

No. 08-1129

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRTEENTH CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellant

v.

NORTON PHARMACEUTICALS, INC.,
Defendant-Appellee

JOINT APPENDIX

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASON

FEDERAL TRADE COMMISSION, Plaintiff,)	
)	
v.)	No. 08-1574
)	
NORTON PHARMACEUTICALS, Defendant)	
)	

**ORDER GRANTING DEFENDANT’S MOTION FOR SUMMARY JUDGMENT
AND DENYING PLAINTIFF’S MOTION FOR SUMMARY JUDGMENT**

This is a suit for a permanent injunction brought by the Federal Trade Commission to enforce Section 5 of the FTC Act, which prohibits, in part “unfair methods of competition.” Section 5 has been interpreted to incorporate the standards of the Sherman Antitrust Act, and the parties agree that the Sherman Act governs this case. Section 1 of the Sherman Act, 15 U.S.C. 1, prohibits, in relevant part, any “contract, combination * * * , or conspiracy, in restraint of trade.”¹

The defendant is Norton Pharmaceuticals (“Norton”), a pharmaceutical manufacturer best known for its blockbuster drug Logotor®, the only medicinal palliative for logorrhea -- the curse of excessive wordiness sometimes referred to as “diarrhea of the mouth.”

The complaint alleges that Norton violated the Sherman Act by settling a patent infringement suit Norton had brought against rival drug firm QuikClone Laboratories (“QuikClone”). QuikClone had sought to market a generic alternative to Logotor.

¹ The Commission’s authority to bring a suit for “permanent injunction” to enforce the FTC Act is conferred by Section 13(b) of the FTC Act, 15 U.S.C. § 53(b). The parties both agree that the Commission has authority to bring this suit and that all requirements of personal jurisdiction, venue, and interstate commerce are satisfied.

According to the complaint, as a result of the settlement, “generic alternatives to Logotor are likely to enter the market at a later date than had the settlement not occurred, with the result that consumers will pay millions of dollars more for treatment of logorrhea than had the settlement not occurred.”

The FTC’s complaint was filed on April 14, 2007, and following discovery the parties made cross-motions for summary judgment on liability. For the reasons given below, the court will deny the Commission’s motion and grant defendant’s.²

FINDINGS OF FACT

Norton Pharmaceuticals and Logotor®

Defendant Norton Pharmaceuticals (“Norton”) is a Mason corporation incorporated in 1965. Norton manufactures and sells a wide variety of prescription and OTC drugs, although more than half of its revenues currently derive from three patented blockbuster products – the weight control drug Nogueine, the anticoronary HeartStart, and Logotor. In 1997, following years of research by its scientists, at a cost it estimates at over \$800 million, Norton secured a patent for Logotor, which Norton’s studies showed, when taken daily, could control all symptoms of logorrhea.

Historically, logorrhea in the colloquial sense was viewed as a mere affectation or personality quirk, to be tolerated in one’s superiors and shunned in one’s peers.³ In 1999, however, the influential Mason Academy of Psychiatry declared that logorrhea was a

² QuikClone was originally named as a defendant in the case, but was dismissed after agreeing to abide by any final decision (including all appeals) issued in this matter. The only relief sought by the FTC in this case is injunctive. Several class actions seeking monetary damages for purchasers of Logotor, are also pending before this court and have been stayed pending the resolution of the antitrust merits in the FTC’s case. See In re Consolidated Logotor Class Action Litigation, No. 07-8159 (D. Mason).

³ Less commonly, logorrhea may be a symptom of traditionally recognized mental diseases such as schizophrenia or bipolar disorder. In such cases, treatment of the underlying illness is required. Logotor is not effective in such cases; it is designed only for relief of logorrhea that is not itself the product of other mental diseases.

mental disease, and one that had infected certain segments of society, such as universities and legislatures, in “epidemic proportions.” A 2001 study performed by the Center for Science and Economics at Old Mason University (with a generous grant from Norton Pharmaceuticals), estimated that the deadweight loss to the economy from untreated logorrhea was “in excess of \$15 billion annually.” Presented with this information, as well as studies demonstrating Logotor’s efficacy in treating logorrhea, the Food and Drug Administration (“FDA”), in 2002, granted Norton’s New Drug Application, authorizing the prescription sale of Logotor for the treatment of logorrhea.

Initially, insurance reimbursement for Logotor was spotty and sales were weak. But all that changed with a celebrated incident in 2004 involving the senior Senator from Mason, Hubert Hornblower. Senator Hornblower served on a Senate oversight committee investigating a bridge collapse in Mason that had allegedly resulted from malfeasance by the Army Corps of Engineers. Hornblower was expected to take the lead in extracting critical answers from the Corps’ key witness. However, when the Senator’s turn to speak arrived, he spent five minutes asking the first question. Before the witness could provide the answer that the citizens of Mason had been eagerly awaiting, the committee chairperson ruled that further discussion was out of order because Senator Hornblower’s time limit had expired.

A video clip of the Hornblower/Army Corps exchange soon made its way to YouTube and from thence to the network news. Public reaction was harsh. Facing a re-election campaign against a little known challenger, Hornblower found himself suddenly trailing in the polls. With his wife by his side, the Senator appeared on Oprah, where he announced that he suffered from untreated logorrhea and would immediately undertake

an intensive two-week regimen of anti-blovia therapy at the Mayo Clinic to bring his logorrhea under control. The strategy was a medical and electoral success. A sympathetic Mason populace re-elected Hornblower overwhelmingly, and the newly taciturn legislator took the oath of office for his fourth term in January, 2005.

The national publicity arising from the Hornblower episode raised public consciousness about logorrhea and gave sales of Logotor an enormous boost. The cause was helped by a public service message cut by Senator Hornblower himself, making light of his past difficulties (“It used to take me five minutes just to ask a question, but now that I take Logotor, there’s even time left for my witnesses to answer * * *”). Blue Cross, Aetna, and other major insurers soon decided to reimburse for Logotor, and sales soared to \$1 billion in 2006, with projections of substantial increases in outlying years.

Because Logotor must be taken daily and indefinitely to maintain effectiveness, the potential market for the product remains enormous. A 20 milligram tablet of Logotor (the most commonly prescribed dosage) retails for \$1, while Logotor40 (prescribed only for the seriously verbose), sells for \$1.50. Experts have estimated that as many as 10-15 million Americans may suffer from untreated logorrhea. At a time when other drug companies were fretting about “empty pipelines,” Norton was soon being hailed on Wall Street as “the next Pfizer, Merck, and Lilly rolled into one.”

Seeking to capitalize on the success of Logotor, Norton has also patented a drug to control the prose equivalent of logorrhea – blogorrhea. Safety testing on Blogotor® is now ongoing. Norton also plans to market a combination, timed-release product (working name STFU), that will enable those who suffer from both logorrhea and blogorrhea to control their diseases with a single tablet that combines Logotor and Blogotor and need

only be taken weekly. However, with the necessary safety testing and pre-clearances, Norton does not anticipate receiving FDA approval to market Blogotor until 2011, and to market STFU until 2012.

QuikClone's Generic Challenge to Logotor

The patent rights and obligations of pharmaceutical innovators and generic drug manufacturers are governed by the Food, Drug, and Cosmetic Act, as significantly amended by the Hatch-Waxman Act in 1984. The Hatch-Waxman Act sought to encourage generic competition in the pharmaceutical marketplace. See, e.g., SmithKline Beecham Corp. v. Apotex Corp., 383 F. Supp. 2d 686, 690 (E.D. Pa. 2004).

FDA approval is required before any drug may be introduced or delivered for introduction in interstate commerce. 21 U.S.C. §§ 331(d), 355(a). The FDA will approve a New Drug Application ("NDA"), such as that filed by Norton for Logotor, only if the applicant demonstrates that the drug is both safe and effective for its intended use(s). *Id.* at § 355(b)(1). Upon approval of an NDA, the holder of patents covering the approved drug must identify those patents to the FDA, which in turn lists them in a publication called Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." After the FDA approved Norton's NDA for Logotor in 2002, the FDA listed Norton's patent on Logotor in the Orange Book.

By contrast, a generic drug manufacturer like QuikClone Laboratories, which seeks to copy an innovator drug, may submit to the FDA an Abbreviated New Drug Application ("ANDA"). An ANDA need not independently demonstrate safety and efficacy, but need only show that the proposed generic is "bioequivalent" to an approved branded drug. 21 U.S.C. § 355(j)(2)(A).

If the manufacturer of a generic copy of an approved innovator drug does not wish to wait for expiration of the patent(s) covering the innovator drug to begin marketing its product, it must submit a so-called “Paragraph IV” certification to the FDA, alleging that the relevant Orange Book patents on the innovator drug are either invalid or will not be infringed by the generic copy.

A “Paragraph IV” certification is itself an act of infringement, 35 U.S.C. § 271(e)(2), that triggers the patent holder’s right to enforce its patent immediately.⁴ If the patent holder does not file suit to enforce its patent within 45 days of the Paragraph IV certification, the FDA may approve the ANDA as soon as it finds that bioequivalence is established. However, if the patent holder does file suit within 45 days of a Paragraph IV certification, then FDA approval of the ANDA is automatically stayed for 30 months from the date of the patent infringement suit, or until the court hearing the suit finds that the patent is invalid, unenforceable, or not infringed by the generic challenger, if sooner. 21 U.S.C. § 355 (j)(2). During this time, the FDA may grant “tentative approval” for the ANDA, meaning the application is otherwise acceptable, but may not grant final approval until the stay has expired.

As a further incentive for generic firms to challenge patents, the law provides that the first firm to file an ANDA and Paragraph IV certification with respect to a particular drug receives six months of generic exclusivity. This means that only that firm may sell a generic version of the patented drug for the first six months after patent protection ends. 21 U.S.C. § 355(j)(5)(B)(iv).

⁴ This feature of the Hatch Waxman Act is designed to encourage generic challenges, because it allows the challenger to litigate the enforceability of a patent before actually selling the product. Ordinarily, the validity of a patent may only be tested after a challenger has begun selling an allegedly competing product. Then, if the patent is held valid, the challenger might be subject to enormous damages, the prospect of which can act as a deterrent to mounting a generic challenge in the first place.

Acting under the relevant statutory framework described above, on March 1, 2005, QuikClone filed an ANDA to market a generic version of Logotor (which it named Quiescence). On the same date, QuikClone gave its Paragraph IV certification, indicating that it intended to begin marketing Quiescence as soon as it received FDA approval, despite Norton's patent.

The Patent Infringement Litigation and Settlement

On April 14, 2005, 45 days after QuikClone had filed its Paragraph IV certification, Norton sued it for patent infringement in QuikClone's headquarters district in the State of Madison. (Norton Pharmaceuticals v. QuikClone, Inc., No. 06-5413 (N.D. Mad., complaint filed 4/14/05). QuikClone defended the infringement suit both by arguing that Norton's patent was invalid because of obviousness. QuikClone also alleged that Quiescence did not infringe the Logotor patent even if that patent were otherwise valid.

Following discovery, Norton and QuikClone filed cross-motions for summary judgment. The district court heard argument on the motions in May, 2006, and took the case under advisement. However, before the court could issue its ruling, Norton reached a settlement with QuikClone and the infringement suit was dismissed.

The settlement provided that QuikClone would not market Quiescence until January 1, 2012, but after that date it could do so without objection from Norton, even though the Logotor patent does not expire until January 1, 2014.⁵ The settlement also provided that Norton would pay QuikClone \$150 million "as compensation for attorney fees and various opportunity costs attendant to settlement."

⁵ In December 2005, the FDA had granted tentative approval for QuikClone to market Quiescence, along with the right to generic exclusivity provided by law, subject to resolution of the patent litigation.

In reaching their settlement, the parties first attempted to negotiate an agreement that did not involve the payment of any money by the patentholder, Norton, to the generic challenger, QuikClone. However, according to witnesses from both Norton and QuikClone, this proved impossible.

QuikClone maintained that its legal position was a strong one, that Norton's patent would be invalidated or held not infringed if the case proceeded to judgment. (QuikClone's patent counsel estimated its chances of prevailing on at least one of its claims at 60%). QuikClone insisted that it needed to begin marketing Quiescence by January 1, 2010, at the latest, to satisfy its lenders, who would insist upon seeing some cash flow from QuikClone's investment in this area in order to continue their financial assistance.

Norton, on the other hand, asserted that its patent was clearly valid and infringed by Quiescence. (Norton's patent counsel estimated that its chances of prevailing on all issues if the case proceeded to judgment were 70%.) Norton argued that QuikClone's attempt to enter before 2014 was "highway robbery" and that allowing entry in 2010 would be tantamount to "abandoning the franchise." Norton stated that it was willing to allow earlier entry, but no sooner than January 1, 2012. By that time, Norton estimated that it would be positioned to retain the patronage of most Logotor users by switching them over to Blogotor and STFU.

With the parties at a seeming impasse, their patent counsel came up with a "win-win" compromise as they put it. Norton would pay QuikClone \$150 million – a good chunk of the after-tax profits Quikclone might stand to realize from entry in 2010 rather than 2012 – and Quikclone would accept Norton's January 1, 2012 entry date.

As required by the Medicare Prescription Drug Improvement and Modernization Act of 2003⁶, the parties submitted their settlement to the antitrust agencies (the FTC and the Department of Justice) for review. Following its review, the FTC concluded that the settlement, though perhaps a “win-win” for the parties, was a big loss for consumers, and the instant lawsuit (and consolidated private class actions) ensued.

LEGAL ANALYSIS

Antitrust analysis of patent settlements involving so-called “reverse payments” (the payment of money by a patent holder to generic challengers) has proven to be a vexing topic. See, e.g., Herbert Hovenkamp et al., “Anticompetitive Settlement of Intellectual Property Disputes,” 87 Minn. L. Rev. 1719 (2003). This court is under no illusion that its opinion will provide the last word on this subject – even in this particular case. Our analysis will, therefore, be brief.

Ordinarily, if the only two manufacturers of a given product agreed between themselves that only one of them would sell the product, and share its monopoly profits with the other, both competitors would be guilty of violating Section 1 of the Sherman Act. See, e.g., Palmer v. BRG of Georgia, Inc., 498 U.S. 46 (1990) (per curiam). Market division by horizontal competitors or potential competitors is, after all, one of the most egregious violations of the antitrust laws.⁷

The situation is different, however, where the product at issue is subject to a patent. If the patent is valid, then the patent holder has a legal monopoly on the sale of

⁶ Pub L. No. 108-173, Title XI, §§ 1111-18, 117 Stat. 2066, 2461-64 (Dec. 8, 2003), contained in 21 U.S.C. §355, notes).

⁷ The parties agree that antibloval drugs (drugs that treat logorrhea) are a relevant antitrust product market, that the relevant geographic market is the United States, and that Logotor currently holds a 100% share of the relevant market.

the patented product for the duration of the patent. In that circumstance, an agreement that allows competition within the scope of the patent may actually be procompetitive. In Defendant Norton's view, that is the situation here. Norton claims its patent gives it the exclusive right to market Logotor until 2014. By allowing others to market infringing products in 2012, Norton argues that the settlement actually helps consumers, by providing them with a cheaper generic alternative two years sooner than otherwise.

The FTC maintains, however, that defendant's argument is premised on the presumption that its patent is valid and infringed by Quiescence, and that such a presumption is unwarranted in a situation where a generic competitor has mounted a vigorous challenge to the patent's validity and desisted from its challenge only upon payment of a large amount of money from the patentholder.

The FTC argues that these reverse payments by a patentholder whose product constitutes an antitrust monopoly (see n.7, supra) to a patent challenger in excess of its attorney fees are inevitably anticompetitive, and that any patent settlement that includes such payments should be held to be per se unlawful.⁸ There is no doubt some theoretical force and appeal to the Commission's position. See, e.g., C. Scott Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem," 81 N.Y.U.L. Rev. 1553 (2006). If adopted, it would produce valuable clarity in an area beset by uncertainty.

Nevertheless, the FTC's position has not found great favor in the courts. See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig., No. 2008-1097, 2008 WL

⁸ While the settlement agreement between Norton and QuikClone recites that the \$150 million reverse payment was made for "attorney fees" and "opportunity costs," Norton has not challenged the FTC's assertion in its summary judgment motion that QuikClone's reasonable attorney fees and costs in the settled patent litigation were "at most \$2 million."

4570669 (Fed. Cir. Oct. 15, 2008); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005). This court, to be sure, is not bound by precedents outside the Thirteenth Circuit in an area of evolving law. Nevertheless, the court must recognize that reverse payments may serve useful, procompetitive purposes in some cases, and a hard and fast rule that prohibits them would be too extreme. For this reason, the court rejects the Commission's position that a settlement involving reverse payments by a monopoly patentholder in excess of a generic challenger's attorney fees is per se illegal, and the Commission's motion for summary judgment will be denied.

Turning then to a rule of reason analysis, which follows whenever per se treatment fails, Defendant Norton argues that such an analysis in this case may be brief. In Norton's view, any patent settlement should be lawful so long as it is within the "scope" or "exclusionary zone" of the patent and is not a sham, following its reading of the decisions in Ciprofloxacin Hydrochloride, Tamoxifen Citrate, and Schering-Plough, supra. The FTC concedes that the factual predicates for Norton's test, as Norton defines it, are met in this case. The settlement is within the scope or exclusionary zone of the patent, in the sense that the Logotor patent runs until 2014, while QuikClone has agreed to refrain from competing only until 2012. Likewise, the FTC concedes that the settlement is not a "sham" because both parties to the patent settlement had reasonable good faith arguments in support of their positions.

The FTC contends, however, that Norton's highly truncated rule of reason analysis would allow for too much anticompetitive conduct in the guise of settling patent litigation. The Commission points out that, despite Norton's protestations, there is reason

to question the strength of its patent and whether or not it is actually infringed by Quiescence.⁹ The FTC also points out that the peculiar economics of prescription drugs – in which price reductions of 50-75% after a blockbuster goes “off-patent” are not uncommon – create an enormous incentive for branded and generic competitors to share the patentholder’s monopoly profits by means of reverse payments, rather than bestowing the benefits of vigorous competition on consumers.¹⁰

The FTC’s concerns are not without merit. However, the bright-line test that Norton proposes at least provides certainty for litigants and encourages settlements – important values that the law must consider. Rejecting Norton’s position (unless one adopts the FTC’s per se ban on reverse payments), would seemingly require that the antitrust court determine the validity and enforceability of the challenged Logotor patent – thus defeating the purpose of Norton’s and QuikClone’s good faith settlement of their patent suit. Given the breadth and imprecision of the rule of reason inquiry that the Commission would apparently have it undertake, the court concludes that the proper test is, as Norton contends, whether the settlement falls within the scope of the patent and is not a sham. Because those criteria are satisfied here, summary judgment for Norton will be granted.

⁹ In this regard, the Commission points, among other items of evidence, to an internal memorandum by Norton’s CEO commenting to his Board of Directors that “I feel as if this settlement has added three years to my life * * * three years that I didn’t think we would see.” While these remarks do seem somewhat at odds with patent counsel’s “70% success” estimate, a trial on the merits would obviously be required to determine the exact strength of Norton’s patent. Short of litigating here in the District Court of Mason the very patent case that Norton and QuikClone settled in the District Court of Madison,, it is not clear how the FTC proposes that the court should resolve this question.

¹⁰ Indeed, economic experts for both sides in this case agreed that if Quiescence entered the market, a tablet of Quiescence 20 would likely retail for 25-30 cents, and the price of Logotor20 would likely fall to 50 cents (compared to \$1 at present). Additional generic entry following Quiescence’s six-month period of generic exclusivity (which will now begin in 2012) would drive prices of the imitator drugs down even further, perhaps to as low as 10-15 cents according to the government’s economic expert.

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SCHEDULING ORDER

The parties' motion for expedited hearing is granted. By stipulation of the parties, the case will be limited to the following issues:

1. Is the settlement of patent infringement litigation involving a "reverse payment" by a monopoly patentholder in excess of a generic challenger's attorney fees per se illegal under Section 1 of the Sherman Act?
2. If such a settlement is not per se illegal, is the settlement lawful under a rule of reason analysis that focuses solely on whether the settlement terms fall within the scope of the challenged patent, absent evidence of a sham?

The parties shall file simultaneous briefs on or before January 21, 2009.

Oral argument will be held on February 7, 2009, in Washington, D.C.

Clerk of Court

November 14, 2008