

No. 08-1129

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

FEDERAL TRADE COMMISSION,

Petitioner-Appellant,

v.

NORTON PHARMACEUTICALS, INC.,

Defendant-Appellee.

BRIEF FOR THE PETITIONER

Team E
Federal Trade Commission
2580 Pennsylvania Ave., N.W.
Washington, D.C.
Counsel for the Petitioner

QUESTIONS PRESENTED

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 unlawful 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?

TABLE OF CONTENTS

QUESTIONS PRESENTED.....	i
TABLE OF CONTENTS.....	ii
TABLE OF AUTHORITIES	iv
OPINIONS BELOW.....	1
STATUTORY PROVISIONS INVOLVED.....	1
STANDARD OF REVIEW	4
STATEMENT OF THE CASE.....	4
SUMMARY OF THE ARGUMENT	6
ARGUMENT	8
I. The settlement of patent infringement litigation involving a “reverse payment” by a monopoly patentholder in excess of the challenger’s attorney fees is per se illegal under Section 1 of the Sherman Act.	8
A. The Agreement horizontally allocates the entire U.S. market for Logotor, which is a per se violation of Section 1 of the Sherman Act.	8
B. A per se rule approach to Norton’s market allocation agreement with QuikClone is not overbroad, and, actually encourages market stability.....	11
C. The per se illegality of the Agreement is not influenced by Norton’s claims as a patentholder.	12
II. The settlement of patent infringement litigation involving a “reverse payment” by a monopoly patentholder in excess of the challenger’s attorney fees is unlawful under Section 1 of the Sherman Act when subjected to a rule of reason analysis.....	13
A. The settlement should be found unlawful under a full rule of reason analysis.....	14
i. A full rule of reason analysis is the appropriate judicial test.....	14
ii. A full rule of reason analysis should consider the strength of the patent, along with market definition and calculated market shares.....	15
iii. The relevant facts show that the settlement is unlawful under a full rule of reason analysis.....	17
a. Facts indicate that Norton’s patent is not strong.....	17
b. The settlement restricts the relevant product market to one producer instead of potentially several.	18

c. Alternative restraints could be imposed to achieve defendant’s procompetitive objective that are less harmful to competition.	19
B. In the alternative, the settlement would be unlawful under an abbreviated rule of reason analysis.	21
i. The exclusionary scope of the patent includes the legal limits of patent rights as defined by the Hatch-Waxman Act.	22
ii. The exclusionary scope of the settlement exceeds the scope of the patent because it delays legal challenges.	23
iii. Anticompetitive effects result from settlement agreement.	25
iv. Other circuit opinions using the abbreviated rule of reason are distinguishable.	26
 CONCLUSION.....	 27
 CERTIFICATE OF SERVICE	 28
 CERTIFICATE OF COMPLIANCE.....	 28

TABLE OF AUTHORITIES

United States Supreme Court Cases

<u>Arizona v. Maricopa County Med. Soc'y</u> , 457 U.S. 332 (1982).....	9, 11, 12, 13
<u>Bd. of Trade of Chicago v. United States</u> , 246 U.S. 231 (1918)	15, 16
<u>Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.</u> , 441 U.S. 1 (1979).....	9, 14, 15
<u>California Dental Association v. Federal Trade Commission</u> , 526 U.S. 756 (1999)	14, 15
<u>Continental T.V., Inc. v. GTE Sylvania Inc.</u> , 433 U.S. 36 (1977).....	12
<u>Copperweld Corp. v. Independence Tube Corp.</u> , 467 U.S. 752 (1984).....	10
<u>National College Athletic Ass'n (“NCAA”) v. Board of Regents</u> , 468 U.S. 85 (1984)	9
<u>Northern Pacific Ry. Co. v. United States</u> , 356 U.S. 1 (1958)	9, 10
<u>Palmer v. BRG of Georgia, Inc.</u> , 498 U.S. 47 (1990).....	7, 10
<u>Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.</u> , 324 U.S. 806 (1945).....	22
<u>Standard Oil Co., Ind v. United States</u> , 283 U.S. 163 (1931).....	16
<u>State Oil Co. v. Khan</u> , 522 U.S. 3 (1997)	7, 9
<u>United States v. Singer Mfg Co.</u> , 374 U.S. 174 (1963).....	16
<u>United States v. Socony-Vacuum Oil Co.</u> , 310 U.S. 150 (1940).....	13
<u>United States v. Topco Assocs., Inc.</u> , 405 U.S. 559 (1972).....	7, 10, 11

United States Court of Appeals Cases

<u>Andrx Pharm., Inc. v. Biovail Corp.</u> , 256 F.3d 799 (D.C. Cir., 2001)	4
<u>In re Cardizem CD Antitrust Litigation</u> , 332 F.3d 896 (6th Cir. 2003).....	12, 24
<u>In re Ciprofloxacin Hydrochloride Antitrust Litigation</u> , 544 F.3d 1323 (Fed. Cir. 2008).....	passim
<u>In re: Tamoxifen Citrate Antitrust Litigation</u> , 466 F.3d 187 (2d Cir. 2006).....	passim
<u>Mallinckrodt, Inc. v. Medipart, Inc.</u> , 976 F.2d 700 (Fed. Cir. 1992).....	22
<u>Schering-Plough Corp. v. FTC</u> , 402 F.3d 1056 (11th Cir. 2005)	passim
<u>United States v. Addyston Pipe & Steel Co.</u> , 85 F. 271 (6th Cir. 1898).....	10

United States District Court Cases

<u>Fed. Trade Comm’n v. Norton Pharm.</u> , Case No. 08-1574 (D. Mason).....	1
<u>In re K-Dur Antitrust Litig.</u> , 338 F. Supp. 2d 517 (D.N.J. 2004)	16
<u>Norton Pharmaceuticals v. QuikClone</u> , No. 06-5413	5

Statutes

15 U.S.C. § 1.....	2, 7, 9, 10
21 U.S.C. § 355(j)(5)(B)(iv)	2, 18, 23
Pub. L. No. 98-417, 98 Stat. 1585	18, 22

Agency Opinions

<u>In the Matter of Schering-Plough Corporation, Upsher-Smith</u> , 2003 WL 22989651, Docket No. 9297, (F.T.C. Dec. 8, 2003).....	20
--	----

Secondary Sources

C. Scott Hemphill, <u>Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem</u> , 81 N.Y.U. L. REV. 1553 (2006)	25
Herbert Hovenkamp et al., <u>Anticompetitive Settlement of Intellectual Property Disputes</u> , 87 MINN. L. REV. 1719 (2003).....	20

Other

Petitioner’s Opening Brief, Schering-Plough, (2006) (No. 05-273),
2005 WL 22989651 (F.T.C. Dec. 8, 2003)..... 16

No. 08-1129

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

FEDERAL TRADE COMMISSION,

Petitioner-Appellant,

v.

NORTON PHARMACEUTICALS, INC.,

Defendant-Appellee.

BRIEF FOR THE PETITIONER

OPINIONS BELOW

The decision of the United States District Court for the District of Mason, granting defendant's motion for summary judgment and denying plaintiff's motion for summary judgment, is reported at Fed. Trade Comm'n v. Norton Pharm., Case No. 08-1574 (D. Mason).

STATUTORY PROVISIONS INVOLVED

Title 15 of the United States Code provides in pertinent part as follows:

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by

fine not exceeding \$100,000,000 if a corporation, or, if any other person, \$1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 1

Title 21 of the United States Code provides in pertinent part as follows:

(iv) 180-day exclusivity period.—

(I) Effectiveness of application.— Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions.— In this paragraph:

(aa) 180-day exclusivity period.— The term “180-day exclusivity period” means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant.— As used in this subsection, the term “first applicant” means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application.— As used in this subsection, the term “substantially complete application” means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval.—

(AA) In general.— The term “tentative approval” means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation.— A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

21 U.S.C. § 355(j)(5)(B)(iv).

Title 21 of the United States Code provides in pertinent part as follows:

(D) Forfeiture of 180-day exclusivity period.—

(i) Definition of forfeiture event.— In this subparagraph, the term “forfeiture event”, with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market.— The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) Withdrawal of application.— The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification.— The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval.— The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner.— The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under

paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 45 of title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents.— All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture.— The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) Subsequent applicant.— If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

21 U.S.C. § 355(j)(5)(D).

STANDARD OF REVIEW

When no facts are in dispute, a district court’s decision to dismiss by summary judgment is subject to de novo review. Andrx Pharm., Inc. v. Biovail Corp., 256 F.3d 799, 805 (D.C. Cir., 2001).

STATEMENT OF THE CASE

Plaintiff-Appellant asks this court to reverse the United States District Court for the District of Mason’s decision granting defendant’s motion for summary judgment and denying plaintiff’s motion for summary judgment. The issue presented is whether the settlement of patent infringement litigation involving a “reverse payment” by a monopoly patentholder to a generic challenger is a violation of Section 5 of the Federal Trade Commission (FTC) Act, incorporating Section 1 of the Sherman Act.

Defendant Norton Pharmaceuticals holds a patent for Logotor, which is set to expire in 2014. App. 7. QuikClone Laboratories filed an Abbreviated New Drug Application (ANDA) on March 1, 2005, under the Hatch-Waxman Act to receive Food and Drug Administration (FDA) approval to copy Logotor and market a generic version of the drug. App. 5, 7. In addition, QuikClone Laboratories submitted a “Paragraph IV” certification to the FDA, alleging that Norton Pharmaceuticals’ original Logotor patent was invalid. If uncontested, a Paragraph IV certification would allow QuikClone Laboratories to begin marketing a generic equivalent of Logotor immediately upon FDA approval, without consideration for the expiration of Norton’s patent for Logotor.

Norton Pharmaceuticals brought suit against QuikClone Laboratories to defend and enforce its patent on April 14, 2005, within the 45 day statutory window provided by the Hatch-Waxman Act. App. 6-7, Norton Pharmaceuticals v. QuikClone, No. 06-5413 (N.D. Mad., complaint filed 4/14/05). While this litigation ensued, the Hatch-Waxman Act prevented the FDA from approving QuikClone’s generic drug for a period of 30 months or until the litigation concluded.

In May, 2006, Norton Pharmaceuticals and QuikClone Laboratories settled the patent infringement lawsuit. App. 7. The terms of the settlement provided for Norton to pay QuikClone \$150 million in return for QuikClone’s agreement to delay marketing of the generic drug until January 1, 2012, two years before the patent expiration date of January 1, 2014. App. 7. The parties claimed that Norton’s payment of \$150 million to QuikClone constituted compensation for attorney fees and opportunity costs. App. 7.

Upon review of the settlement terms, the Federal Trade Commission determined that the settlement constituted an unfair method of competition, resulting in a multi-million dollar loss to

consumers by way of the increased price of Logotor resulting from the settlement. App. 1-2. The FTC brought suit in the United States District Court for the District of Mason, on April 14, 2007, for permanent injunction of the settlement agreement under Section 5 of the FTC Act, which incorporates Section 1 of the Sherman Act, 15 U.S.C. 1. App. 1-2.

The United States District Court for the District of Mason granted summary judgment for the defendants, Norton Pharmaceuticals, dismissing the FTC's antitrust challenge. In reaching its opinion, the court reasoned that reverse payments may serve procompetitive effects and should not be per se illegal. App. 11. Citing efficiency reasons, the court applied an abbreviated rule of reason antitrust analysis to the patent settlement. App. 12. According to the district court, the settlement terms fell within the exclusionary scope of the underlying patent rights, and there was no evidence that the litigation was a sham. Therefore, the court concluded that the settlement did not constitute a violation of Section 5 of the FTC Act. App. 1-2.

The FTC appealed to the United States Court of Appeals for the Thirteenth Circuit on November 14, 2008, to seek review of the district court's order granting summary judgment for defendants.

SUMMARY OF THE ARGUMENT

The court should recognize the Agreement between Norton Pharmaceuticals and QuikClone for what it is - a blatant attempt to allocate the entire U.S. market to Norton in exchange for a share of the monopoly profits to QuikClone. This type of market allocation is per se illegal under Section 1 of the Sherman Act, and, in the alternative, fails to be sustainable under the rule of reason analysis developed by the Court..

The Sherman Act provides that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.” 15 U.S.C. § 1. On its face, the Act prohibits any “restraint of trade,” but, admittedly, the Supreme Court “has long recognized that Congress intended to outlaw only unreasonable restraints.” State Oil Co. v. Khan, 522 U.S. 3, 10 (1997) In some cases, however, courts do not need to reach the reasonability question because agreements containing restraints that are so predictably pernicious and anticompetitive are deemed to be per se unlawful under the Sherman Act.

Market allocation agreements are one of the well-established categories of trade restraints that are considered per se unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1. Palmer v. BRG of Georgia, Inc., 498 U.S. 47, 49-50 (1990); United States v. Topco Assocs., Inc., 405 U.S. 559, 608 (1972). The Norton-QuikClone Agreement is a clear example of horizontal market allocation. At its core, Norton paid QuikClone not to compete until 2012, thereby establishing a time for Norton to control the market and a time for Norton and QuikClone to share the market. Because the Supreme Court has determined that type of agreement is per se unlawful, the District Court should have found the restraint to be unlawful.

Even if the court does not grant per se treatment to the settlement between Norton and QuikClone, a rule of reason analysis demonstrates that the settlement results in anticompetitive effects. This settlement agreement should be subject to a full rule of reason analysis (as opposed to an abbreviated rule of reason analysis) due to unfamiliarity with the business relationships and the complexities of the industry. A full rule of reason analysis in this case should consider the strength of the patent, market definition, and the availability of less restrictive restraints to

achieve the defendant's goals, all pointing to the anticompetitive nature of the settlement agreement.

Finally, under the abbreviated rule of reason analysis advanced by some courts, the settlement agreement is anticompetitive and unlawful. Upon full consideration of the nature of the exclusionary scope of a patent, the Norton settlement agreement exceeds the scope of the original patent because it allows Norton to pay to exclude or delay legal challenges to the validity of the patent. If the settlement helps to protect a weak patent from legal challenges, it maintains an artificially high price for consumers and restricts output, producing anticompetitive effects not contemplated by patent law. As a result, because of its anticompetitive effects, the agreement cannot sustain a rule of reason analysis and is unlawful.

Ultimately, Norton's agreement with QuikClone is illegal under either a per se or a rule of reason analysis. The district court's decision should be overturned accordingly.

ARGUMENT

I. The settlement of patent infringement litigation involving a “reverse payment” by a monopoly patentholder in excess of the challenger’s attorney fees is per se illegal under Section 1 of the Sherman Act.

A. The Agreement horizontally allocates the entire U.S. market for Logotor, which is a per se violation of Section 1 of the Sherman Act.

The court should recognize the Agreement between Norton Pharmaceuticals and QuikClone for what it is — a blatant attempt to allocate the entire U.S. market to Norton in exchange for a share of the monopoly profits to QuikClone. This type of market allocation is per se illegal under Section 1 of the Sherman Act.

The Sherman Act provides that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with

foreign nations, is declared to be illegal.” 15 U.S.C. § 1. On its face, the Act prohibits any “restraint of trade,” but, admittedly, the Supreme Court “has long recognized that Congress intended to outlaw only unreasonable restraints.” State Oil Co. v. Khan, 522 U.S. 3, 10 (1997). In some cases, however, courts do not need to reach the reasonability question because agreements containing restraints that have a “predictable and pernicious anticompetitive effect, and ... limited potential for procompetitive benefit” are deemed to be per se unlawful under the Sherman Act. State Oil, 522 U.S. at 10, 118 S.Ct. 275. (citing Northern Pacific Ry. Co. v. United States, 356 U.S. 1, 5 (1958)). A finding of per se unlawfulness “is appropriate ‘[o]nce experience with a particular type of restraint enables the Court to predict with confidence that the rule of reason will condemn it.’ ” Id. (quoting Arizona v. Maricopa County Med. Soc’y, 457 U.S. 332, 344 (1982)). The per se rule should be applied when “the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output.” Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1, 19-20 (1979). Significantly, the per se approach thus applies a “conclusive presumption” of illegality to certain types of agreements, Maricopa Cty., 457 U.S. at 344. If a restraint is determined to be per se illegal, then no consideration is given to the intent behind the restraint, to any claimed pro-competitive justifications, or to the restraint's actual effect on competition. National College Athletic Ass'n (“NCAA”) v. Board of Regents, 468 U.S. 85, 100 (1984).

The Supreme Court has already identified certain types of restraints as subject to the per se rule. In such cases, it is not necessary to examine whether or not the particular activity is “predictable and pernicious.” The classic examples are simple horizontal restraints pertaining to prices or territories. See, e.g., NCAA, 468 U.S. at 100 (“Horizontal price fixing and output limitation are ordinarily condemned as a matter of law under an ‘illegal *per se*’ approach because

the probability that these practices are anticompetitive is so high.”); Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 768 (1984) (“Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal per se without inquiry into the harm it has actually caused.”); United States v. Topco Assocs., 405 U.S. 596, 608 (1972) (“One of the classic examples of a *per se* violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition... This Court has reiterated time and time again that horizontal territorial limitations ... are naked restraints of trade with no purpose except stifling of competition. Such limitations are per se violations of the Sherman Act.” (internal citations omitted)); Northern Pacific Ry., 356 U.S. at 5 (“Among the practices which the courts have heretofore deemed to be unlawful in and of themselves are price fixing, division of markets, group boycotts, and tying arrangements.” (internal citations omitted)).

Market allocation agreements are one of the well-established categories of trade restraints that are considered per se unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1. Palmer v. BRG of Georgia, Inc., 498 U.S. 47, 49-50 (1990); United States v. Topco Assocs., Inc., 405 U.S. 559, 608 (1972). Courts have had more than a century of experience to recognize that it is anticompetitive. See, e.g., United States v. Addyston Pipe & Steel Co., 85 F. 271, 293-94 (6th Cir. 1898), aff'd, 175 U.S. 211 (1899). The Norton-QuikClone Agreement is a clear an example of horizontal market allocation. Norton paid QuikClone not to compete until 2012. Because this type of agreement is per se unlawful, the District Court should have rejected defendants' invitation to embark on a searching inquiry into whether the Agreement was well-intended or “allegedly developed to increase competition.” Topco Assocs., 405 U.S. at 609-10.

In answering the question whether the Agreement here was per se illegal, the following facts are undisputed and dispositive. The Agreement guaranteed to Norton that its only potential competitor at that time, QuikClone, would, for the price of \$150 million, refrain from marketing its generic version of Logotor even after it had obtained FDA approval, thus protecting Norton's exclusive access to the market for Logotor throughout the United States until January 1, 2012 per the Agreement. By delaying QuikClone's entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter the market until the expiration of QuikClone's 180-day period of marketing exclusivity guaranteed under the Hatch-Waxman Act. Norton and QuikClone are horizontal competitors because the companies are potential rivals in the market for Logotor and its generic equivalent; an agreement between them is thus an agreement between horizontal competitors. There is simply no escaping the conclusion that the Agreement was, at its core, a horizontal agreement to eliminate competition in the market for Logotor until January 1, 2012 throughout the entire United States. Again, it is a classic example of a per se illegal restraint of trade through market allocation.

B. A per se rule approach to Norton's market allocation agreement with QuikClone is not overbroad, and, actually encourages market stability.

The application of the per se rule does carry some risk that an agreement, which would otherwise be tolerated under a rule of reason analysis, would be disallowed under a per se legal regime. The Supreme Court has, however, already recognized and tolerated such a risk as a necessary cost of this approach for the sake of market stability and certainty. See, e.g., Maricopa Cty., 457 U.S. at 344 (“As in every rule of general application, the match between the presumed and the actual is imperfect. For the sake of business certainty and litigation efficiency, we have tolerated the invalidation of some agreements that a full-blown inquiry might have proved to be reasonable.”); United States v. Topco Associates, Inc., 405 U.S. 596, 609 (1972) (“Whether or

not we would decide this case the same way under the rule of reason used by the District Court is irrelevant to the issue before us.”).

In essence, the Court has already made the determination that the stability of a bright-line rule in such cases outweighs the potential negative impact from an aggressive application of the per se rule. As explained by the Supreme Court, “[t]he probability that anticompetitive consequences will result from a practice and the severity of those consequences must be balanced against its procompetitive consequences. Cases that do not fit the generalization may arise, but a per se rule reflects the judgment that such cases are not sufficiently common or important to justify the time and expense necessary to identify them.” Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 50 n. 6 (1977).

Thus, any claim that states that the Agreement lacked anticompetitive effects and had procompetitive benefits are simply irrelevant. See, e.g., Maricopa Cty., 457 U.S. at 351. To reiterate, the per se rule allows courts to presume that certain behaviors as a class are anticompetitive without expending judicial resources to evaluate the actual anticompetitive effects or procompetitive justifications in a particular case. The anticompetitive potential in all price-fixing agreements justifies their facial invalidation even if procompetitive justifications are offered for some. In re Cardizem CD Antitrust Litigation, 332 F.3d 896, 906 -909 (6th Cir. 2003).

C. The per se illegality of the Agreement is not influenced by Norton’s claims as a patentholder.

The Agreement cannot be fairly characterized as merely an attempt to enforce patent rights. Admittedly, a patentholder has a legal right to a temporary monopoly over the sale of a specific good. However, the Agreement allowed Norton to exclude a horizontal competitor from the market not by enforcing its rights as a patentee, but instead by ceasing to enforce its rights

prior to the expiration of its patent and paying the competitor \$150 million. It is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor to stay out of the market. Nor does the fact that this is a “novel” area of law because of the intersection between antitrust and intellectual property preclude per se treatment, see Maricopa Cty., 457 U.S. at 349, 102 S.Ct. 2466. To the contrary, the Supreme Court has held that “ ‘[w]hatever may be its peculiar problems and characteristics, the Sherman Act, so far as price-fixing agreements are concerned, establishes one uniform rule applicable to all industries alike.’ ” Id. at 349 (quoting United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 222 (1940)). The Commission sees no reason for Norton’s agreement to be the exception to the rule.

II. The settlement of patent infringement litigation involving a “reverse payment” by a monopoly patentholder in excess of the challenger’s attorney fees is unlawful under Section 1 of the Sherman Act when subjected to a rule of reason analysis.

Even if the settlement is not found to be per se illegal, the settlement is unlawful under a rule of reason analysis. The settlement should be evaluated under the traditional rule of reason, whereby consideration of all relevant facts leads to the conclusion that the settlement is unlawful because it confers market power in a way not contemplated by patent law. An abbreviated rule of reason analysis is inappropriate in this unsettled area of law. This shortened analysis, advocated by the Eleventh and Federal Circuits, considers only whether the settlement terms fall within the scope of the challenged patent, absent evidence of a sham. In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323, 1333 (Fed. Cir. 2008) (hereinafter, Cipro); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005) (hereinafter, Schering). However, even under the abbreviated rule of reason analysis, the settlement is unlawful because the scope of the agreement exceeds the exclusionary nature of the underlying patent.

A. The settlement should be found unlawful under a full rule of reason analysis.

The settlement should be found unlawful under a full, unabbreviated rule of reason analysis. The full rule of reason analysis is appropriate when the court does not have considerable experience with the business relationships at issue or when the complexities of the industry make anticompetitive effects not intuitively obvious. When determining the reasonableness of a restraint of trade, the issue turns on whether the restraint promotes and regulates competition or suppresses competition. In patent settlements, courts have identified relevant factors to be the strength of the patent, definition of relevant geographic and product markets, and calculated market shares. Schering, at 1065.

i. A full rule of reason analysis is the appropriate judicial test.

When determining the antitrust analysis to apply to a particular case, courts have identified several factors indicating that a full rule of reason analysis is required. In Broadcast Music v. Columbia Broadcasting System, 441 U.S. 1 (1979), the court analyzed a blanket licensing system designed to facilitate copyright enforcement for music artists. A customer alleged that the companies offering the blanket license were fixing prices by bundling the licenses into one, priced product. The court held that a full rule of reason analysis was appropriate unless courts had considerable experience with the business relationships at issue. Id. at 2. In California Dental Association v. Federal Trade Commission, 526 U.S. 756 (1999), the court addressed a dental association rule that prohibited advertising based on quality or price. This rule was designed to avoid misleading or deceptive advertising claims, but the government alleged that a ban on this type of advertising led to decreased consumer choice, raised prices, and restricted output. The court held that when the “anticompetitive effects are far from intuitively

obvious,” a full rule of reason analysis was necessary to understand the economics of the market and consequences of the restraint. *Id.* at 757.

Similar to *Broadcast Music* and *California Dental Association*, patent settlements under the Hatch Waxman Act require a full rule of reason analysis, as opposed to the “rule of thumb” analysis constructed by several courts. The court is unlikely to have considerable experience with the business relationships at issue due to the recent passage in 2003 of the relevant Hatch Waxman amendments. Similarly, due to the complex nature of the economics underpinning Hatch Waxman patent settlements, the anticompetitive effects are far from intuitively obvious. In fact, because a patent is involved, it is not always clear that any anticompetitive effects are necessarily an evil to be avoided via antitrust enforcement. Only a full rule of reason analysis can determine whether Hatch Waxman antitrust settlements are contrary to sound antitrust policy.

ii. A full rule of reason analysis should consider the strength of the patent, along with market definition and calculated market shares.

The Supreme Court has said that when determining the reasonableness of a restraint of trade, the issue turns on whether the restraint “merely regulates” competition or whether the restraint suppresses competition. *Bd. of Trade of Chicago v. United States*, 246 U.S. 231, 238-239 (1918). The factors relevant to this analysis for most industries range from the facts specific to the business, the business’s condition before and after the restraint, the nature and effects of the restraint, the history of the restraint, the harm that the restraint allegedly causes, the reason for the restraint, and the goal of imposing the restraint. *Id.* In the specific patent settlement context, courts have identified relevant factors to be the strength of the patent, definition of relevant geographic and product markets, and calculated market shares. *Schering*, at 1065.

Procedurally, a rule of reason analysis typically has three steps. First, a plaintiff must show that a restraint of trade has a harmful effect on competition in the relevant market. If the plaintiff succeeds, then the defendant must put forth a valid pro-competitive justification for the restraint of trade. Finally, the plaintiff may still rebut the pro-competitive justification by showing that the pro-competitive goal could be accomplished by other, less anticompetitive means. Cipro, at 1332; Schering, at 1065; In re: Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187, 202, n.13 (2d Cir. 2006) (hereinafter, Tamoxifen).

An important factor in a traditional rule of reason analysis is a thorough consideration of the restraint in question. Bd. of Trade of Chicago, 246 U.S. at 238-239. In the present case, the settlement agreement restraining trade is inextricably linked with the underlying patent upon which the dispute and settlement are based. Further, as the FTC has argued in Schering, the most significant aspect of patent settlement agreements is the validity of the underlying patent and the uncertainty surrounding the patent. Petitioner's Opening Brief at 15, Schering-Plough, (2006) (No. 05-273), 2005 WL 22989651, slip op. at 19 (F.T.C. Dec. 8, 2003). For this reason, to properly assess the reasonableness of a settlement agreement, a court must not cease its analysis upon determining that the litigation was not a sham. The strength of the patent is a crucial consideration before dismissing an antitrust challenge to a patent settlement agreement. Tamoxifen, at 225 (Pooler, J., dissenting) (citing Standard Oil Co., Ind v. United States, 283 U.S. 163, 180 (1931), and United States v. Singer Mfg Co., 374 U.S. 174 (1963) (White, J., concurring)). While many courts will give patents a presumption of validity in similar cases, it is important to note that this presumption is rebuttable. In re K-Dur Antitrust Litig., 338 F. Supp. 2d 517, 534, n.23 (D.N.J. 2004). Obviously weak patents that are protected only by high payouts to generic challengers are harmful to consumers, and these patents should not be insulated from

antitrust review. Such settlements insulate invalid patents from legal and economic competition, keeping prices artificially high and restricting output, while providing monopoly profits to the wrongful holders of the invalid patents and any generic challengers who are willing to be paid off.

iii. The relevant facts show that the settlement is unlawful under a full rule of reason analysis.

a. Facts indicate that Norton's patent is not strong.

Despite Norton's express claim that they would have a 70% chance of a successful patent defense, the facts indicate that Norton's patent is not strong. Norton agreed to pay \$150 million to QuikClone to delay entry into the market for only two years. App. 7. \$150 million is an approximation of the profits QuikClone would earn from two years of generic sales. App. 8. It is not an amount equivalent to the attorney fees that Norton would pay to defend their patent lawsuit, even though it is cleverly explained as "compensation for attorney fees and various opportunity costs attendant to settlement." App. 7. This indicates that Norton is not just paying QuikClone because settling is cheaper than litigating; Norton is paying QuikClone because it estimates that it would lose in litigation. These facts serve to rebut any presumption of validity that may be afforded to patents by the court. Additionally, unlike the facts in Tamoxifen, there is no evidence that district courts have upheld the validity of the patent in the face of multiple generic challengers. Tamoxifen, at 194-195. Therefore, the restraint of trade is currently suppressing economic and legal competition, not merely regulating or promoting competition. If the settlement helps to protect a weak patent from legal challenges, it maintains an artificially high price for consumers and restricts output, producing anticompetitive effects not contemplated by patent law.

b. The settlement restricts the relevant product market to one producer instead of potentially several.

The relevant product market consists of drugs used to treat the affliction called logorrhea: currently only Logotor and any generic bioequivalents. App. 4. Consumers generally do not have a preference for an original (i.e., name-brand) drug over its generic equivalent, especially when there is a drastic difference in price. In fact, consumers often prefer a generic equivalent if it is less expensive and/or covered by their insurance. Presently, there is only one producer in the market, due to the patent held for Logotor by Norton. The market is currently very profitable due to increased publicity about logorrhea and its effects. App. 4. The market is regulated by patent laws, specifically the Hatch-Waxman Act, which seeks to encourage generic production of pharmaceutical products. Tamoxifen, at 191; Pub. L. No. 98-417, 98 Stat. 1585 (codified at U.S.C. Titles 21 and 35). As a patented market, the regulatory environment of the market plays a unique role in market definition and market power. If QuikClone mounted a successful Paragraph IV challenge to Norton's patent, then the market would consist of two firms for a period of 180 days, after which the market could consist of several producers. 21 USC § 355(j)(5)(B)(iv) (2000 & Supp. III 2003). The settlement restricts the market to one producer, who shares profits with another producer. The settlement also, at least temporarily, blocks other generic producers from entering the market.

Thus, the settlement agreement reduces the number of producers to one, with profits shared among potential new competitors, suppressing competition and legal challenges to the validity of Norton's patent. This lack of competition increases prices and reduces output in a way not contemplated by the patent laws of the United States. The Hatch Waxman Act was specifically enacted in order to facilitate the entry of generic firms into pharmaceutical markets. The legislative history indicates that an express purpose of the Act was to alleviate the anti-

competitive effects of the exclusion of generics from the pharmaceutical marketplace. H.R. Rep. 98-857 (II), 98th Cong., 2nd sess., 1984 U.S.C.C.A.N. 2686, 2688. Therefore, a settlement agreement based on this law that serves to restrict the number of generic firms poses anticompetitive effects that are not contemplated by patent law.

c. Alternative restraints could be imposed to achieve defendant's procompetitive objective that are less harmful to competition.

In a traditional rule of reason analysis, once plaintiffs establish that the restraint poses actual anticompetitive harm, the burden shifts to the defendants to provide a procompetitive justification for the restraint. Cipro, at 1332; Schering, at 1065; Tamoxifen, at 202, n.13. As discussed above, plaintiffs can prove anticompetitive effects due to the evidence indicating a weak patent combined with market power in the logorrhea drug market achieved by Norton that is not anticipated by patent law. Appellee-defendants argue that their settlement is procompetitive, because it provides consumers with a cheaper generic drug two years earlier than would be permitted under the patent. App. 10. This argument is exceedingly weak, and makes the assumption that the patent is valid and will be challenged by no other generic manufacturers. If the patent were held invalid by a court, consumers would receive cheaper generic drugs as soon as the patent was successfully challenged.

Alternatively, defendants may argue that the procompetitive object of their settlement agreement is to protect innovation through strong patent laws that reward those who produce new products. However, this is directly rebutted by the many alternative settlement arrangements available to the parties, other than pure reverse payments which protect monopoly profits and provide no counterbalancing benefit for consumers. Alternative arrangements to pure reverse payments are numerous and varied. They provide settlement arrangements that represent

a compromise by the parties, but they do not pose such a naked restraint to competition as to be harmful to consumers.

The simplest arrangement is discussed in the Commission's opinion in Schering-Plough. In the Matter of Schering-Plough Corporation, Upsher-Smith, 2003 WL 22989651, Docket No. 9297, (F.T.C. Dec. 8, 2003) n.105 (discussed in Schering at 1073). By prohibiting reverse payments (i.e., via a per se rule discussed above), a patent validity settlement would only alter the time at which generic products could enter the market. These settlements would still avoid litigation costs, but they would transfer the settlement benefits from the producers to the consumers. Under these arrangements, if the producer was confident that the patent was valid, settlement would result in a generic entry date that is closer to the expiration time of the original patent. If the producer was not confident of patent validity, or if the generic firm was confident of invalidity, the date of generic entry would be closer to the settlement date.

Alternative, but more complicated arrangements may include non-exclusive, unrestricted licenses and non-exclusive cross-licenses in favor of alleged infringers, whereby the defendant gives a license to practice the patent in exchange for royalties or other consideration. Herbert Hovenkamp et al., Anticompetitive Settlement of Intellectual Property Disputes, 87 MINN. L. REV. 1719, 1739-1740 (2003). Purely vertical agreements create arrangements similar to a producer and seller relationship. Id. at 1741-1743. Other types of settlements may include exclusive licenses to alleged infringers, exclusive cross-licenses and pools, concerted refusals to deal, restricted licenses or cross-licenses, and licenses containing field-of-use restrictions. Id. at 1743-1749. Not all of these settlements will always be free from antitrust challenge. However, they are alternative ways to protect patent innovation and avoid litigation costs, without resulting

in a naked restraint of trade that is as harmful to consumers as pure reverse payments. Id. at 1749-1763.

The Norton settlement agreement fails to pass the appropriate rule of reason test. An abbreviated rule of reason test is inappropriate where the court is not completely familiar with the business relationships involved and the complexities of the industry make the anticompetitive effects difficult to understand. The full rule of reason analysis should determine anticompetitive effects by examining the strength of the patent, the relevant market, market shares, and the availability of alternative, less harmful restraints to satisfy the defendant's goals. Plaintiffs show an insufficiently strong patent due to the terms of the settlement agreement, and the willingness of the patent-holder to depart with large portions of potential profits. Plaintiffs retain total market share in the relevant and lucrative market, and the settlement agreement maintains this market power, while dividing the monopoly profits among the parties to the settlement. Many alternative settlement arrangements exist for the parties to avoid litigation while passing on appropriate cost savings to the consumers, instead of retaining all monopoly profits at the producer level for a patent of questionable validity. The settlement agreement is anticompetitive and invalid under the rule of reason.

B. In the alternative, the settlement would be unlawful under an abbreviated rule of reason analysis.

Although the abbreviated rule of reason analysis articulated by the Eleventh and Federal Circuits is not appropriate for complex patent settlement agreements, even if the court uses this analysis, the settlement would still be unlawful under an abbreviated rule of reason analysis. Patent settlements pose a unique problem in applying a rule of reason analysis under antitrust law. While the rule of reason analysis attempts to determine legality by assessing competitiveness, courts have reasoned that the very nature of a patent attempts to encourage

innovation through a legal but anticompetitive market. Schering, at 1065; Cipro, at 1333. Therefore, these courts posit that determining illegality in terms of competitiveness, as in a traditional rule of reason analysis, may be confusing or counterproductive.

Instead, the Eleventh and Federal Circuits advance an abbreviated rule of reason analysis to focus the antitrust inquiry to the crucial facts and clarify the issues before the court. The abbreviated rule of reason analysis for patent settlements requires determination of 1) the exclusionary scope of the patent, 2) whether the agreement exceeds that scope, and 3) anticompetitive effects resulting from an agreement that exceeds the scope of the patent. Schering, at 1066; Cipro, at 1333. As mentioned above, this analysis disregards the strength of the patent, thereby giving no weight to the nature of the restraint itself. Therefore, this analysis is not ideal for determining such a complex antitrust matter. However, even using the abbreviated rule, Norton's patent settlement fails to constitute a reasonable restraint.

i. The exclusionary scope of the patent includes the legal limits of patent rights as defined by the Hatch-Waxman Act.

The Patent Act allows the patentee to exclude competition until expiration of the patent. Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945). However, a patent cannot confer more rights to a patentee than is provided for by the patent laws, i.e., it cannot extend a patent monopoly beyond the statutory patent right to exclude. Schering, at 1067 (citing Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 708 (Fed. Cir. 1992)). A crucial limit to a patentee's rights is found in the Hatch Waxman Act, which sets forth a regulatory scheme by which generic drug manufacturers can enter pharmaceutical markets more easily and increase competition. Pub. L. No. 98-417, 98 Stat. 1585 (codified at U.S.C. Titles 21 and 35).

The exclusionary scope of Norton's patent allowed Norton to have full patent rights until 2014. The patent permitted Norton to exclude QuikClone or any subsequent generic drug

challengers in the marketplace until QuikClone or another manufacturer could prove that Norton's patent was invalid. However, the patent did not permit Norton to use a settlement agreement with QuikClone in order to exclude or delay subsequent legal challengers under the Hatch Waxman Act. The district court erred by not considering the legal limits, as set forth by the Hatch Waxman Act, of the exclusionary scope of Norton's patent.

ii. The exclusionary scope of the settlement exceeds the scope of the patent because it delays legal challenges.

The abbreviated rule of reason determines whether the exclusionary scope of the settlement agreement exceeds the exclusionary scope of the underlying patent. If the settlement is within the scope of the patent, then the settlement does pose an antitrust violation. Schering, at 1066; Cipro, at 1333.

The terms of the settlement agreement between Norton and QuikClone allow for QuikClone to refrain from competing until 2012, two years before the expiration of the patent. In return, Norton pays QuikClone \$150 million. Ostensibly, and as the district erroneously concluded, this agreement appears to fall within the scope of the underlying patent, because it excludes QuikClone from competing for a period that is less than the original term of the patent. However, due to manipulation of provisions of the Hatch Waxman Act, this agreement also delays subsequent generic challengers of the validity of Norton's patent.

The Hatch Waxman Act provides a 180-day exclusivity period for the first generic firm to file an ANDA-IV. This prevents the FDA from approving a subsequent generic firm's ANDA until 180 days after the first firm 1) initiates commercial marketing, or 2) receives a court determination on the validity of the original patent. 21 U.S.C. § 355(j)(5)(B)(iv) (2000 & Supp. III 2003). New statutory provisions take some of the teeth out of this anticompetitive effect by

mandating that the first generic filer forfeit their 180-day exclusivity period upon settlement with the original patent-holder. 21 U.S.C. § 355(j)(5)(D) (Supp. III 2003).

A similar settlement to the present case, but brought under the previous statutory 180-day exclusivity period was struck down by the Sixth Circuit as anticompetitive in In re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003). The court held that the settlement was per se anticompetitive mostly due to the fact that the generic firm agreed not to relinquish their 180-day exclusivity period until they began marketing the product. This effectively delayed any other legal challenges by generic firms until the date upon which the original parties agreed to begin marketing the generic product. Id. at 908. The ability to delay legal challenges until the original patent expiration created an exclusionary settlement that was outside the scope of the original patent.

While the amended statute no longer allows such an egregious manipulation, the same reasoning applies in the instant case: the scope of the original patent does not include the ability to pay in order to delay legal challenges and prolong a wrongful monopoly based on an invalid patent. Once Norton initiated proceedings against QuikClone, the Hatch-Waxman Act provided Norton with a thirty-month stay of FDA approval of the generic drug. The thirty-month stay, combined with 180-day exclusivity period, serves to prolong the period in which no other generic firms may bring a challenge against the existing patent. Once a settlement was reached with QuikClone, a subsequent challenger could begin the process of filing an ANDA-IV, but due to the time involved in these litigations and settlements, Norton was unlikely to face more than two to three challenges before the expiration of the patent. Thus, the settlement agreement allows Norton to pay in order to delay legal challenges to the validity of its patent, thereby exceeding the original exclusionary scope of a traditional patent.

iii. Anticompetitive effects result from settlement agreement.

The settlement agreement between Norton and QuikClone results in anticompetitive effects under the abbreviated rule of reason analysis. Competitive harm results from a restraint of trade when it raises price and reduces output, transferring wealth from the consumers to producers who hold market power. C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553, 1572 (2006). While United States patent law generally results in an anticompetitive market, the Hatch Waxman Act was enacted to encourage generic production of pharmaceuticals, increasing consumer access to new drugs. H.R. Rep. 98-857 (II), 98th Cong., 2nd sess. 1984, 1984 U.S.C.C.A.N. 2686, 2688. Therefore, settlements that manipulate Hatch-Waxman provisions in order to provide excess benefits to drug manufacturers harm consumers and result in anticompetitive effects.

By allowing Norton to pay QuikClone for a delay of competition, the settlement agreement keeps consumer prices higher than they would be if QuikClone, or any subsequent generic filer, mounted a successful ANDA-IV challenge to Norton's patent. When two competitors make an agreement to keep prices artificially high, a classic Section 1 violation of the Sherman Act occurs. Hemphill, at 1572. Consumers are harmed by the lack of legal challenges and potentially resulting competitive reduction in price. Finally, economic modeling on the whole has shown that pay-for-delay settlements on average result in a greater harm to consumers than would result if patent litigation was resolved by other means. Id., at 1572-1573.

The settlement agreement allows Norton to pay for the ability to delay legal challenges to the validity of its patent. This exceeds the exclusionary scope of a patent, which only grants the patent-holder statutory patent rights of exclusion. These statutory rights are defined and limited by the Hatch-Waxman Act, legislation enacted to encourage generic firms to enter

pharmaceutical markets. Ultimately, the exclusionary nature of the settlement agreement exceeds the scope of the patent and results in anticompetitive harm to consumers.

iv. Other circuit opinions using the abbreviated rule of reason are distinguishable.

Other circuit opinions have allowed similar settlements, but these opinions are either distinguishable or erroneous. The Eleventh Circuit's decision in Schering is distinguishable because it involved two settlements, neither of which were pure reverse-payment settlements. One, the settlement between Schering and Upsher, involved a licensing arrangement. Schering, at 1059. The other, between Schering and ESI, involved payment from Schering to ESI, conditional only upon ESI's ability to obtain FDA approval for its generic drug. Schering, at 1060-1061. Both of these arrangements complicate the rule of reason analysis and do not constitute such a clear case of a settlement that exceeds the patent's scope by paying to delay legal challenges.

The Federal Circuit's opinion in Cipro was also not such a simple case of paying to delay legal challenge. The generic firms agreed to convert their Paragraph IV certification to a Paragraph III certification, indicating that they were dropping their validity challenge entirely. Cipro, at 1328-1329. In exchange, the original patent-holder granted a resale-supply agreement with the generic firms. Id., at 1329. Similar to the facts in Schering-Plough, this case did not contain a clear pay-for-delay arrangement. Thus, the parties could argue that payments were in consideration of other services, as opposed to a simple delay of legal challenge.

Finally, the Second Circuit, in Tamoxifen, ruled on a case with very similar facts to Cipro. The generic firm agreed to convert Paragraph IV certification to Paragraph III certification, and the two parties agreed on a non-exclusive licensing arrangement. Tamoxifen, at 193-194. Again, the facts do not indicate a naked pay-for-delay settlement.

All three circuit decisions above fail to recognize the importance of a full rule of reason analysis that analyzes the strength of the underlying patent. They also all fail to consider the legal limits of the exclusionary scope of a patent along with the simple market scope of the patent. However, all three cases are distinguishable from the present case because they do not involve an express payment that is solely in consideration for a delay of legal challenge. The ability of an invalid patent-holder to share monopoly profits with a competitor simply to avoid legal challenges to the patent is outside the legal scope of patent rights. The settlement agreement exceeds the scope of the patent in the present case and must be struck down as anticompetitive.

CONCLUSION

For the reasons stated above, this court should determine that the Norton-QuikClone Agreement is per se unlawful under Section 1 of the Sherman Act. In the alternative, this court should find for the appellant because the settlement is unlawful under the rule of reason analysis. Ultimately, the decision of the United States Court District Court for the District of Mason should be reversed.

Respectfully submitted,

Team E
Federal Trade Commission
2580 Pennsylvania Ave., N.W.
Washington, D.C.
Counsel for the Petitioner-Appellant

January 21, 2009

CERTIFICATE OF SERVICE

This document certifies Registered First-Class Mail delivery of six copies of the foregoing brief to the Committee, at George Mason University School of Law, 3301 N. Fairfax Drive, Arlington, VA 22201, on this 21st day of January, 2009. This document also certifies electronic delivery of one copy of the foregoing brief to the Committee, at lec@gmu.edu, on this 21st day of January, 2009.

CERTIFICATE OF COMPLIANCE

This document certifies that this brief was completed in accordance with the Rules governing The Henry G. Manne Moot Court Competition for Law & Economics. This brief, representing the Plaintiff-Appellant, is the work product solely of Julie Byrne and Erin Cleary, team members for The Ohio State University Moritz College of Law.

Julie Byrne

Erin Cleary
