279, 1311 (S.D. Fla. 2005). Thus, unless enhanced competition is so unlikely to ever be significant, a “per se” rule is generally improper. *See Cardizem I*, 332 F.3d at 909.

In contrast, under the more searching and widely-used “rule of reason,” an inquiry is made as to whether a restraint “merely regulates and perhaps thereby promotes competition, or

whether it is such as may suppress or even destroy competition.” *Terazosin*, 352 F. Supp. 2d at 1312. This analysis gives proper consideration to each restraint’s actual competitive significance, adhering to antitrust law’s command that only “unreasonable restraints” be condemned. Indeed, in the “general run of cases a plaintiff must prove an antitrust injury under the rule of reason.” *Capital Imaging*, 996 F.2d at 543.

In this case, the agreement is the settlement of a patent infringement litigation, including a “reverse payment,” in the context of the complex statutory scheme, the Hatch-Waxman Act. The agreement effectively protects Norton’s patent rights and allows a generic to enter the market two years prior to the expiration of Norton’s patent on Logotor. Therefore, the agreement is not manifestly anticompetitive, but rather likely pro-competitive and beneficial to consumers. Necessarily, then, a settlement that includes a “reverse payment,” in excess of a generic’s attorneys’ fees, such as the agreement between Norton and QuikClone, is not “per se” illegal.

A. As a “delicate balance” is necessary to suitably accommodate the two competing policies of patent law and antitrust law, and patent litigation settlements including “reverse payments” in the context of the Hatch-Waxman Act remain a “vexing topic,” “per se” antitrust liability is improper.

A significant tension exists between antitrust and patent law because while antitrust law regulates unreasonable restraints, patent law “grants an innovator ‘the right to exclude others from making, using, offering for sale, or selling the [patented] invention . . .’ for a limited term of years.” *Tamoxifen*, 466 F.3d at 201-02; *see also* 35 U.S.C. § 154(a)(1) (2002) (“Every patent shall . . . grant to the patentee . . . the right to exclude others from making, using, offering for sale, or selling the invention.”); *United States v. United Shoe Mach. Co.*, 246 U.S. 32, 57 (1918) (recognizing that patent law “confers on the patentee ‘the right to exclude others . . .’”). Indeed, it is this tension, as complicated by the Hatch-Waxman Act, that underlies this appeal. *See Tamoxifen*, 466 F.3d at 202. Thus, “[a] suitable accommodation between antitrust law’s free

competition aim and the patent regime's incentive system . . ." is required, as opposed to an antitrust regime that fails to accord due weight to a patentee's right to exclude. *See Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1307 (11th Cir. 2003).

More specifically, although Congress hoped to increase the availability of generic drugs through the Hatch-Waxman Act, it also intended to continue protecting the patent rights of pioneer applicants. *See Andrx Pharm., Inc. v. Biovail Corp. Int'l, Inc.*, 256 F.3d 799, 802 (D.C. Cir. 2001). Thus, patent litigation settlements in the context of the Hatch-Waxman Act are not mere horizontal restraints of trade; rather, courts "must recognize the exclusionary rights conferred by patents, and protect them to promote innovation." *Tamoxifen*, 466 F.3d at 202. Necessarily, then, a "delicate balance" must be drawn between patent and antitrust law such that the competitive effects of a patent litigation settlement are meaningfully evaluated and not deemed "per se" illegal based solely on the presence or size of a "reverse-payment." *See id.* at 206; *see also Valley Drug*, 344 F.3d at 1304 (declining to condemn these agreements as "per se" illegal because such a characterization is "premature without further analysis . . .").

Indeed, the Hatch-Waxman Act "redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude." *Tamoxifen*, 466 F.3d at 207; *see also Cipro II*, 261 F. Supp. 2d at 251-52 (explaining that because of the statutory scheme, consideration flows from the patent-holder to the challenger, not vice-versa). Specifically, a settlement including a "reverse payment" should not be "per se" illegal because Norton was forced to mount an infringement suit in which it had no damages to bargain with, and faced the enormous risk of losing its patent protection, while QuikClone faced minimal loss and a huge potential windfall. *See Valley Drug*, 344 F.3d at 1309. Accordingly, it is evident that in the context of the Hatch-Waxman Act, "patents, payments and settlements are . . . all symbiotic components that must

work together for the larger abstract to succeed.” *Schering-Plough*, 402 F.3d at 1074. Significantly, it is recognized that these settlements are indeed a “natural by-product of the Hatch-Waxman process.” *Tamoxifen*, 466 F.3d at 208 (noting that “suspicion” about payments to generics “abates” because they are a by-product of incentives and risks of Hatch-Waxman). Certainly, then, while that recognition does not imply a presumption of legality, the opposite extreme of “per se” illegality is likewise improper.

Moreover, courts do not have the requisite experience with this particular type of agreement to predict with confidence that, even with “reverse payments” of a particular size, it will be condemned by the “rule of reason.” *See Cardizem I*, 332 F.3d at 906. Specifically, this agreement is not a mere *market allocation* or *horizontal price-fixing* restraint, but rather is a *settlement* agreement in a complex and “novel area” of the Hatch-Waxman Act. *See id.* at 908. As such, the competitive effects of the settlement agreement between Norton and QuikClone, including a “reverse payment,” are not “intuitively obvious,” and accordingly, the agreement should not be condemned as “per se” illegal. *See Cal. Dental Ass’n.*, 526 U.S. at 757.

B. As no pattern or experience demonstrates that a settlement, such as that between Norton and QuikClone, is obviously or manifestly anti-competitive, and any anti-competitive effects alleged are merely hypothetical, the settlement is not “per se” illegal.

A settlement agreement, such as that between Norton and QuikClone, is not “per se” illegal because it is not obviously or “manifestly anti-competitive.” *See Consultants & Designers, Inc. v. Butler Serv. Group Inc.*, 720 F.2d 1553, 1561 (11th Cir. 1996); *see also Cont’l T.V. Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 50 (1977) (“Per se rules of illegality are appropriate only when they relate to conduct that is manifestly anticompetitive.”); *Schering-Plough*, 402 F.3d at 1064 n.11 (noting that a “per se” rule is applicable only when the “class of restraint is manifestly anti-competitive”). Significantly, “[o]nly if a patent settlement is a device for

circumventing antitrust law is it vulnerable to an antitrust suit.” *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 992 (N.D. Ill. 2003). Here, the agreement aimed to – and successfully did – settle a patent infringement litigation, and promoted earlier generic competition. In essence, the settlement was “merely an attempt to enforce patent rights,” and not to “bolster the patent’s effectiveness in inhibiting competitors” *Cardizem I*, 332 F.3d at 908; *see also Schering-Plough*, 402 F.3d at 1073 (limiting the products subject to the agreement demonstrates an “effective narrowness”). Therefore, because no pattern or experience demonstrates that the settlement of a patent infringement litigation, such as the one between Norton and QuikClone, is “manifestly anti-competitive,” or has any *actual* anti-competitive effects, beyond that granted by a presumptively valid patent, it should not be “per se” illegal.

1. No pattern or experience demonstrates that a settlement, such as that between Norton and QuikClone, including a “reverse payment,” is obviously or manifestly anti-competitive, and thus, it is facially improper to condemn it as “per se” illegal.

The agreement between Norton and QuikClone is merely ancillary to the legitimate transaction of settling a valid patent litigation, and as such, is “exempt from the per se rule.” *See Andrx Pharm.*, 256 F.3d at 814-15. Indeed, the more appropriate analysis of such settlement provisions may “depend on the nature of the provision challenged.” *Valley Drug*, 344 F.3d at 1313. Here, Norton’s presumptively valid patent does not expire until January 1, 2014, granting Norton the lawful right to exclude QuikClone from producing an infringing version of Logotor. (R. 7, R. 10, R. 11). Furthermore, the agreement does not extend the patent beyond its grant. Thus, it is not “manifestly anticompetitive” and should be exempt from “per se” illegality.

In *Cardizem*, an interim settlement between a patent-holder and a generic “restrained [the generic] from marketing non-infringing or potentially non-infringing versions of Cardizem” in addition to infringing versions, producing anti-competitive effects beyond the “exclusion zone of

the patent.” *In re Cardizem CD Antitrust Litig.* (Cardizem II), 105 F. Supp. 2d 682, 699 (E.D. Mich. 2000). The agreement also included a restraint on the generic from relinquishing its 180-day exclusivity period under the Hatch-Waxman Act. *Id.* Accordingly, the settlement was not merely an “attempt to enforce patent rights,” but rather was a horizontal agreement to eliminate competition beyond that permitted by a patent-holder’s patent. Thus, the court deemed it to be “a classic example of a *per se* illegal restraint of trade.” *Cardizem I*, 332 F.3d at 908.

In contrast, in *Cipro I*, the patent-holder, Bayer, paid Barr to temporarily not manufacture a generic version of Bayer’s patented drug. *Cipro I*, 544 F.3d at 1329. Bayer also agreed to allow Barr to sell its generic version at least six months before Bayer’s patent expired. *Id.* The Court found that there was no basis to “confidently predict” that the agreement would be unlawful under the “rule of reason,” and declined to adopt “*per se*” illegality. *Id.* at 1332. Similarly, in *Tamoxifen*, a patent-holder, Zeneca, paid a generic, Barr, \$21 million and gave it a license to sell the brand-name drug under Barr’s label. In return, Barr agreed not to market its generic version until Zeneca’s patent *completely* expired. *Tamoxifen*, 466 F.3d at 193-94. Moreover, Zeneca’s payment to Barr was “more than either party anticipate[d] the manufacturer would earn by winning the law suit and entering the newly competitive market” *Id.* at 208. Still, the Court declined to find the agreement “*per se*” illegal. *Id.* at 206.

Here, the settlement permits QuikClone to enter the market with its generic alternative two years prior to the end of Norton’s patent. (R. 7). This is an even earlier market entry allowance than in *Cipro I* and *Tamoxifen*, which permitted the generic to enter six months prior to the patent expiration, or only after the patent expired, respectively. Furthermore, the payment from Norton to QuikClone, in addition to attorneys’ fees, reflects merely “after-tax profits

QuikClone might stand to realize from entry in 2010 rather than 2012” (R. 8), unlike in *Tamoxifen*, where payment was more than what the generic expected to earn if it won the suit.

In addition, in contrast to *Cardizem I*, this settlement merely precludes QuikClone from marketing Quiescence before the agreed upon entry date, rather than other non-infringing products as well. As such, the agreement merely allows Norton to exercise its lawful right to exclude QuikClone from profiting from its patented invention, and gives Norton no advantage beyond that granted by its presumptively valid patent. *See Schering-Plough*, 402 F.3d at 1073 (recognizing that “no other products were delayed by the ancillary restraints contained in the agreements”); *see also Cipro I*, 544 F.3d at 1333 (upholding agreements that merely excluded a generic from profiting from the patented product). Moreover, like in *Cipro I*, there is no evidence that the settlement prevented future challenges by other generics on the validity of Norton’s patent, further underscoring the lack of anti-competitive effects beyond that granted by Norton’s patent. *See Cipro I*, 544 F.3d at 1334. Finally, unlike in *Cardizem I*, the agreement at issue does not preclude QuikClone from relinquishing its claim to the 180-day exclusivity period. As such, the agreement leaves open the possibility for other generics to enter the market earlier upon F.D.A approval. Accordingly, unlike in *Cardizem I*, an agreement such as Norton’s and QuikClone’s is not a naked horizontal restraint; rather, Norton is merely “seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly” over Logotor. *See Tamoxifen*, 466 F.3d at 208-09. Thus, the fact that the settlement temporarily insulated Norton from QuikClone is itself not an antitrust violation, and thus, not “per se” illegal. *See Cipro I*, 544 F.3d at 1334.

Furthermore, because of the nature of patent infringement suits in the context of the Hatch-Waxman Act, in that Norton has no damages from QuikClone to bargain with, a

settlement is not obviously anti-competitive merely because it includes a “reverse payment” in excess of attorneys’ fees. *Schering-Plough*, 402 F.3d at 1074 (“A sizable exclusion payment . . . is not unexpected . . . where the relative risks of litigation are redistributed.”). Specifically, because of Norton’s presumptively valid patent on Logotor and its corresponding lawful right to exclude QuikClone, it is simply “not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit . . .” *Id.* at 1073; *Valley Drug*, 344 F.3d at 1390. In *Schering-Plough*, the F.T.C. proposed a limit of a \$2 million payment for a generic’s litigation costs. However, the Court found this arbitrary allowance to be “naïve.” *Schering-Plough*, 402 F.3d at 1075. In particular, patent litigation and settlement, “breed[] a litany of direct and indirect costs” which accrue because of “uncompromising legal positions, differing strategic objectives, heightened emotions, lawyer incompetence or sheer moxie.” *Id.*

Similarly, here, although the F.T.C.’s arbitrary stance on “reverse payments” is not as narrow as in *Schering-Plough*, it still fails to take into account many other costs a firm may have in settling. By proposing to pre-maturely condemn any settlement with a payment in excess of attorneys’ fees as illegal, the F.T.C. fails to acknowledge that “litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public . . .” and costs may certainly exceed a generic’s mere attorneys’ fees. *See id.* at 1073. Indeed, all of QuikClone’s costs associated with partially litigating and ultimately settling a suit must be properly considered, and “per se” illegality because a “reverse payment” exceeds an arbitrary limit is “naïve.” Finally, Norton’s payment to QuikClone to delay its entry – not preclude indefinitely – was merely “subordinate and collateral in the sense that it served to make the main transaction” of settling its patent litigation and enforcing its presumptively valid patent right “more effective in accomplishing its purpose.” *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d

210, 224 (D.C. Cir. 1986). Therefore, because a settlement with a “reverse payment” in excess of a generic’s attorneys’ fees, such as the agreement between Norton and QuikClone, is not manifestly anti-competitive, it cannot be condemned as “per se” illegal.

2. Any anti-competitive effects alleged are merely hypothetical, and thus, a settlement such as that between Norton and QuikClone does not warrant “per se” antitrust liability.

Merely hypothetical anti-competitive effects do not render a restraint “per se” illegal; rather, the effects must be actually anti-competitive. *See Schering-Plough*, 402 F.3d at 1072 (citation omitted); *see also Capital Imaging*, 996 F.2d at 543 (“plaintiff bears the initial burden of showing that the challenged action has had an *actual* adverse effect on competition”). In this case, the F.T.C. contends that because of the settlement, “generic alternatives to Logotor are *likely* to enter the market at a later date than had the settlement not occurred” (R. 2) (emphasis added). However, Norton has a presumptively valid patent on Logotor that gives it the right to exclude QuikClone. As such, any alleged anti-competitive effects beyond that granted by Norton’s patent are merely hypothetical. Thus, the settlement cannot be “per se” illegal.

In this case, Norton has predicted it has a 70% chance of “prevailing on all issues” if the infringement suit was fully litigated and resolved. (R. 8, R. 12). This estimate and the fact that QuikClone has challenged the validity of Norton’s patent does not mean that the patent should be deemed effectively invalid; rather “[e]ven if large reverse payments indicate a patent holder’s lack of confidence in its patent’s strength or breadth, we doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder’s fear of losing it.” *Tamoxifen*, 466 F.3d at 201. Indeed, “[t]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case.” *Asahi Glass*, 289 F. Supp. 2d at 992. More significantly, even a patent owner confident in its position will tend to estimate its likelihood of prevailing to be no greater than

70%. *See Cipro II*, 261 F. Supp. 2d at 208; *see also Tamoxifen*, 466 F.3d at 206 (“plaintiff often will have an incentive to pay the defendant not to enter . . . regardless of whether the former expects to win at trial . . . ‘suggest[ing] that reverse payments should not be per se illegal’”).

Moreover, as no one can prove in advance how litigation will turn out, “no one can be *certain* that he will prevail in a patent suit[.]” and courts should not speculate about such outcomes. *See Asahi Glass*, 289 F. Supp. 2d at 992 (emphasis in original); *see also Whitmore v. Ark.*, 495 U.S. 149, 159-60 (1990) (“It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case.”). Significantly, in *Tamoxifen*, a patent-holder’s patent had been declared invalid by a lower court, but the Court still declined to strip the patent of its presumptive validity and speculate on how an appeals court might rule. *Tamoxifen*, 466 F.3d at 203-04. Here, no court has ever ruled Norton’s patent to be invalid, or that QuikClone’s Quiescence is not an infringing product. As such, the mere fact that QuikClone has mounted a challenge does not render the patent invalid, or the non-infringement claim valid. Rather, Norton retains its presumptive right to exclude QuikClone, and as such, the settlement agreement has no actual anti-competitive effect beyond that granted by Norton’s patent and resulting legal monopoly.

Furthermore, that it has been speculated that after Norton’s – or any other brand-name manufacturer’s – patent expires, the price of the patented drug could drop, does not render such a settlement agreement “per se” illegal. (R. 12). Specifically, Norton’s patent remains valid until January 1, 2014, and as such, it gives Norton a legal monopoly over selling Logotor at its current price. Significantly, there is authority that a “patent holder might actually *raise* the price on its branded product, rather than lower it in response to generic competition.” *Tamoxifen*, 466 F.3d at 210 n.23 (emphasis in original) (citation omitted). This possibility further underscores the fact

that the F.T.C.'s allegations of anti-competitive effects are purely hypothetical, and that such a settlement should not be "per se" illegal.

Finally, the "reverse payment" at issue did not necessarily lessen competition any more than if no settlement had resulted, or if the settlement had not included the payment. *See id.* at 211. Essentially, "if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent[.]" if not more, since Norton's patent is valid until January 1, 2014. *Asahi Glass*, 289 F. Supp. 2d at 994. Alternatively, despite a patent-holder's confidence in its patent, it may still be adamant about settling to avoid litigation. Similarly, despite a generic's confidence in its position, it may also wish to settle rather than endure the uncertainty of a lawsuit. Thus, even under the F.T.C.'s proposition, a patent-holder could simply pay the generic the maximum amount permitted, and "the resulting level of competition, and its benefit to consumers, would [be] the same." *Tamoxifen*, 466 F.3d at 211. Accordingly, the F.T.C.'s allegations of anti-competitive effects are merely hypothetical, not actual, obvious or manifest, and as such, the settlement cannot be condemned as "per se" illegal.

C. The likely pro-competitive effects of such an agreement, and the policies of favoring settlements, reducing barriers to entry and encouraging innovation, further highlight the inappropriateness of "per se" illegality.

The Supreme Court has explicitly endorsed parties' right to exchange consideration to settle patent litigation, recognizing the potential pro-competitive effects. *See Standard Oil Co. v. United States*, 283 U.S. 163, 170-71 n.5 (1931). Indeed, whether a Hatch-Waxman Act settlement "promotes the public's interest depends on the facts," thereby acknowledging that a "per se" rule is inappropriate. *See Tamoxifen*, 466 F.3d at 226 (Pooler, J., dissenting). Here, because of the recognized likely pro-competitive effects of such a settlement agreement, as between Norton and QuikClone, it should not be condemned as "per se" illegal.

As an initial matter, the “general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.” *Asahi Glass*, 289 F. Supp. 2d at 994. More specifically, settlement of patent infringement litigation including exchange of consideration is simply not prohibited by the Sherman Act, despite “some adverse effects on competition.” *Cipro I*, 544 F.3d at 1333 (citation omitted). In this case, Norton and QuikClone’s settlement terminated the costly and complex litigation completely. This benefitted consumers by preserving funds of brand-name and generic manufacturers, whose litigation costs would have been ultimately transferred to consumers. Accordingly, terminating the litigation by settling “ultimately [led] to more intense competition” and benefitted consumers in the long run. *See Schering-Plough*, 402 F.3d at 1073. Therefore, a “per se” rule against a settlement based on mere size of a “reverse payment” would severely limit these likely pro-competitive effects.

In *Schering-Plough*, following mediation resulting in “nothing more than an impasse,” a patent-holder settled with a generic for \$10 million in excess of the generic’s legal costs, and the generic could enter three years before the expiration of the branded manufacturer’s patent. *Id.* at 1060-61. The Court concluded that even with the “reverse payment,” there was “no broad provision” that detracts from the efficiency of settlement. *Id.* at 1073. Rather, the public may benefit from a new rival before expiration of the patent, and the resulting increase in production and innovation. *See id.* at 1075. Accordingly, the mere presence or size of a “reverse payment” was not itself an antitrust violation. *Id.*

Similarly, here, the agreement between Norton and QuikClone has the pro-competitive effect of allowing QuikClone’s market entry two years prior to the expiration of Norton’s patent. Although the F.T.C. contends this assertion is unwarranted given QuikClone’s challenge, even a patent-holder with a strong legal position has incentive to make “reverse payments,” especially if

it is particularly risk averse. To be sure, it may be difficult to distinguish between desirable pro-competitive payments resulting from risk aversion, and those made solely to exclude. However, “per se” illegality is not favored in such a situation. Indeed, a “per se” rule would only result in mistaken inferences and false condemnations, which are “especially costly, because they chill the very conduct the antitrust laws are designed to protect.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). Thus, to ensure against these false condemnations, the settlement should not be condemned “per se” illegal based solely on the size of a payment.

In addition, Norton’s plan to market STFU in 2012 further highlights the pro-competitive effects of the settlement. Specifically, QuikClone’s early entry date coincides with Norton’s estimated initial STFU marketing period. (R. 5). Thus, consumers will be presented with two new products simultaneously, stimulating vigorous competition between two new logorrhea treatments. (R. 5). Without QuikClone’s early entry, Norton would have introduced STFU with no competition, and QuikClone’s attempt to compete two years later would be rendered futile.

Moreover, generics equipped with more options to settle with patent-holders will have a greater incentive to challenge patents and negotiate earlier entry dates in the first place. This will ultimately reduce barriers to entry imposed by patents, and achieve the necessary “delicate balance” between patent law and antitrust law. On the other hand, “[a] ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger’s settlement options should he be sued for infringement, and so might well be thought anti-competitive” because of the decreased consumer access to generic products. *See Asahi Glass*, 289 F. Supp. 2d at 994.

Further, by eliminating costly litigation risks, these settlements also facilitate innovation – a recognized pro-competitive effect – by providing certainty over patent rights. Without the

option of paying a potential infringer to settle, parties may be hesitant to further develop or market a product because of the uncertainty of litigation. *Schering-Plough*, 402 F.3d at 1075 (“The caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer’s ability to research, develop and market the patented product or allegedly infringing product.”). Significantly, although generic products may save money, these products cannot exist unless a brand-name product is first developed. Thus, a brand-name firm like Norton must have the flexibility to confidently protect its patented products to make further innovation a worthwhile endeavor. This need to promote innovation is especially pronounced in this case because of the extent to which logorrhea has infected society. (R. 2, R. 3). Thus, it is imperative that Norton and other brand-name manufacturers have the incentive to continue with enormous investments in other drugs in order to help consumers. (R. 2). Indeed, such an ancillary restraint that facilitates productive and innovative behavior is not unlawful “per se.” *See Andrx Pharm.*, 256 F.3d at 810.

Finally, courts simply do not have the prerogative to insist that a firm alter its course of business simply because another approach may yield more competition. *See Verizon Commc’n Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004). Here, Norton and QuikClone tried to settle without payment, but QuikClone was concerned its financial position would not allow it to sustain operations until 2012 without some cash flow. (R. 8). Thus, it was necessary for Norton to provide some payment to facilitate the settlement, and more importantly, for QuikClone to remain a potential competitor in the future. Necessarily, then, these settlements likely include the significant pro-competitive effects of enhancing productivity and innovation, and as such, cannot be condemned as “per se” illegal.

II. THE DISTRICT COURT CORRECTLY HELD THAT THE SETTLEMENT, WHICH PERMITS GENERIC ENTRY TWO YEARS PRIOR TO THE EXPIRATION OF THE

PATENT, IS LAWFUL UNDER A “RULE OF REASON” ANALYSIS THAT FOCUSES SOLELY ON WHETHER THE SETTLEMENT TERMS FALL WITHIN THE SCOPE OF THE PATENT, ABSENT EVIDENCE OF A SHAM.

Although the Sherman Act provides that “every contract . . . in restraint of trade or commerce . . . is declared to be illegal[.]” 15 U.S.C. § 1 (2004), the Supreme Court “has long recognized that Congress intended to outlaw only unreasonable restraints.” *Khan*, 522 U.S. at 10. Furthermore, courts will presumptively apply a “rule of reason” analysis, under which “the plaintiff bears the initial burden of proving that the agreement has had an actual anti-competitive effect on the relevant market.” *Texaco, Inc. v. Dagher*, 547 U.S. 1, 5 (2006); *Clorox Co. v. Sterling Winthrop, Inc.*, 117 F.3d 50, 56 (2d Cir. 1997).

Significantly, however, it is also well-recognized that “a patent-holder does not run afoul of the Sherman Act unless the patent-holder acts beyond the confines of the patent monopoly.” *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) (citation omitted). Indeed, “a patent by its very nature is anticompetitive” and any adverse anti-competitive effects within the scope of a firm’s patent “[can]not be redressed by antitrust law.” *See Cipro I*, 544 F.3d at 1333. Accordingly, if the settlement of a patent infringement litigation falls within the scope of the patent and there is no evidence of sham, the agreement has no actual anti-competitive effect beyond that granted by the patent. As such, it is exempt from antitrust liability. *See id.*; *Tamoxifen*, 466 F.3d at 201-02; *Schering-Plough*, 402 F.3d at 1066. Moreover, “the validity of the patent need not be considered in the analysis of whether the settlement agreement violates the antitrust laws unless the infringement suit was objectively baseless.” *Cipro I*, 544 F.3d at 1336. In this case, there is no evidence that the patent infringement lawsuit was objectively baseless, or a sham. The settlement also falls well within the scope of Norton’s patent on Logotor. Thus, the agreement between Norton and QuikClone is lawful under a “rule of reason” analysis that

focuses solely on whether the settlement, absent evidence of a sham, falls within the scope of Norton's patent.

A. The litigation between Norton and QuikClone was not a sham because Norton had a good faith argument that QuikClone's generic Quiescence infringed Norton's patent on Logotor, and there is no evidence that Norton's patent is invalid.

If a patent is properly procured and a suit for its enforcement is not objectively baseless, "there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." *Tamoxifen*, 466 F.3d at 213. Significantly, "a properly granted patent is presumed to be valid and thus entitles the patentee to "exclude those who infringe on the product." *Schering-Plough*, 402 F.3d at 1068. Furthermore, litigation to enforce that presumptively valid patent cannot be considered a sham if "a reasonable litigant could realistically expect success on the merits." *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993); *GP Indus., Inc. v. Eran Indus., Inc.*, 500 F.3d 1369, 1374 (Fed. Cir. 2007). Here, because Norton's patent has never been ruled invalid, and it had a good faith argument that QuikClone's Quiescence would infringe the patent, Norton's suit against QuikClone to enforce its patent was not objectively baseless so to constitute a sham. *See Tamoxifen*, 466 F.3d at 213.

In *Tamoxifen*, the court found that the patent infringement litigation was not a sham because the "plaintiffs [could] not . . . establish that Zeneca's patent litigation was baseless" in light of subsequent decisions upholding the patent's validity. *Id.* Similarly, in *Schering-Plough*, the court noted that "there ha[d] been no allegation that . . . the infringement suits . . . were 'shams' . . ." and that "without any evidence to the contrary, there is a presumption that the patent is a valid one." *Schering-Plough*, 402 F.3d at 1068.

In this case, as in *Tamoxifen* and *Schering-Plough*, the F.T.C. has “concede[d] that the settlement is not a ‘sham’ because both parties to the patent settlement had reasonable good faith arguments in support of their positions.” (R. 11). Furthermore, there is no evidence that Norton’s patent on Logotor is invalid, as the patent has a presumption of validity and no court has ever held the patent to be invalid. In any event, Norton’s litigation against QuikClone was not objectively baseless because QuikClone had certainly infringed on Norton’s presumptively valid patent by filing its “Paragraph IV” certification. *See* 35 U.S.C. § 271(e)(2) (recognizing that a “Paragraph IV” certification is itself an act of infringement).

In addition, Norton had estimated its chance of success on all claims as 70%, while QuikClone had estimated its chance of failure on any one claim as 40%. (R. 8). These estimates further demonstrate that a “reasonable litigant [in Norton’s position] could expect success on the merits.” Necessarily, then, Norton’s lawsuit against QuikClone for patent infringement was not objectively baseless and not a sham, thus precluding any inquiry into the patent strength.

B. The settlement is clearly within the scope of Norton’s patent because Norton has the right to exclude QuikClone from the Logotor market, QuikClone was still permitted to enter the market two years prior to the expiration of Norton’s patent, and the settlement definitively terminated the patent infringement litigation.

The idea that a patent has a “zone of exclusion” derives from the principle that “the essence of a patent grant is the right to exclude others from profiting by the patented invention.” *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980); 35 U.S.C. § 154(a)(1). Thus, “a patent holder does not incur antitrust liability when it chooses to exclude others from producing its patented work.” *Valley Drug*, 344 F.3d at 1305; *see also Schering-Plough*, 402 F.3d at 1067 (explaining that “application of antitrust law to markets affected by patent law cannot discount exclusionary rights of patent holder”). Indeed, a proper antitrust analysis of a settlement of a patent infringement litigation inquires as to “whether the agreements restrict

competition beyond the exclusionary zone of the patent.” *Cipro I*, 544 F.3d at 1336 (recognizing that this inquiry has been adopted by multiple circuits and is “completely consistent with Supreme Court precedent”). In addition, the fact that the settlement prohibits the generic from “challeng[ing] the validity of the patent” does not render the settlement “violative of the antitrust laws.” *See id.* Specifically, a settlement that “end[s] all litigation . . . thereby open[ing] the patent to immediate challenge by other potential generic manufacturers” does not fall outside the scope of the patent. *See Tamoxifen*, 466 F.3d at 214; *see also Diversey Lever, Inc. v. Ecolab, Inc.*, 191 F.3d 1350, 1351 (Fed. Cir. 1999) (settlement upheld where agreement stated that “[n]either party is entitled to any further relief than granted herein”). Moreover, if a settlement does not “tend[] to prolong the dispute” and thus “delay generic entry for a longer period of time than the patent[,]” the agreement does not unlawfully extend the scope of the patent. *Cardizem I*, 332 F.3d at 907. Furthermore, settlements that do not prohibit the marketing of an unrelated non-infringing product will unlikely fall outside the scope of a patent. *Id.*; *see also Tamoxifen*, 466 F.3d at 213 (“Settlement Agreement did not extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products.”).

In *Cipro I*, the court upheld a settlement where the generic defendant agreed not to market a generic version of the plaintiff’s patented drug until six months prior to the expiration of the patent. *Cipro I*, 544 F.3d at 1333; *see also Tamoxifen*, 466 F.3d at 214-15 (upholding a settlement that ended the litigation between the patent-holder and generic, provided that the generic would not market a generic version of the patented drug until expiration of the patent). In contrast, in *Cardizem I*, an interim settlement was held “per se” illegal, implying that it would also violate the rule of reason, because the settlement provided that the generic would not market non-infringing versions of the generic drug as well. *Cardizem I*, 332 F.3d at 907.

Here, Norton, as the owner of the Logotor patent, has the right to prohibit QuikClone from marketing and profiting from Quiescence as part of a settlement agreement. Specifically, Logotor is the *only* medicinal palliative for logorrhea. As such, the Logotor patent is a compound patent, which covers the actual biochemical composition of the drug. (R. 1); *see Cipro I*, 544 F.3d at 1333 (stating that the “patent is not a formulation patent, which covers only specific formulations or delivery methods of compounds; rather, it is a patent on a compound that, by its nature, excludes all generic versions of the drug”). Significantly, QuikClone concedes that Quiescence is a bioequivalent of Logotor because of its ANDA application. (R. 6). Also, the F.D.A. has recognized that Quiescence is a bioequivalent through its tentative approval of QuikClone’s ANDA application. (R. 6). Thus, Norton clearly has the right to exclude QuikClone from entering the market for Logotor.

Additionally, the settlement does not go beyond the confines of Norton’s patent because it allows QuikClone to market Quiescence *two years prior* to – not after – the expiration of Norton’s patent. (R. 7). As noted, this entry date is earlier than that allowed in both *Cipro I* and *Tamoxifen*, where settlement agreements were still upheld as lawful under the rule of reason. Furthermore, the settlement definitively ended the litigation between Norton and QuikClone, as the suit was dismissed upon the parties settling. (R. 7). Thus, the settlement does not delay other generics from entering the Logotor market after the expiration of Norton’s patent. Finally, in contrast to *Cardizem I*, the settlement prohibits QuikClone from marketing only Quiescence, further demonstrating that the settlement is explicitly within the scope of Norton’s patent.

Furthermore, any anti-competitive effects alleged by the F.T.C. fall squarely within the scope of Norton’s patent. Specifically, Norton’s legal monopoly over Logotor is a direct result of Norton’s patent over the drug. *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324

U.S. 806, 816 (1945) (stating “a patent is an exception to the general rule against monopolies and to the right of access to a free and open market”). As such, the fact that prices for Logotor may have been lower if QuikClone had chosen not settle is of no import because Norton has the *right* to exclude QuikClone from the Logotor market. Accordingly, any alleged “detriment” suffered by consumers derives from Norton’s patent alone, not the settlement agreement itself. *See Standard Oil*, 283 U.S. at 171 (holding that settlement of patent claims by agreement rather than litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition). Thus, Norton’s settlement with QuikClone clearly falls within the scope of Norton’s patent on Logotor, and is lawful under a “rule of reason” analysis.

C. The preservation of QuikClone’s claim to the exclusivity period does not have any actual anti-competitive effects beyond the exclusionary zone of Norton’s patent because QuikClone has no definitive right to the period, and as such, any anti-competitive effects alleged are merely speculative.

A settlement that preserves a generic’s claim to the exclusivity period does not “restrain competition outside the scope” of a patent where the generic “has no right to the exclusivity period.” *Cipro I*, 544 F.3d at 1339; *see also Tamoxifen*, 466 F.3d at 219 (holding that because the generic “was not entitled to the 180-day period of exclusivity . . . the settlement agreement had indeed cleared the field so that other generic challengers could enter the market”). This rule is intuitive because other generic manufacturers will not be deterred from challenging a patent if the right to the exclusivity period is still available. Nevertheless, “an agreement to time the deployment of the exclusivity period to extend a patent’s monopoly power might well constitute anticompetitive action outside the scope of a valid patent.” *Tamoxifen*, 466 F.3d at 217. Still, however, the plaintiff must show an actual anti-competitive effect of an alleged antitrust violation in order to state a claim under the Sherman Act. *See Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977).

In both *Cipro I* and *Tamoxifen* the settlements had allowed the generic to re-file its “Paragraph IV ANDA (presumptively for the purpose of reclaiming the 180-day exclusivity period) if the [patent] was subsequently declared by a court to be invalid or unenforceable. . . .” *Cipro I*, 544 F.3d at 1340; *Tamoxifen*, 466 F.3d at 218. At that time, those settlements were upheld as lawful because the generic “failed to satisfy the successful defense requirement necessary to be eligible for the 180-day exclusivity period.” *Cipro I*, 544 F.3d at 1340; *see also Tamoxifen*, 466 F.3d at 218 (“at the time the Settlement Agreement was entered into, the established law was that a generic manufacturer ‘successfully defend’ a patent infringement lawsuit in order to obtain exclusivity”); 21 C.F.R. § 314.107(c)(1) (1995) (stating that the 180-day exclusivity period was available to the first ANDA filer to elect a paragraph IV certification, but only if the ANDA filer successfully defended against a law-suit for infringement), *revoked* 63 Fed. Reg. 59719, 59711 (Nov. 5, 1998). In addition, plaintiffs in both *Cipro I* and *Tamoxifen* failed to show an actual anti-competitive result from the preservation of the generic’s claim. In both cases “other ANDA filers with paragraph IV certifications” sought to invalidate the brand name’s patent after the settlement was entered into. *Tamoxifen*, 466 F.3d at 220; *see also Cipro I*, 544 F.3d at 1340 (“since the agreements were executed, [the brand-name manufacturer] has sued four other generic manufacturers that filed ANDAs . . .”).

In this case, although the regulations have since eliminated the “successful defense” requirement, QuikClone still does not have a definitive right to the exclusivity period, as in *Cipro I* and *Tamoxifen*. To be sure, the F.D.A. did grant QuikClone the right to the exclusivity period, but “subject to resolution of the patent litigation.” (R. 7). Furthermore, the relevant F.D.A. regulation does state that the first “Paragraph IV” ANDA filer is entitled to the exclusivity period even without having successfully defended its application against the patent

holder. *See* 63 Fed. Reg. 59710, 5911. However, the clear purpose behind abolishing the successful defense requirement was to give first “Paragraph IV” ANDA filers who were *not sued* by the patent owner an entitlement to the exclusivity period. *See* U.S. DEP’T OF HEALTH AND HUMAN SERVS., CTR. FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: 180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WATCHMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 7 (1998) [hereinafter GUIDANCE FOR INDUSTRY], <http://www.fda.gov/cder/guidance/2576fnl.pdf> (“although you [the first paragraph IV ANDA filer] were not sued as a result of the notice you provided to the holder of the NDA and the patent owner, you are nonetheless eligible for 180 days of market exclusivity.”); *see also Mova Pharm. Corp. v. Shahala*, 140 F.3d 1060, 1067 (D.C. Cir. 1998) (holding that the FDA had exceeded its statutory authority in enacting a successful defense requirement where the first “Paragraph IV” ANDA filer had not been sued).

Essentially, then, abolishing the “successful defense” requirement does not necessarily entitle QuikClone to the 180-day exclusivity period post-settlement with Norton because QuikClone had been sued, and the litigation itself was not literally resolved, but rather settled. Indeed, since the issue of whether the first “Paragraph IV” filer who later settles a patent infringement suit brought by the patent-holder still retains a right to the exclusivity period has not yet been litigated, the most that can be said for the settlement is that it preserved QuikClone’s claim. *See* GUIDANCE FOR THE INDUSTRY at 5 (explaining that “whether a ANDA applicant that was not sued for patent infringement as a result of its paragraph IV certification would nonetheless be eligible for exclusivity” involves “many additional issues . . . that have yet to be resolved.”). Therefore, the F.D.A. may still revoke the 180-exclusivity period from QuikClone because the grant had been conditioned on the resolution of the patent litigation. More

specifically, the new regulation could merely have permitted the F.D.A. to bestow the exclusivity period upon generics that had not successfully defended because they had not been sued by the patent-holder – not necessarily those who had been sued and settled with the patent-holder.

As such, the F.T.C. cannot point to any actual anti-competitive effects resulting from the settlement, or the preservation of QuikClone’s claim to the exclusivity period. Significantly, there is no evidence that other generic manufacturers will be delayed or deterred from challenging Norton’s patent because of the settlement agreement. In contrast, the settlement has the pro-competitive effect of allowing QuikClone’s entry two years prior to the expiration of Norton’s patent. Finally, nothing in the settlement gives rise to an inference that Norton and QuikClone agreed to time the deployment of QuikClone’s claim to deter other market entry. Necessarily, then, the settlement agreement is lawful under a “rule of reason” inquiry.

D. The exclusionary zone of Norton’s patent should not be tempered by this Court with the subjective expected value of the patent infringement lawsuit because such an approach would be too uncertain, and would discourage settlements and pharmaceutical innovation.

The F.T.C. has recommended that the exclusionary zone of a patent be tempered by this Court with the subjective “expected value” of the patent infringement lawsuit at the time of settlement. *See Cipro I*, 544 F.3d at 1337. Essentially, the F.T.C. proposes that “the expected value of the lawsuit should relate directly to the relative strength of the claim” which in turn “depends on the subjective views of the parties.” *Id.* However, the F.T.C.’s approach has been considered and rejected by a number of courts. *Id.*; *see also Tamoxifen*, 466 F.3d at 210 (stating “the private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case.”) (citation omitted).

The F.T.C.'s proposed approach for determining the exclusionary zone of a patent is problematic for a number of reasons. First, "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." *See Whitmore*, 495 U.S. at 159-60; *see also Asahi Glass*, 289 F. Supp. 2d at 933 ("[n]o one can be certain that he will prevail in a patent suit"). Second, adopting the F.T.C.'s approach would increase the uncertainty in patent infringement litigations because the proposed standard is governed by purely subjective considerations. In turn, this uncertainty would unduly chill patent settlements because even good faith settlements could be invalidated because of a court's evaluation of the strength and enforceability of a patent based on subjective determinations. Furthermore, chilling these patent litigation settlements would violate the policies of encouraging and upholding settlements, which are desirable and important goals, especially in the area of patent law. *See Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1368 (Fed. Cir. 2001); *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 477 (Fed. Cir. 1991). Moreover, the uncertainty would stifle innovation in the pharmaceutical industry, defeating the whole purpose of the Hatch-Waxman Act of making drugs more readily available to consumers. *See Daniel A. Crane, Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 749 (2002). Therefore, this Court should decline to adopt the F.T.C.'s proposed standard in light of its negative consequences.

However, even under the F.T.C.'s proposed standard, Norton's settlement agreement with QuikClone would still fall within the exclusionary zone of Norton's patent. Specifically, QuikClone's own estimate of success on *one* of its claims was only 60%. In contrast, Norton's estimate of success on *all* of its claims was 70%. (R. 8). These estimates show that Norton's position was a strong one backed by good faith arguments for the validity of its patent. Even so,

the settlement allowed QuikClone to enter the market two years prior to the expiration of Norton's patent. (R. 7). This grant further demonstrates that Norton did not extend the enjoyment of its patent beyond that reflected by the uncertainty in the patent infringement litigation. To the contrary, Norton permitted QuikClone to compete in the market well within the grant of its patent. Thus, even under the F.T.C.'s proposed standard, the settlement is lawful as it falls within the exclusionary zone of Norton's presumptively valid patent.

Finally, Norton's C.E.O.'s comments regarding the settlement agreement does not alter this conclusion. Those comments were taken from an internal memorandum which was likely sent in order to persuade the Norton board of directors to approve the settlement agreement. (R. 12). These private thoughts certainly cannot be assumed to reflect the actual views of Norton on the expected value of the patent infringement litigation, or even play a part in tempering the strength of Norton's presumptively valid patent. Rather, it is more plausible to assume that the C.E.O.'s statement merely reflects the risks that Norton could avoid should the board decide to approve the settlement. Therefore, because there is no evidence of a sham, the settlement between Norton and QuikClone is lawful under a "rule of reason" analysis that focuses solely on whether the settlement terms fall within the scope of the patent.

CONCLUSION

For the reasons stated in Point I, the decision of the United States District Court for the District of Mason denying the F.T.C.'s motion for summary judgment should be affirmed. For the reasons stated in Point II, the decision of the United States District Court for the District of Mason granting Norton's motion for summary judgment should also be affirmed.

Respectfully submitted,

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