

## **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 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?

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## STATEMENT OF FACTS

Norton Pharmaceutical (“Norton”) holds the patent for the logorrhea treatment drug known as Logotor. Joint Appendix, 2, F.T.C. v. Norton Pharma., Inc., No. 08-1129 (D. Mason filed Nov. 14, 2008) [hereinafter “Joint Appendix”]. Norton’s received the patent in 2002 and it is set to expire in 2014. *Id.* at 5, 9. The U.S. sale of drugs derived from pharmaceutical patents is governed by the United States Food and Drug Administration (“FDA”) under the guidance of the Hatch-Waxman Act of 1984 (“Hatch-Waxman”). Hatch-Waxman sought to encourage competition in the pharmaceutical industry from generic drug manufacturers. *See, e.g., SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 690 (E.D. Pa. 2004).

To that end, the FDA allows generic drug manufactures seeking to sell bioequivalent drugs to build off the clinical trials conducted by a pharmaceutical patent holder while for their drug’s approval with an Abbreviated New Drug Application (“ANDA”). 21 U.S.C. 355(j)(2)(A). With a typical ANDA application, the generic drug will only be approved for U.S. sale after the original patent is declared invalid or expires. Joint Appendix, 6. A “Paragraph IV” ANDA, though, claims that the original patent is invalid or will not be infringed by the generic drug, enabling the immediate entry of the generic drug onto the market. 21 U.S.C. 355(j)(2)(A). The first Paragraph IV filer enjoys 180 days of exclusivity on the generic market after the patent protections end, by FDA declaration, judicial decision or other agreement. 21 U.S.C. 355(j)(5)(B)(iv). Filing a Paragraph IV ANDA is an act of infringement under patent law, and the patent holder has 45 days to bring a suit to enforce its patent. 35 U.S.C. 271(e)(2).

On March 1, 2005 Quikclone Laboratories (“Quikclone”) filed its Paragraph IV ANDA for the logorrhea drug Quiescence. Joint Appendix, 7. Norton filed a timely suit to enforce its patent. *Id.* Though the suit progressed through the discovery stage, the parties settled in May

2006. *Id.* The parties reached an agreement (“Norton-Quikclone Agreement”) with the following terms: 1) Quikclone would not market Quiescence until January 1, 2012 after which date Norton would not object to the sale of Quiescence through the remainder of the patent term, and 2) Norton would pay Quikclone \$150 million for attorney’s fees and associated opportunity costs, known as *reverse payments*. *Id.* at 7. In accordance with law, the parties submitted their settlement to the Federal Trade Commission (“FTC”) and the Department of Justice for antitrust review. *Id.* at 9.

The FTC believed the Norton-Quikclone Agreement violated the Section 1 of the Sherman Act and sued Norton. *Id.* The parties stipulated that Norton has a monopoly in the logorrhea drug market. Joint Appendix, 9 n.7. In District Court, the FTC argued that when a patent created monopoly exists, reverse payments from the patent holder “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.” *Id.* at 10. In summary judgment, the District Court rejected this argument because “reverse payments may serve useful, pro-competitive purposes in some cases, and a hard and fast rule that prohibits them would be too extreme.” *Id.* at 11.

A rule of reason analysis duly followed. The FTC urged that the rule of reason analysis that looked at the particular circumstances of pharmaceutical patents and drug sales in general. *Id.* at 11-12. The District Court rejected this argument in favor of a bright line test asserted by Norton that any agreement with the patents exclusionary zone should not be considered anticompetitive. *Id.* at 11. The Logotor patent expires in 2014, so the agreement in question, regardless of the reverse payments, falls within the exclusionary zone. *Id.*

We, as appellants, brought this appeal in a proper and timely manner.

### **SUMMARY OF THE ARGUMENT**

The District Court erred in both its findings. Not only is the Norton-Quikclone Agreement with reverse payments per se anticompetitive under the Sherman Act, but the legality of reverse payments also fails a properly rule of reason analysis. If the court rules in Appellant's favor on either of these grounds, the Norton-Quikclone Agreement must be deemed anticompetitive and in violation of the Sherman Act.

The District Court's reasoning against per se illegality fails for two reasons. First, the court clearly assumed that Norton's patent was valid. Both patent law and the Hatch Waxman system clearly undermine the validity of that assumption. If the assumption of patent validity does not stand, then a reverse payment agreement which artificially extends the life of a patent cannot be considered procompetitive. Second, the District Court ignored the significant opportunities for anticompetitive behavior created by Hatch-Waxman. Reverse payments delay the entry of competition into the market, which serves no procompetitive purpose. Reverse payments, therefore, are per se illegal.

Further, the District Court's rule of reason analysis was improperly truncated. The exclusionary zone of a patent applies extends to the temporal duration of the patent, as well as to the claims asserted by the patent and the exclusionary rights associated with those claims. A rule of reason analysis, therefore, should define the scope of the patent along all these dimensions.

When doing so, one discovers that the Hatch Waxman Act extends a pharmaceutical patent's scope by greatly enlarging the patent's exclusionary rights. Norton's reverse payments fall outside the scope of a patent's exclusionary rights because the patent is likely invalid.

Further, reverse payments exercise rights beyond the scope of the patent because they supplant a decision on the patent's validity. As such, the reverse payments disrupt the statutory balance between innovation and competition struck in Hatch-Waxman.

Reverse payments, therefore, result in anticompetitive arrangements. Reverse payments extend Norton's monopoly, thereby fixing monopolistic anticompetitive prices. Also, recent changes to the Hatch-Waxman system do little to stem the anticompetitive effects of reverse payments. Accordingly, this court should find that reverse payments violate the Sherman Act.

## **ARGUMENT**

**I. The settlement agreement between Norton Pharmaceuticals ("Norton" or "Patentee") and QuickClone Laboratories ("QuickClone" or "Challenger"), which includes a "reverse payment" from Patentee to Challenger as compensation for Challenger's agreement to delay entry into the market, is per se illegal under section 1 of the Sherman Antitrust Act**

Section 1 of the Sherman Antitrust Act indicates that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States...is declared to be illegal." Despite this absolute prohibition 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).

The Supreme Court conducts two different types of analysis in section one cases, per se analysis and rule of reason analysis. Per se analysis is reserved for agreements with a "predictable and pernicious anticompetitive effect, and . . . limited potential for procompetitive benefit" Id. at 10. This reflects recognition by the Court that "certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anti-competitive that each is illegal per se without inquiry into the harm it has actually caused." Copperweld Corp. v.

Independence Tube Corp., 467 U.S. 752, 768 (1984). *See e.g.*, Palmer v. BRG of Ga., Inc., 498 U.S. 46 (1990) (per curium) (finding a horizontal market allocation agreement per se illegal); United States v. Topco Associates, Inc., 405 U.S. 596, 608 (1972) ("one of the classic examples of a violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition").

In its legal analysis, the District Court implicitly acknowledged that the agreement between Norton and QuickClone constitutes a horizontal market allocation agreement between competitors or potential competitors, and that this type of agreement is “one of the most egregious violations of the antitrust laws.” Joint Appendix, 9. Despite this, the court rationalizes that because Logotor is the subject of a patent-which provides Norton with a legal monopoly on the sale of the product if valid-any agreement that allows competition within the scope of the patent may “serve useful, pro-competitive, purposes in some instances,” and is thus not per se illegal. Joint Appendix, 9-11. This conclusion is erroneous because it assumes that the patent is valid and characterizes a purchased entry delay of over 4 years as pro-competitive. This conclusion further fails to recognize that because of the incentives and restrictions unique to pharmaceutical patents under the Hatch Waxman Act the alleged precompetitive benefits are so unlikely to be realized as to be negligible.

**A. The District Court’s findings on per se illegality were based upon an erroneous assumption that the challenged patent is valid and not infringed.**

Although patent law does provide for a presumption of validity for patents, it also provides that this presumption is rebuttable and provides guidance on rebutting the presumption in court. 35 U.S.C. 282. *See also*, Brief for Plaintiffs-Appellants at 22, In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323. Courts have recognized that the rebuttable

presumption “is a procedural device, not substantive law.” Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983). This procedural presumption allocates burdens among litigants but cannot “acquire an independent evidentiary role in any proceeding.” In re Etter, 756 F.2d 852, 856 (Fed. Cir. 1985).

An additional example of the falsity of any substantive assumption of patent validity can be found in proceedings where the patentee seeks a preliminary injunction against an alleged infringer. In these cases the “the patentee carries the burden of showing likelihood of success on the merits with respect to the patent's validity.” Nutrition 21 v. United States, 930 F.2d 867, 869 (Fed. Cir. 1991) (emphasis in original). Citing the alleged infringer’s right to compete, courts frequently deny these preliminary injunctions. *See, e.g.*, Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 684 (Fed. Cir. 1990).

Further example of the inappropriateness of a substantive assumption of patent validity arises from within the facts of this case. Norton has estimated that its chances of prevailing on all claims were only 70%. Joint Appendix, 8. Although this assertion is clearly contradicted by an internal memo from Norton’s CEO to his Board (Joint Appendix, 12, FN 9), even an assumption that this 70% is accurate results in less than substantive certainty. This presumption of validity cannot stand in the face of an aggressive challenge that has been deterred only by a large payment from the patentholder to stay out of the market. In the absence of this presumption of validity, the purchased four year entry delay cannot be construed as pro-competitive, but is instead a bargained for result driven by the positions of the two parties and influenced by the incentives and structure of the Hatch-Waxman environment.

**B. Large reverse payments to a competitor in order to delay market entry are per se illegal, because they are naked horizontal restraints and have no procompetitive justification.**

The structure of the pharmaceutical patent process created by Hatch-Waxman creates significant opportunity and incentive for collaborative anticompetitive behavior. When this incentive results in agreements with a large reverse payment to a competitor in order to delay market entry they are naked horizontal restraints, have no procompetitive justification and are therefore per se illegal.

In an attempt to maintain incentives for innovation among pharmaceutical companies while easing the path to entry for generic competitors in an attempt to reduce prices for consumers the Hatch Waxman Act created three important procedures that dramatically effected economic incentives and created significant incentives for anticompetitive collaboration. The first established a patent listing process for the pioneer and a corresponding abbreviated approval process for generics, who could now avoid the expensive clinical trial process by showing that the bioequivalence of their drug through an Abbreviated New Drug Application (“ANDA”) 21 U.S.C. 355 (j)(2)(A). The manufacturer of the generic may avoid waiting for the pioneer patent to expire by filing a “Paragraph IV” certification with the FDA that alleges either that the generics drug does not infringe upon the pioneer’s patent, or that the pioneer’s patent is invalid. This filing is itself a patent infringement that provides the patent holder with the immediate right to file suit to enforce his patent. 355 U.S.C. 271(e)(2). When filed, the pioneer has 45 days to file suit or the FDA may approve the ANDA once bioequivalence is established. The filing of suit by the patent holder triggers the second significant provision, an automatic stay of 30 months or until the patent is found to be not infringed, invalid or unenforceable, is sooner. 21 U.S.C. 355(j)(2). The third provision was intended as an incentive for generic manufacturers to challenge patents and created a 180 day generic exclusivity for the first to file a challenge. The

exclusivity begins at the time the generic manufacturer begins to market the generic drug and only applies to the first filer. 21 U.S.C. 355 (j)(5)(B)(iv).

These provisions created significant opportunity for anticompetitive behavior, particularly in relation to settlements between the parties. In recognition of this concern submission of settlements between pharmaceutical patent holders and challengers to the FTC and the Department of Justice is required. 21 U.S.C. 255. In a normal patent action the patent holder sues the infringer and the infringer either chooses to go to court to defend its position that the patent is invalid or not infringed, or agrees to pay the patent holder damages for infringement. These situations raise few antitrust concerns because it can be assumed that the actions of the parties derive from their perception of the relative strength of their position. Antitrust concerns have typically arisen in situations where the patentholder settles their suit with the challenger and pays a large fee in return for the challenger's agreement to stay out the market for a period of time, or completely. See e.g., In re Cardizem CD Antitrust Litigation, 105 F. Supp. 2d 682 (E.D. Mich. 2000). The FTC has recognized that often these exclusivity payments provide more profit for both parties than if the generic had entered the market. "In nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the profit the brand-drug company makes from the same sales. Consequently, it typically will be more profitable for both parties if the brand-name manufacturer pays the generic manufacturer to settle the patent dispute and agree to defer entry." Prepared Statement of the Federal Trade Commission before the Special Committee on Aging of the United States Senate on Barriers to Generic Entry, p. 11 (July 20, 2006), available at:

<http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySe7202006.pdf>.

Settlements involving these large exclusion payments raise particular concerns, because they can

result not only in reduced competition due to the generic challenger's refusal to enter the market, but they create barriers to challenges by other generic manufacturers as well. This is caused by the interaction of the 30 month automatic stay of ANDA actions and the 180 day exclusivity for first filers. First, the action of the original challenger is delayed by 30 months. Although it is possible that other generic manufacturers could file, their incentive to do so is very low because of the uncertainty involved in the first challengers action and the fact that the first filer will have access to the 180 day exclusivity. Once the first filer and the patent holder settle after the 30 month stay a second generic could file an ANDA but again the incentive to do so has been reduced because entry will be delayed by another 30 month stay, and the second filer still has no access to the 180 day exclusive. This incentive is particularly low where, as in the Norton case, entry of the first filer has only been delayed, not completely excluded because the first filer is still entitled to the 180 day exclusivity. While it is now theoretically possible for a secondary challenger to force the triggering or forfeiture of the 180 day stay by getting a declaratory judgment of non infringement while the first filer is absent from the market, this still takes considerable time and may simply result in the first filer entering the market to claim the 180 day exclusive. 21 U.S.C. 355 (j)(5)(D)(bb)(AA). “[P]harmaceutical patentees who agree to exclusion payments seek more than enforcement of patent rights: they seek “a guaranteed insulation from competition, without the risk that the patent is held invalid.” 1 Herbert Hovenkamp et al., IP and Antitrust § 7.4, at p. 7-41 (2007 Supp.). “IP policy does not offer such a guarantee, and does not immunize from antitrust scrutiny those who seek it by entering into agreements that exclude potential competitors.” Id. Because these agreements are always anticompetitive and lack any procompetitive justification, they are per se illegal.

**II. Even if this Court should find that the reverse payment settlement in question is not per se illegal, the settlement is still outside the scope of the patent and produces unreasonable anticompetitive effects when analyzed under the rule of reason.**

**Standard of Review:**

A grant of Summary Judgment requires “that there be no genuine issue of material fact” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Summary Judgment must also be denied if a jury could reasonably find in favor of the non-moving party Id. at 252.

Furthermore, whenever a court performs a rule of reason analysis, the “plaintiff bears the burden of demonstrating that the agreement produces anti-competitive effects.” F.T.C. v. Indiana Federation of Dentists 476 US 447, 460-61 (1986). Therefore, the burden is on the FTC to show that the reverse payment settlement agreement is anti-competitive. In this situation, however, the FTC can present significant evidence to shoulder this burden.

**A. Determining the Appropriate Parameters of the Rule of Reason Analysis for Settlements of Pharmaceutical Patents**

The Supreme Court first laid a foundation for performing the rule of reason analysis in 1918. When faced with a possibly anticompetitive action, the Court found that the “true test of legality is whether the restraint imposed is such as merely regulates and [] thereby promotes competition or whether [the restraint] may suppress or even destroy competition.” Board of Trade of City of Chicago v. U.S. 246 U.S. 231, 238 (1918). In order determine whether the restraint in fact was an unreasonable restraint on trade the Court realized it was necessary to engage in detailed factual inquiry. The Court listed several factors that are vital to an analysis of this type including; “the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect,

actual or probable.” Id. at 238. Essentially, in a traditional rule of reason analysis “[t]he probability that anticompetitive consequences will result from a practice and the severity of those consequences must be balanced against its pro-competitive consequences.” Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 50 n. 6 (1977).

This traditional rule of reason analysis, however, does not take into account a patent holder’s right to exclude others from use of the patented product. Therefore, “deciding the antitrust implications of these exclusionary effects requires an analysis of the effects of antitrust liability on the innovation and disclosure incentives created by the patent regime, with the aim of achieving a suitable accommodation between the differing policies.” Valley Drug Co. v. Geneva Pharmaceuticals, Inc. 344 F.3d 1294, 1311 (11th Cir. 2003). As it is recognized that the exclusionary rights of a patent are at odds with the competition enhancing aims of antitrust law, “courts normally construe patent rights narrowly in deference to the public interest in competition.” U.S. v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1127 (D.D.C. 1981) (citing Mercoird Corp. v. Mid-Continent Inv. Co., 320 U.S. 661, 665-66 (1944)). When approaching a case where patent and antitrust policies collide the proper analysis seems to be a “consideration of the scope of the exclusionary potential of the patent, the extent to which these provisions of the agreements exceed that scope, and the anticompetitive effects thereof.” Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294, 1311-12 (11th Cir. 2003). In other words, patent settlements must not be agreements that enforce arrangements beyond the scope of the patent. Furthermore, these arrangements cannot be anticompetitive. The patent settlement in the present case does not meet standard set in *Valley Drug*.

## **B. The District Court Selected the Appropriate Parameters for the Rule of Reason Analysis, but Conducted the Analysis Improperly**

Norton and the District Court purport to follow this analysis, yet conclude that an in depth factual analysis of the anticompetitive effects of the settlement is unnecessary. Joint Appendix, 9-12. Only defining the scope of the patent temporally, *id.*, the District Court failed to complete an appropriate rule of reason analysis because it adopted an inappropriately narrow definition of the scope of the patent. The true scope of a patent should not only be defined merely by its temporal aspects, but also by its substantive claims and the rights a patent holder has to exclude others from those claims. *See U.S. v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1127 (D.D.C., 1981) (“[the] right to exclude others from profiting from the patented invention . . . to suppress the invention while continuing to prevent all others from using it, to license others, or to refuse to license, and to charge such royalty as the leverage of the patent monopoly permits.” (citations omitted)).

Had Norton and QuikClone simply settled the case and fixed a date prior to the expiration of the patent for Quiescence’s entry into the market, only the temporal aspect of the patent’s scope would have been effected. Under such an agreement, the District Court’s analysis would have been completely appropriate. The agreement, however, provides for Norton’s reverse payments. Such payments purport to enforce rights beyond the temporal scope of the patent, and in fact, are anticompetitive. Commentators have noted that agreements with reverse payments in excess of attorneys fees do not seek to enforce a patent right, rather, they seek “guaranteed insulation from competition, without the risk that the patent is held invalid.” 1 HERBERT HOVENKAMP, MARK D. JANIS, AND MARK A. LEMLEY, *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 7.4, at p. 7-41 (2007 Supp.). In other words, reverse payment agreements attempt to immunize market allocation

agreements from antitrust scrutiny. All market allocation agreements, even those founded on patent rights, are subject to antitrust scrutiny. *See* U.S. v. U.S. Gypsum Co., 333 U.S. 364, 392 (1948).

### **C. A Proper Rule of Reason Analysis for the Norton-QuikClone Agreement**

A proper rule of reason analysis of the Norton-QuikClone agreement must clearly define the scope of the Logotor patent, assess whether the reverse payment elements of the agreement fall outside the scope of the patent, and determine whether reverse payments are in fact anticompetitive. The next three sections complete such an analysis.

#### **1. Defining the Scope of the Logotor Patent**

##### **a) General Principles on the Scope of Patents**

A patent's scope reaches in two dimensions. Primarily, patents only grant patentees exclusionary rights as to the claims listed on the patent. Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251 (Fed. Cir. 1989); *see also* Morton Salt Co. v. Suppiger Co., 314 U.S. 488, 492 (1942). A patent holder, therefore, cannot attempt to exclude a competitor's products that fall outside the patent's scope. Nor can a patent holder exclude competitors in a manner beyond the scope of the patent holder's exclusionary rights. A patent's temporal duration meets the second dimension of a patent's scope. A patent holder cannot enforce its claims beyond the temporal duration of the patent. Warner-Lambert Pharmaceutical Co. v. John J. Reynolds, Inc., 178 F. Supp. 655, 664, (S.D.N.Y. 1959) ("when the parties agree upon a license under a patent or copyright the court will assume, in the absence of express language to the contrary that their actual intent as to the term is measured by the definite term of the

underlying grant fixed by the statute"), *aff'd on other grounds*, 280 F.2d 197 (2nd Cir. 1960).

Accordingly, a patent's scope is defined by its ability to exclude others based on its claims and its duration.

As a general matter, a patent's scope only extends as far the validity of its claims. For example, a licensee is not required to continue to pay royalties after a patent's claims have been found invalid. Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co., 112 F.3d 1561 (Fed. Cir. 1997), *reh'g denied, en banc suggestion declined* (Jun 27, 1997), *cert. denied* 522 U.S. 996 (1997). Typically, therefore, a patent holder only has rights to exclude others from the market in so far as the patent claims are valid.

#### **b) Hatch-Waxman Extends the Temporal Duration of Pharmaceutical Patents**

The reach of a pharmaceutical patent's scope is different from other patents. Specific to the issues at hand, the Hatch-Waxman Act modified both the enforceability of the claims and the patent's duration. *See Biotechnology Industry Organization v. District of Columbia*, 505 F.3d 1343, 1347 (Fed. Cir. 2007) ("The legislative history of the Hatch-Waxman Act demonstrates that the Act's readjustment of the scope of the patent right for pharmaceutical products..."). Regarding the duration of the patent, the Hatch-Waxman act added a year for every two years the patented drug is in clinical trials in addition to the time spent in FDA approval after the trials. 35 U.S.C. 156(c), (g)(1)(B), & (g)(6).<sup>1</sup> The FDA also has the option to extend a patent's life if it determines the patent has pediatric benefits and applications. 21 U.S.C. 355(a). A pharmaceutical patent's duration, therefore, is modified by the FDA under Hatch-Waxman.

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<sup>1</sup> All U.S. Code citations throughout this brief refer to the 2006 version of the U.S. Code.

### **c) Hatch-Waxman Modifies the Exclusionary Rights Associated with Pharmaceutical Patents**

Hatch-Waxman also changed the enforceability rights of a pharmaceutical patent's claims in several ways. First, the pharmaceutical patent holders with FDA approval do not need to enforce their patent claims for at least four years after the drug enters the market. Second, the pharmaceutical patent holders enjoy lower pleading standards than other patent holders. Third, even after a claim challenge is filed, the claim challenge typically cannot take effect for at least thirty months. Fourth, pharmaceutical patent holders can still effectively enforce their patent claims against some parties even after a judicial determination that the patent is either valid or not infringed.

#### **i. Absolute Exclusionary Rights for at Least Four Years**

Under the Hatch-Waxman system, a drug maker interested in selling a generic version of the patented drug would gain little from challenging the validity of the patent directly. Even a successful challenge to a patent would not allow the challenging drug maker to sell the drug. No drug can be sold in the U.S. without FDA approval. 21 U.S.C. 355(a); US FDA, CDER: The Consumer Watchdog for Safe and Effective Drugs, <http://www.fda.gov/fdac/special/testtubetopatient/cder.html> (last visited Jan. 20, 2009). A generic drug maker, accordingly, must apply for approval from the FDA. Hatch-Waxman, though, established that applications for approval of generic drugs would not be accepted for at least four years, and in some cases, up to five. 21 U.S.C. 355(j)(5)(F)(ii). A pharmaceutical patent holder with FDA approval, therefore, is effectively free from patent challenge during the FDA stay period. The enforceability of the patent's claims is ensured for at least four years

under Hatch-Waxman. This can be understood to expand the scope of the patent enforceability rights.

## **ii. Pharmaceutical Patent Have a Lower Pleading Standard in Defense of Patent Claims**

Once the FDA stay expires, a generic drug maker can apply for approval of its drug with an Abbreviated New Drug Application, under paragraph IV (ANDA-IV), which claims that the relevant patent “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” 21 U.S.C. 355 (2)(A)(vii)(IV); 21 U.S.C. 355(j)(5)(B)(iv). The first drug manufacturer to file an application under ANDA-IV receives a 180 day exclusivity period for the sale of its generic drug. 21 U.S.C. 355(j)(5)(B)(iv). The FDA assures the exclusivity period by delaying the approval of ANDA-IV’s from other generic manufacturers. *Id.*

The ANDA-IV and the subsequent 180 day exclusivity modify the enforceability rights of the claims in the pharmaceutical patent. Filing an ANDA-IV is, by statutory definition, an act of infringement of the patent. 35 U.S.C. 271(e)(2)(A)(2). The patent holder, therefore, can bring a suit against the ANDA-IV filer. The nature of this suit is different from other patent suits. Most patent suits for infringement of pharmaceutical patents allege that the generic manufacturer induced another to violate the patent. 35 U.S.C. 271. The elements of the inducement cause of action must be pled specifically. 35 U.S.C. 271(b); MEMC Electronic Materials, Inc. v. Mitsubishi Materials Silicon Corp., 420 F.3d 1369, 1378 (Fed. Cir. 2005); *see also* Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1304-05 (Fed.Cir.2002). A suit in response to an ANDA-IV filing, though, does not require pleading of inducement. *See* Abbott Laboratories v.

TorPharm, Inc., 503 F.3d 1372 (Fed. Cir. 2007). The patent holder, therefore, has a lower pleading standard for enforcement of its claims under Hatch-Waxman.

### **iii. Exclusionary Rights Continue after a Challenge is Filed**

Hatch-Waxman takes other steps to protect the claims in the patent. Patent holders bringing suit in other industries can receive preliminary injunctions after they establish irrevocable harm or the likelihood of success on the merits. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). Under Hatch-Waxman, patent holders need neither bring suit, nor establish irrevocable harm, nor determine the likelihood of success on the merits, nor post a bond to pay the alleged infringer's damages in case of a loss in order to effectively stop action against the patent's claims. C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y. U. L. Rev. 1553, 1608 (2006). The FDA automatically stays the approval of the ANDA-IV application for at least thirty months after the patent holder receives notice of the application. 21 U.S.C. 355(j)(5)(B)(ii) & (iii). A judicial decision can cut that time short. 21 U.S.C. 355(j)(5)(B)(iv). After the thirty months though, regardless of whether a judicial decision has been reached, the FDA can approve the ANDA-IV, thereby finally allowing competition in a market previously occupied by the patent's claims. 21 U.S.C. 355(j)(5)(B)(ii) & (iii); *cf. Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 130 (D.D.C. 1997), *aff'd*, 140 F.3d 1060, 1074 (D.C. Cir. 1998) (noting that the 180 exclusivity need not be triggered by a successful defense of a ANDA-IV suit). Accordingly, Hatch-Waxman creates a lower standard for triggering blanket protection of the patent's claims. Also, a patent's claims are protected against competition from ANDA-IV filer's for at least thirty months. Hatch-Waxman, therefore, expands the enforceability rights associated with a patent's claims.

#### **iv. Exclusionary Rights Continue after the Patent is Found Invalid or Not Infringed**

Hatch-Waxman continues to extend a patent's enforceability rights even after the FDA starts the 180 exclusivity period, regardless of a judicial decision that the patent was invalid or not infringed. In other industries, a successful challenge to a patent promptly opens up the patent to competition from all competitors because the patentee cannot no longer assert the validity of the patent. *See Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313 (1971). Hatch-Waxman allows competition from only one competitor during the 180 exclusivity period, whether a judicial decision trigger FDA approval or not. During those 180 days, the FDA bars the entry of other competitors into the market, a market which at that point is defined by patent drug within the scope of the patent's claims and the generic drug. If another generic drug manufacturer attempts to enter the market, the patent holder, at least acting through the FDA, can enjoin its entry until the new generic has FDA approval. Therefore, the 180 day period effectively allows the continued enforcement of the patent claims at the limit of their original scope towards all market entrants other than the first successful ANDA-IV filer. Hatch-Waxman, accordingly, effectively allows the continuation of a patent's enforceability rights for 180 days, even after a judicial decision that would keep the patent holder from enforcing its patent claims.

#### **d) Summary of Scope Distinctions & Policy Considerations**

In summary, the Hatch-Waxman Act modifies the scope of a pharmaceutical patent in several ways. A patent typically has a statutorily fixed duration and its claims can be challenged in court at any time. Hatch-Waxman specifically extends the duration of a pharmaceutical patent. Further, a pharmaceutical patent's claims cannot be effectively challenged for at least

four years after the drug enters the market. Once the patent holder has to begin defending those claims, it is typically granted at least an additional thirty months where claim challenge cannot take effect. This amounts to a preliminary injunction, but without the typical judicial requirements needed to obtain the injunction. After the ANDA-IV first filer enters the patent holder's market, that injunction still applies to all other generic manufacturers who would enter the market during the first 180 days. Also, holders of pharmaceutical patents enjoy lower pleading standards in order to defend their claims. Therefore, the scope of pharmaceutical patent is different from patents in other industries because Hatch-Waxman expands enforceability of the patent's claims.

It is important to note that changing the scope of a pharmaceutical patent was a policy decision. The 180 exclusivity period rewards early suits which would challenge pharmaceutical patents. Hemphill, supra, at 1579-80. Extending patent terms and bolstering the patent holder's ability to enforce its claims balances against the inducement of suits. Biotechnology Industry Organization v. District of Columbia, 505 F.3d 1343, 1347 (Fed. Cir. 2007) ("it was precisely the balance between these two interests that Congress intended to carefully calibrate when it passed the Hatch-Waxman Act, which not only extended the patent term for pharmaceutical products but also simplified the process of approval for generic products." (citation omitted)). Courts have noted the importance of balancing the dual interests of encouraging innovation through patents and increasing competition. *Id.* (specific to the drug market); Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 152 (1989) (noting that a Congressionally struck balance between patent law and antitrust cannot be second guessed). Any settlement between patent holders and ANDA-IV filers must not only operate within the scope of the patent, but also advance the policy interest of balancing innovation and competition. The next section demonstrates that the

settlement reached clearly both goes beyond the scope of the patent established here and is contrary to the policies of the Hatch-Waxman act.

## **2. The Norton-QuikClone Agreement Goes Beyond the Scope of the Logotor Patent**

The Norton-QuikClone Agreement includes terms which not only potentially delay the entry of QuikClone into the market, but also provide for reverse payments from Norton to QuikClone above the cost of litigation. Joint Appendix, 10 n. 8. A settlement which would only fix a date for the delayed entry of a QuikClone into the market and cover litigation costs would not be beyond the scope of the Logotor patent. As demonstrated in the previous section, a pharmaceutical patent under the Hatch-Waxman system enjoys extensive exclusionary rights. *See supra* Parts 3(1),(3), (4). Those exclusionary limits are only limited by an FDA ruling that the ANDA-IV first filer can enter market, whether triggered by a judicial decision or not. *Id.* A settlement without exclusion payments mimics the FDA or judicial decision because it sets a starting date for the generic entry into the market at a point in time in the future which the FDA could have reached on its own. That point in time could have been set after a delayed judicial proceeding, or after the minimum thirty month stay imposed by the FDA. By coming to a settlement, the parties save judicial and regulatory expense because judicial and FDA involvement is minimal in settling the dispute. Also, assuming the parties are rational actors, they will reach a start date that reflects the relative strengths of their positions. *See* Petition for Writ of Certiorari at 18, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006). This encourages an honest exchange of information between the parties, which in turn benefits competition. Thus, a settlement, which only includes delayed entry and the cost of litigation advances the

policy interest of balancing innovation and competition. Accordingly, a settlement without exclusion payments is not beyond the scope of the patent.

A settlement with reverse payments, as is present between Norton & QuikClone, extends beyond the scope of the patent for several reasons. First, such a settlement does not directly reflect the actual validity of the patent claims. Second, the reverse payments abuse the already extensive exclusion rights already attached to the Logotor patent.

**a) Norton is Exercising Exclusion Rights for a Likely Invalid Patent**

Although it is not necessary to determine the actual validity of the patent, it is necessary – and feasible – to take a probabilistic look at the patent’s strength. If it can be said with a degree of certainty that the patent probably would have been declared invalid, then the reverse payment settlement is outside the scope of the patent and creates an anticompetitive environment. It is vital that the probable failure or success of a patent be considered in a rule of reason analysis because “[i]f courts do not discount the exclusionary power of the patent by the probability of the patent's being held invalid, then the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity.” In re Ciprofloxacin Hydrochloride Antitrust Litigation, 363 F. Supp. 2d 514, 534 (E.D.N.Y. 2005). As the appellate court found in *in Re Cardizem* “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 by inhibiting competitors by paying the only potential competitor [] million[s] per year to stay out of the market.” In re Cardizem CD Antitrust Litigation, 332 F.3d 896, 908 (6th Cir. 2003).

In the present case there is strong evidence to point towards the Logotor patent’s probable invalidity. First, in an internal memo, Norton’s own CEO questioned the validity of the Logotor patent as he stated that this settlement added years to his life that he “didn’t think we would see.”

Joint Appendix, 12. Second, Norton’s counsel during the patent validity suit with QuickClone was similarly unsure of the patent’s absolute ability to succeed in litigation – he estimated that there was a 30% chance that the Logotor patent would be declared invalid. Joint Appendix 8. Third, although QuickClone was not entirely sure that they would prevail either, their counsel still estimated at least a 60% chance that they would prevail and that the patent would be declared invalid. Joint Appendix 8.

Lastly, the strongest factor pointing towards the patents probable invalidity is the enormity of the settlement payment by Norton to QuickClone. While the FTC acknowledges that the presence of a reverse payment itself is not dispositive of a patent’s probable invalidity, the presence of an extremely large reverse payment raises serious concerns. Scholars have recognized that the “size of the expected exclusion payments are inversely related to the strength of the patentee's case: the less likely the patentee is to win, the more it is willing to pay a generic to stay out of the market.” Herbet Hovenkamp et al., Anticompetitive Settlement of Intellectual Property Disputes, 88 Minn. L. Rev. 1719, 1758-59 (2003). Without a reverse payment (or a reverse payment up to the cost of litigation), “the resulting settlement presumably would reflect the parties' own assessment of the strength of the patent.” Petition for Writ of Certiorari at 18, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006).

In this situation, Norton agreed to pay QuickClone \$150 million to essentially stay off the market for two years - this amount exceeds the both the \$2 million in attorneys fees and QuickClone’s expected profits during that time. Currently, Norton receives \$1 billion in annual revenues from the sale of Logotor at a price between \$1 and \$1.50 per pill. Joint Appendix, 4. Assume production costs at 10%. This number is based on the assumption that in a state of perfect competition where production cost meets price, the estimated price of Logotor in a fully

competitive market is 10 cents. *Id.* at 12 n. 10. Therefore, Logotor realizes profits of approximately \$900 million annually.

When Quiescence would enter the market, a duopoly would exist, driving prices down by half.<sup>2</sup> Despite the new competition, assume the price drop would allow sales volume to remain the same. Therefore, both Norton and Quikclone would rationally expect to earn profits of \$450 million in one year. Quikclone's exclusivity period would only run for six months, and thus it could only enjoy duopoly profits of \$225 million dollars for six months, followed by greatly reduced profits as prices fell close to costs. Assume Quikclone's sales volume would remain the same after other generics enter the market. Experts assume that prices after generic entry will be at most 15 cents per pill. *Id.* Quikclone profits would be 5 cents per pill over eighteen months, coming to roughly \$75,000 for that time. Accordingly, if Quikclone would win the patent litigation case, its profits during those two years would be approximately \$225,075,000.

As a rational actor, Norton would only pay QuikClone the full amount of its expected profits if QuikClone were sure to win the case. Norton only believes that there is 30% chance that QuikClone would win. Therefore, rationally, Norton should only pay QuikClone \$67,522,500 plus \$2 million in legal fees. Even if Norton adopts QuikClone's belief that there is a 60% chance the patent will be invalid, Norton should only pay \$135,045,000 plus \$2 million in legal fees.

Both of these figures are tens of millions of dollars below the reverse payment Norton has offered to Quikclone. Norton is paying above and beyond the scope of the claims in the Logotor patent. The reverse payment, therefore, is beyond the scope the patent.

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<sup>2</sup> The District Court makes the assumption that prices would drop by more than half in their calculations of the market price after Quiescence enters the market. Joint Appendix, 13 fn 10. Therefore, the numbers presented here reflect the highest possible profits that QuickClone could enjoy.

#### **D. Reverse Payments Exercise Exclusion Rights beyond the Scope of the Patent**

As demonstrated in above, the scope of a pharmaceutical patent, such as the Logotor patent, has extensive exclusion rights. These rights include an absolute exclusion right during the first four years after FDA approval and an additional, thirty month minimum stay (typically) from patent challenge taking effect. These stays only operate on a time dimension. While time clearly equals money when pharmaceutical patents are involved, the Hatch-Waxman system only extends the exclusionary rights of pharmaceutical patents along the time dimension. As judicially noted, the Hatch-Waxman system implements a Congressionally mandated balance between competition and innovation. Innovation is spurred by a guaranteed time period free from competition, independent of the validity of the patent. Competition is encouraged by the prospect of guaranteed limited competition with the innovator. After the limited competition period, consumers benefit from prescription drugs available at low prices. Under Hatch-Waxman, therefore, the patent holder and the ANDA-IV first filer could reach an agreement where the start date for the 180 exclusivity is negotiated relative to their strengths. Initiation of the start date then signals the imminent drop in prices from increased competition.

In the present case, the Logotor patent has exclusion rights that have lasted a minimum of four years already. Those rights have been challenged by the potential entry of Quiescence because the act of filing the ANDA-IV is an act of infringement. If Logotor did not feel its patent could have withstood a patent dispute, then Quiescence could have entered the market after the thirty month FDA stay, effectively agreeing that the patent had not been infringed. A judicial decision confirming the invalidity or non-infringement of the patent could have cut that time short, but still deciding the patent had not been infringed. Even a settlement that simply

adjusted the entry date of Quiescence on the market would have reflected the likelihood of the patent being found invalid or not infringed. All these outcomes reflect the need for a decision on the validity of the patent to be actually, or constructively reached.

Reverse payments disrupt this system. A decision on the validity of the patent balances the competing interest of innovation and competition because competition can start once the patent is deemed invalid or not infringed. Reverse payments, though, align the interests of the innovator and the competitor. Because Quikclone is getting paid to stay out of the logorrhea market, it is no longer interested in competing. In other words, Norton has taken advantage of its extensive enforceability rights, which are intended to increase innovation, in order to disrupt the balance between innovation and competition inherent in the Hatch-Waxman Act. By delaying the entry of Quiescence, Norton can still reap monopolistic profits. The longer Norton keeps monopoly profits, the less incentive Norton has to innovate in other fields.

In short, reverse payments allow Norton's exclusion rights to continue without a determination of the validity of the patent. The Hatch-Waxman system uses the determination of the patent's validity to trigger the competitive aspects of the statutory scheme. Therefore, Norton's extensive exclusionary rights only exist to the extent that they are balanced with the competitive purposes served by finding patents invalid or not infringed. Reverse payments extend those rights improperly. Therefore, reverse payments are beyond the scope of the patent's exclusionary rights.

## **E. The Norton-Quikclone Agreement is Anticompetitive**

### **1. Monopoly Prices are Inherently Anticompetitive**

Reverse payments in the Norton-Quikclone agreement are beyond the scope of the Logotor patent because the patent's claims are likely invalid and the reverse payments abuse

exclusionary rights, which apply to the Logotor patent through the Hatch-Waxman system. By delaying entry of Quiescence in the market through reverse payments, Norton is preventing other generics from entering the market because of the 180 day exclusivity period which Quiescence will enjoy. This delay has strong anticompetitive effects.<sup>3</sup> Therefore, reverse payments have strong anticompetitive effects.

While Logotor is the only drug in the logorrhea market, it has a monopoly and can charge monopoly prices. The Hatch-Waxman act intends the filing of an ANDA-IV to start a period of limited competition, followed by a period of greatly increased competition. Consumers benefit from any increase in competition with lower prices. The longer the market only has high monopoly prices, the less consumers benefit. As demonstrated, reverse payment agreements induce these monopolistic prices for an artificially prolonged period of time. *Cf. Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993) (outlining the cause of action for an attempt to monopolize, which includes “overt anticompetitive acts in furtherance of the attempt...”). Price restrictions are categorically anticompetitive. *See Business Electronics Corp. v. Sharp Electronics Corp.*, 485 U.S. 717 (1998). Therefore, reverse payments are anticompetitive.

## **2. Recent Changes to the Hatch-Waxman System do not Decrease the Anticompetitive Effects of Reverse Payments**

Even the recent changes to the Hatch-Waxman system do little to improve anticompetitive effects of settlements with reverse payments. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 eliminated the guaranteed 180 exclusivity period for the first ANDA-IV filer. *See* Thomas Carvey, “Reverse Payments” Pass Another Test:

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<sup>3</sup> Section 1 of the Sherman Antitrust act prohibits any “contract, combination. . . or conspiracy in restraint of trade.” 15 U.S.C. 1

Federal Circuit Adopts Rule of Reason, at 1 n.1, <http://www.bromsun.com/media/>

PaymentsV6DEC.pdf. So long as a later filer obtains a declaratory judgment that its drug does not infringe the original patent, the later filer gets the 180 exclusivity period if the first filer does not enter the market within 75 days. 21 U.S.C. 355(j)(5)(D)(bb)(AA). Viewed in the light of reverse payment settlements, one could conclude that reverse payment settlements become less attractive to the patent holder because another generic could simply obtain the 180 exclusivity period. In other words, reverse payments, while anticompetitive, are no worse than the pre-existing monopoly because the monopoly is likely to end sooner because of the later competitor.

Drawing such a conclusion would be erroneous for several reasons. First, later competitors file their ANDA-IV applications in part based on the information made publically available by the first-filer. More specifically, the judicial decision of bioequivalence provides invaluable information as to how to formulate the generic drug in order obtain a successful declaratory judgment. Settlements with reverse payments prevent the issuance of a judicial decision which makes such information publicly available. Therefore, the later filer could have similar research costs, and take an equivalent risk as the first filer in trying to obtain the declaratory judgment. A reverse payment settlement, therefore, would increase the likely cost of market entry for the later filer. In increasing the cost, it is anticompetitive.

Second, nothing in this new system prevents the patent holder from reaching another settlement agreement with the later filer. If the patent is sufficiently strong, the patent holder may be rational in assessing that it can make reverse payments to multiple filers and still earn a profit. Accordingly, the anticompetitive effects of the original reverse payments are not changed.

## **CONCLUSION**

For the foregoing reasons, this court should rule that reverse payments are per se illegal. Alternatively, the court can rule that reverse payments are anticompetitive under a rule of reason analysis. A favorable decision on either point establishes that the Norton-Quikclone Agreement is anticompetitive and violates the Sherman Act.