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Infringement Lawsuits: The Continuing Battle Between Patent Law and Antitrust Law in the Pharmaceutical Industry

Lisa M. Natter*

There are certain agreements . . . which because of their pernicious effect on competition . . . are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use. This principle of per se unreasonableness not only makes the type of restraints which are proscribed by the Sherman Act more certain to the benefit of everyone concerned, but it also avoids the necessity for an incredibly complicated and prolonged investigation into the entire history of the industry involved, as well as related industries, in an effort to determine at large whether a particular restraint has been unreasonable—an inquiry so often wholly fruitless when undertaken.¹

Justice Black

I. Introduction

The average cost of a drug prescription in the United States in 2004 was \$96.² The average cost of a prescription for the generic equivalent, containing the same active ingredients, was \$29.³

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¹ Northern Pacific R. Co. v. United States, 356 U.S. 1, 5 (1958).

² U.S. Census Bureau, *Statistical Abstract of the United States: 2006, Section 3 Health & Nutrition*, Table 126, (2006), available at <http://www.census.gov/prod/2005pubs/06statab/health.pdf>.

³ *Id.*

American drug prices are the highest in the world, and as a result roughly two million Americans have turned to other countries such as Canada, generating an \$800 million online market for Canadian pharmacies.⁴ To address this aspect of the health care crisis, Congress has enacted legislature to ensure that generic drugs can enter the marketplace quickly and be available to the consumer.⁵ Yet, there are instances where business agreements not to compete arise between a brand-name drug manufacturer and a generic drug manufacturer under the umbrella of patent infringement laws. These agreements have the direct effect of blocking consumer access to the less expensive generic alternatives.

The courts are split as to how to analyze these agreements for potential antitrust liability. On one hand, there is the desire to protect the exclusivity of a patent in an effort to further promote the research and development of new drugs.⁶ On the other, such blatant agreements not to compete violate antitrust laws under the Sherman Act and ultimately have a negative impact on the consumer.⁷

The Supreme Court has repeatedly refused to grant certiorari in order to decide whether it is unlawful *per se* under the Sherman Act for a pharmaceutical patentee to pay a competitor to keep the competitor's generic drug off the market during pending litigation between the patentee and the competitor.⁸ The Sixth Circuit held that such an agreement is inherently a horizontal agreement to eliminate competition for the drug in question, and is therefore unlawful *per se* under the Sherman Act.⁹ In direct contrast, the Eleventh Circuit held that such agreements were not unlawful *per se*, in part because the

⁴ Clifford Krauss, *Canada is Drafting Regulations to Curb Bulk Drug Exports to U.S.*, N.Y. TIMES, June 30, 2005, at A11; see also CBS News, 60 Minutes, *Prescriptions and Profit*, Mar. 14, 2004, available at <http://www.cbsnews.com/stories/2004/08/19/60minutes/main637050.shtml>.

⁵ See generally Hatch-Waxman Act, 21 U.S.C. § 355 (West, 2006); See also Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, §§ 1101-2, 1112 (2003).

⁶ Yee Wah Chin & Kathryn E. Walsh, *Antitrust Counseling in Intellectual Property Licensing*, at 267, 271 (PLI Patents, Copyrights, Trademarks, & Literary Prop. Course Handbook Series No. 832, 2005).

⁷ *Id.*

⁸ See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2002), *cert. denied sub nom.*, *Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004).

⁹ *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 908.

exclusion of infringing competition “is the essence of the patent grant.”¹⁰ In its analysis, the court stated that it was not applying a rule of reason standard,¹¹ but then held that a factual inquiry assessing the anticompetitive effects of the agreement was necessary before determining if antitrust laws had been violated.¹² The question becomes whether such agreements between brand-name drug manufacturers and their generic competitors are unlawful *per se*, or whether courts must apply a rule of reason standard to each individual set of circumstances, and how either standard would affect the drug manufacturers and eventually the consumer.

This article will examine the circuit split and consider both ways of analyzing a patent infringement suit for antitrust liability. Part II of this article provides a background to the antitrust and patent law that comes into play in the analysis of this issue, and specifically explains the development of the Hatch-Waxman act and how a patent infringement suit develops under current law. Part III discusses the two primary cases illustrating the circuit split: *In re Cardizem CD Antitrust Litigation*, in the Sixth Circuit, and *Valley Drug Co. v. Geneva Pharmaceuticals*, in the Eleventh Circuit. Additionally, Part III summarizes an opinion drafted by the Federal Trade Commission (FTC), in the matter of Schering-Plough Corporation, which further highlighted the circuit split, and suggested the current opinion of the FTC. Finally, Part IV suggests that the Sixth Circuit’s decision in the *In re Cardizem CD Antitrust Litigation* holding that such horizontal agreements are unlawful *per se* is the better decision because it is consistent with consumer-protecting legislation and is not unfairly restrictive to brand-name drug manufacturers.

II. Background

The primary background issues that are relevant to the circuit split are the antitrust principles embodied in the Sherman Act and the FDA’s requirements for introducing new and generic drugs to the market under the Hatch-Waxman Act. An understanding of these laws and regulations highlights how courts are having difficulty balancing the protection of patent owners’ exclusivity rights against the well-established principles of antitrust law.

¹⁰ *Valley Drug Co.*, 344 F.3d at 1306.

¹¹ See *supra* Part III.B for a discussion of the rule of reason standard.

¹² *Valley Drug Co.*, 344 F.3d at 1306.

A. Analysis of Antitrust Liability Under the Sherman Act: Rule of Reason versus Unlawful *Per Se*

Under Section 1 of the Sherman Act, “every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce . . . is declared to be illegal.”¹³ While the language of the statute is absolute in prohibiting all such agreements, it has been consistently interpreted as Congress’ intent only to outlaw “unreasonable restraints.”¹⁴ Because a court must determine what is “unreasonable,” most antitrust claims are analyzed according to the rule of reason standard, under which the finder of fact takes several factors into consideration including details about the relevant business at hand, its condition before and after the restraint was imposed, and the nature, history, and effect of the restraint.¹⁵

There are, however, situations in which a restraint on trade is considered unlawful *per se* under the Sherman Act because it will have such a predictable and egregious anticompetitive effect.¹⁶ In particular, applying *per se* treatment is appropriate when experience with a particular kind of restraint would allow the court to confidently predict that the rule of reason would likely condemn such a restraint.¹⁷ A classic example of a *per se* violation of the Sherman Act is what is known as a “horizontal” agreement between competitors at the same level of the market structure to minimize competition.¹⁸ These agreements between competitors, such as price-fixing or territory allocations, are viewed as more dangerous than vertical agreements between persons at different levels of the market structure, such as manufacturers and distributors.¹⁹ The Supreme Court has repeatedly held that such horizontal agreements to allocate territories are “naked restraints of trade with no purpose except stifling of competition.”²⁰

Applying antitrust standards to intellectual property rights,

¹³ 15 U.S.C. § 1 (2004).

¹⁴ *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997).

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *U.S. v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972).

¹⁹ *Id.*

²⁰ *Id.* (citing *White Motor Co. v. United States*, 372 U.S. 253, 263 (1963)).

and specifically, to patent law presents unique issues because the courts must balance the constitutionally protected exclusivity rights extended to patent owners against the antitrust laws embodied in the Sherman Act. The federal antitrust enforcement agencies have provided some guidelines when it comes to analyzing the intersection between antitrust law and patent law, in an attempt to provide guidance to various industries.²¹ The publications attempt to define markets as they may be relevant to antitrust analysis, and also discuss the role of patents, the courts, and the impact of various intellectual property licensing practices on consumer welfare.²² However, these guidelines only indicate the position of the federal enforcement agencies and are not binding authority, and, while they tend to be consistent with prior court decisions, there are some areas where they deviate from case law precedent.²³ As a result, there is still great uncertainty in how protecting an exclusivity period for inventors is best accomplished without violating antitrust laws established under the Sherman Act.

B. The Pharmaceutical Industry: Development and Introduction of Drugs to the Market

In the pharmaceutical industry, there are drug manufacturers known as “pioneers,” or “innovators” who conduct research and development and introduce new drugs to the market.²⁴ Additionally, there are generic drug manufacturers that research and develop copies of those pioneer brand-name drugs.²⁵ These generic drugs contain the same active ingredients as the brand-name drug and therefore treat

²¹ Chin & Walsh, *supra* note 6, at 274. See generally U.S. Dept. of Justice & the FTC, *Horizontal Merger Guidelines*, (1992) (outlining the agencies’ enforcement policy concerning horizontal acquisitions and mergers), available at <http://www.usdoj.gov/atr/public/guidelines/hmg.pdf>; U.S. Dept. of Justice & the FTC, *Antitrust Guidelines for Collaborations Among Competitors*, (2000) (explaining how the agencies analyze antitrust issues raised by collaborations among competitors), available at <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>; FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, (2003), available at <http://www.ftc.gov/opp/intellect/index.htm>.

²² Chin & Walsh, *supra* note 6, at 275.

²³ *Id.* at 274.

²⁴ Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 586-87 (2003).

²⁵ *Id.*

the same ailments, and they generally vary only in the inactive ingredients.²⁶ The generic drugs cost significantly less than the pioneer brand-name drugs, and it is the competition that arises between the two that highlights the tension between patent law and antitrust law.

The Federal Food, Drug, and Cosmetics Act (FDCA) was passed in 1938, creating what is now the Food and Drug Administration (FDA), which is responsible for reviewing the safety of any new drug before it is marketed to the public.²⁷ According to the FDCA, any drug manufacturer attempting to market a new product must submit a new drug application (NDA) demonstrating scientific studies showing that the new drug is safe for human consumption.²⁸ Prior to the enactment of the Hatch-Waxman Act, information related to a drug's safety and effectiveness was considered confidential in order to prevent generic manufacturers from introducing similar drugs to the market without having to bear the initial costs borne by the pioneer manufacturer.²⁹ As a result, a generic drug applicant had to conduct time-consuming and expensive research that likely was merely duplicating the studies already conducted by the brand-name manufacturer. This was inefficient and delayed the introduction of generic drugs to the marketplace.

C. The Hatch-Waxman Act: How a Patent Infringement Suit Develops

In the 1980s, concern began to grow in regard to the escalating cost of the average price of pharmaceuticals, and the prevailing thought was that increasing competition would help drive the costs back down.³⁰ As a result, the Hatch-Waxman Act was passed in 1984 and was intended by Congress to balance two competing interests: "to induce brand name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."³¹ There were two

²⁶ *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 901 (6th Cir. 2002), *cert. denied sub nom.*, *Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004).

²⁷ *Danzis*, *supra* note 24, at 587.

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.* at 590.

³¹ *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.D.C. 1990). *See Hatch-*

major changes that initially resulted from the enactment of this legislation, both of which acted to encourage the development of generic drug competition in the marketplace. First, it was no longer a patent infringement to use patented drugs for the testing of possible generic drugs.³² Second, generic drug manufacturers had an incentive to develop these drugs because the Act guaranteed them a period of exclusivity, during which other generic firms were blocked from competing with the same drug in the marketplace.³³ However, also inherent in the enactment of the Hatch-Waxman Act was a process that increased the likelihood of patent infringement litigation brought by the brand-name manufacturer, and therefore the unintended incentive for the parties involved to agree to reverse payment settlements.³⁴

Under the Hatch-Waxman Act, instead of filing an NDA, a generic drug manufacturer now only has to file an abbreviated new drug application (ANDA).³⁵ In order to be approved, the generic drug manufacturer must certify that the generic drug is not infringing any patent covering an approved drug and is the same, or the “bioequivalent,” to a drug already listed with an approved NDA in the FDA’s “Orange Book.”³⁶ There are several ways to certify that the generic drug will not infringe an existing patent, including a “paragraph IV certification,” stating that the existing patent for the pioneer drug is invalid or “will not be infringed by the manufacture, use, or sale” of the generic drug for which the ANDA is being submitted.³⁷

Waxman Act, 21 U.S.C. § 355 (West, 2006).

³² Danzis, *supra* note 24, at 605 (noting that the Hatch-Waxman Act reversed the decision in *Roche Products, Inc. v. Bolar Pharm., Co.* which had held that use of a patented drug for testing and investigation related to FDA drug approval requirements was an act of patent infringement).

³³ Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1077 (2004).

³⁴ *Id.*

³⁵ *Id.* at 1076; 21 U.S.C. §355(j).

³⁶ Danzis, *supra* note 24, at 594-95; 21 U.S.C. § 355(j)(2)(A). The FDA issues a publication entitled Approved Drug Products With Therapeutic Equivalence Evaluations, more commonly known as the “Orange Book,” that contains a list of approved patents. FDA, *Orange Book* (2006), available at <http://www.fda.gov/cder/ob/default.htm>.

³⁷ 21 U.S.C. § 355(j)(2)(A)(vii). The other ways of satisfying the certification requirement are to state that patent information for the pioneer drug has not been

An applicant filing a paragraph IV certification must give notice to the original patent holder, who then has forty-five days to file a patent infringement suit against the ANDA applicant.³⁸ If the patent holder of the pioneer drug does file suit, it obtains an automatic thirty-month stay of FDA approval of the ANDA, unless before thirty months a court finds that the patent is invalid or not infringed.³⁹ Originally, under the Hatch-Waxman Act, in an attempt to balance the impact of this thirty-month stay on the generic applicant, other generic manufacturers were blocked from competing in the market for that drug until 180 days after the first ANDA applicant began selling its product or the NDA applicant's patent was held to be either invalid or not infringed.⁴⁰

However, the procedures for filing an ANDA that arose out of the Hatch-Waxman Act had the unintended consequence of encouraging patent infringement suits brought by the brand-name drug manufacturer, and ultimately encouraging some anticompetitive reverse-payment settlements.⁴¹ First, the fact that a paragraph IV certification even exists suggests that it is not out of the question that patents filed by the pioneer drug manufacturer are invalid.⁴² Studies have shown that more than a quarter of litigated pharmaceutical patents may be invalid, and a July 2002 study conducted by the FTC suggested that almost seventy-five percent of the ANDA applicants

filed, *Id.* at § 355(j)(2)(A)(vii)(I), that the patent for the pioneer drug has expired, *Id.* at § 355(j)(2)(A)(vii)(II), or that the patent for the pioneer drug will expire on a specified date *Id.* at § 355(j)(2)(A)(vii)(III).

³⁸ *Id.* at § 355(j)(5)(B)(iii).

³⁹ *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 901 (6th Cir. 2002), *cert. denied sub nom.*, *Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004) (citing 21 U.S.C. § 355(j)(5)(B)(iii)(I)).

⁴⁰ *Id.* (citing 21 U.S.C. § 355(j)(5)(B)(iv)). The exclusivity period was amended with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 which made some significant changes to the Hatch-Waxman Act. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, §§ 1101, 1102, 1112 (2003). These changes included the creation of certain events that would cause generic manufacturers to forfeit their 180-day exclusivity period, clarification that pioneer drug manufacturers are entitled to only one thirty-month stay per drug, and identification of certain settlement agreements between drug manufacturers that must be reported to the FTC and the Department of Justice. *Id.*

⁴¹ Cotter, *supra* note 33, at 1077.

⁴² *Id.* at 1078.

whose cases had reached a decision at that time were victorious.⁴³ Second, the pioneer drug manufacturer who owns the patent has an incentive to sue regardless of the strength of its case because the thirty-month stay will be automatically triggered.⁴⁴ Finally, patent owners with a low probability of winning their patent infringement suit are likely interested in settling the case in exchange for reverse payments to the generic drug applicant, because the patent owner's potential loss often greatly exceeds the generic applicant's potential gain from marketing the substitute drug.⁴⁵

In fact, a reverse payment agreement may be appealing to both parties if the patent owner's potential loss exceeds the generic applicant's potential gain by a significant enough amount.⁴⁶ However, this is where the antitrust liability issues arise because if the generic applicant has a good chance of winning the infringement suit, the patent owner is then simply paying the generic applicant not to compete, in other words to stay out of a market that it likely has a right to enter.⁴⁷ Therefore, while both parties may benefit financially from entering into the non-compete agreement, the party ultimately feeling the negative impact is the consumer, who does not have access to the less expensive, and likely equally beneficial, generic drug.⁴⁸

III. The Circuit Courts Split: Unlawful *Per Se* or Case by Case Analysis?

The courts are split as to whether reverse payment agreements violate antitrust laws or are merely an extension of patent protection laws. On one hand, there is the desire to protect the exclusivity of a patent in an effort to further promote the research and development of new drugs.⁴⁹ On the other, such blatant agreements not to compete violate antitrust laws under the Sherman Act and ultimately have a

⁴³ *Id.* (citing FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>).

⁴⁴ 21 U.S.C. § 355(j)(5)(B)(iii).

⁴⁵ Cotter, *supra* note 33, at 1079-80.

⁴⁶ *Id.* at 1080.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ Chin & Walsh, *supra* note 6, at 271.

negative impact on the consumer.⁵⁰ In each of the cases highlighting the circuit split, the circumstances leading to litigation were similar, but the courts reached very different conclusions. The FTC provided its viewpoint in the *Schering-Plough* opinion,⁵¹ which further highlighted the split. The Supreme Court, however, has yet to grant certiorari and settle the matter.

A. *In re Cardizem CD Litigation*: Non-Compete Agreements are *Per Se* Illegal Restraint of Trade in Violation of Sherman Act

In 2004 the Supreme Court denied certiorari in *In re Cardizem CD Antitrust Litigation*, where the Sixth Circuit held that a patent owner's reverse payment to settle a suit against the defendant generic applicant was a horizontal market allocation agreement, and therefore unlawful *per se* under the Sherman Act.⁵² Hoechst Marion Roussel (HMR) was the manufacturer of Cardizem CD, a brand-name drug used to treat hypertension and to prevent heart attacks and strokes.⁵³ In 1995, Cardizem CD was experiencing sales of over \$700 million annually, and HMR's patent for the active ingredient in Cardizem had expired in November 1992.⁵⁴ In September 1995, Andrx filed an ANDA seeking approval to manufacture and market a generic alternative, and thus became eligible for the 180-day exclusivity period under the Hatch-Waxman Act.⁵⁵ HMR, anticipating that the generic drug competition would lead to a forty percent drop in Cardizem sales, filed a patent infringement suit against Andrx that triggered the thirty-month stay of FDA approval, which would end in July 1998.⁵⁶

In September 1997, the FDA approved Andrx's ANDA for the generic drug, which meant that it would be completely approved as soon as either the thirty-month stay had expired, or earlier if a

⁵⁰ *Id.*

⁵¹ *In re Schering-Plough Corp.*, (Opinion of the Comm'n), No. 9297, slip op. at 29, 2003 WL 22989651 (Dec. 18, 2003) [hereinafter FTC Opinion], available at <http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf>.

⁵² *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 900 (6th Cir. 2002), *cert. denied sub nom.*, *Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004).

⁵³ *Id.* at 901.

⁵⁴ *Id.*; Chin & Walsh, *supra* note 6, at 303.

⁵⁵ *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 902.

⁵⁶ Chin & Walsh, *supra* note 6, at 303. HMR based the suit on a U.S. patent issued in November 1995. *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 902.

court found that HMR's patent had not been infringed.⁵⁷ However, roughly one week after the FDA's approval, HMR and Andrx entered into an agreement providing that (1) Andrx would not market its generic drug even after its ANDA was approved at the end of the thirty-month stay, (2) Andrx would not forfeit or transfer its 180-day exclusivity period to another generic applicant, and (3) Andrx would refrain from marketing any non-infringing generic drugs that it might develop.⁵⁸ In return, HMR agreed to pay Andrx \$10 million quarterly beginning from the time the ANDA was approved, and an additional \$60 million annually beginning July 1998 and continuing until the lawsuit was finally decided.⁵⁹ When the thirty-month waiting period finally expired in July 1998, as per the terms of its agreement, Andrx did not begin to market its generic product even though it had received final approval from the FDA, and HMR began making the \$10 million quarterly payments as promised.⁶⁰

In September 1998, Andrx supplemented its previously filed ANDA to request approval for a reformulated generic version of Cardizem CD, and in February 1999 certified to HMR that the reformulated drug did not infringe the patent originally at issue.⁶¹ In June 1999, the FDA approved Andrx's reformulated drug, and HMR and Andrx agreed to settle the patent infringement case and terminate their earlier agreement.⁶² At that time, including its final payment, HMR had paid Andrx a total of roughly \$90 million and after its release, Andrx's generic substitute for Cardizem began to capture a substantial portion of the market and was selling at a significantly lower price than Cardizem CD.⁶³

In August 1998, just one month after the original thirty-month stay had expired and Andrx had received full approval to market its generic drug, a complaint was filed by direct and indirect purchasers of the Cardizem drug challenging the legality of the agreement.⁶⁴

In reaching its conclusion that the agreement was unlawful

⁵⁷ *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 902.

⁵⁸ *Id.* at 902-03.

⁵⁹ *Id.* at 903.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 903.

⁶³ *Id.*

⁶⁴ *Id.* at 903-04.

per se, the court reasoned that the purpose of the Sherman Act was to assure customers the benefits of price competition, and that this was an example of customers being injured by higher prices for drugs “as a result of the contractually mandated absence of competition between HMR and Andrx.”⁶⁵ The court held that where a *per se* approach to antitrust liability applies, there is a presumption of illegality and no consideration is given to the intent behind the restraint, or to the restraint’s actual effect on competition.⁶⁶ In response to the defendants’ arguments that the agreement was an attempt to enforce patent rights, the court held that this kind of agreement cannot be characterized as a mere attempt to enforce patent rights because there is a significant difference between taking advantage of market exclusivity naturally arising from a patent and attempting to bolster the patent’s effectiveness.⁶⁷ Furthermore, the defendants could not argue that a brand-name drug manufacturer and a generic applicant were not horizontal competitors because HMR and Andrx were in fact potential rivals in the market for Cardizem CD.⁶⁸ In conclusion, the Sixth Circuit held the agreement between HMR and Andrx to be unlawful *per se*, and, consistent with a *per se* analysis, it was therefore irrelevant to further investigate any claims of lacking anticompetitive effects or of the presence of procompetitive effects possibly resulting from the agreement between the defendants.⁶⁹

B. *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*: Using Rule of Reason Analysis to Consider Patent Considerations as Exceptions to Antitrust Liability

In direct contrast to the Sixth Circuit *Cardizem* decision, in *Valley Drug* the Eleventh Circuit held that agreements not to compete between generic and name-brand manufacturers were not unlawful *per se* to the extent that they had no broader exclusionary effect than that provided by the patents in question.⁷⁰ The court held that the *per se* standard was not appropriate and instead applied a rule of reason

⁶⁵ *Id.* at 904.

⁶⁶ *Id.* at 906.

⁶⁷ *In re Cardizem CD Antitrust Litig.*, 332 F.3d at 908.

⁶⁸ *Id.* at 909.

⁶⁹ *Id.*

⁷⁰ *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004).

analysis. Under the rule of reason, a court determines whether certain behavior violates antitrust laws by examining factors unique to the businesses, the industry and the specific behavior in question.⁷¹

In this case, Abbott Laboratories manufactured Hytrin, a very successful pioneer drug used to treat hypertension and enlarged prostate.⁷² Geneva Pharmaceuticals filed multiple ANDAs based on Hytrin between 1993 and 1996, each time making paragraph IV certifications, and Abbott filed patent infringement suits in response, thereby triggering the thirty-month stay on Geneva's applications.⁷³ Included in Geneva's ANDAs were requests for the approval of a tablet form and a capsule form of the generic alternative to Hytrin.⁷⁴ Abbott filed suit claiming that the tablet form of the drug infringed one of its patents, but failed to file an infringement suit based on the capsule form, apparently through oversight.⁷⁵ The capsule ANDA was therefore approved by the FDA in March 1998, and the thirty-month stay that would end in December 1998 applied only to Geneva's ANDA for its tablet product.⁷⁶

Abbott, estimating it would lose approximately \$185 million in Hytrin sales in the first six months of the launch of the generic drug, entered into a confidential agreement with Geneva in April 1998.⁷⁷ The terms of the agreement established that Geneva was not to market any of its generic Hytrin products until the earlier of either the final resolution of the infringement lawsuit or the entry into the market of another generic version of Hytrin; and Geneva would not forfeit or transfer its 180-day market exclusivity to other generic applicants.⁷⁸ In return, Abbott agreed to pay Geneva \$4.5 million monthly until the district court decided the case, and if Geneva prevailed, Abbott would place \$4.5 million each month in escrow pending the final disposition of the case; the prevailing party would

⁷¹ *White Motor Co. v. U.S.*, 372 U.S. 253, 261 (1963).

⁷² *Valley Drug Co.*, 344 F.3d at 1298.

⁷³ *Id.* at 1298-99.

⁷⁴ *Id.* at 1299.

⁷⁵ *Id.* When Abbott learned of the approval of the generic capsule product, it attempted to amend its complaint to allege that the capsule was also a patent infringement. *Id.*

⁷⁶ *Id.*

⁷⁷ Chin & Walsh, *supra* note 6, at 301.

⁷⁸ *Valley Drug Co.*, 344 F.3d at 1300.

then get the escrowed funds.⁷⁹

In September 1998, the district court held that Abbott's patent was invalid because the product claimed in the patent had been on sale in the United States more than one year before Abbott had even applied for the patent.⁸⁰ However, even though the district court held that Abbott's patent was invalid, Geneva did not enter the market and continued to receive payments from Abbott in escrow per the agreement.⁸¹ The Federal Circuit affirmed the district court's decision in July 1999 and Abbott's petition for certiorari was denied in January 2000.⁸² Abbott and Geneva terminated their agreement in August 1999, apparently due to an FTC investigation, and Geneva's product entered the market.⁸³

In reaching its conclusion that the agreement between Abbott and Geneva was not illegal *per se*, the Eleventh Circuit relied on the fact that, because a patent was involved, the case was not simply an instance of one firm making payments to potential competitors to keep its product out of the marketplace.⁸⁴ The court relied heavily on the idea that the exclusion of infringing competition is the essence of the patent grant, and a patentee can choose to exclude everyone from producing the patented product, even if the agreement results in lower production and higher prices to the customer.⁸⁵

Ironically, in reaching its conclusion, the court stated that, while applying *per se* analysis was inappropriate, applying a rule of reason analysis was similarly inappropriate.⁸⁶ However, it then stated that the analysis should focus on the facts and on what type of anticompetitive effects result from the agreement in each individual set of circumstances.⁸⁷ Whereas the Sixth Circuit emphasized that *per se* analysis meant there was no further inquiry necessary into the intent behind the agreement or its potential anticompetitive or

⁷⁹ *Id.* The final disposition of the case required a judgment from which no appeal could be taken, including a petition for certiorari to the Supreme Court. *Id.*

⁸⁰ *Id.* at 1301.

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Valley Drug Co.*, 344 F.3d at 1301.

⁸⁴ *Id.* at 1304.

⁸⁵ *Id.* at 1305-06.

⁸⁶ *Id.* at 1311.

⁸⁷ *Id.* at 1303-04.

procompetitive effects, the Eleventh Circuit acknowledged that it respectfully disagreed and held instead that the potential exclusionary power of the patent must first be considered.⁸⁸ The court reasoned that, since there was no categorical line to be drawn between agreements that create an “obvious inference of anticompetitive effect and those that call for more detailed treatment,” there is nonetheless a requirement to look to the circumstances, details and logic of the agreement in each individual case.⁸⁹ Despite not wanting to label its approach as “rule of reason,” this type of inquiry into the particular facts and circumstances of the case is synonymous with a rule of reason analysis.⁹⁰

On remand, under the direction of the Eleventh Circuit, the district court first reviewed the facts specific to the case in order to evaluate the potential exclusionary effect of the patent.⁹¹ After reviewing the facts, the court determined that at the time the agreement was made the likelihood was that the patent would be found to be invalid.⁹² The court therefore concluded that the agreement exceeded the scope of the patent and only then held the agreement to be illegal *per se*.⁹³

C. In the Matter of Schering-Plough Corporation: the Opinion of the FTC

In 2003, the FTC addressed patent settlements between pioneer and generic drug manufacturers by issuing an opinion in the matter of Schering-Plough Corporation, holding that such agreements between a brand-name drug manufacturer and two generic applicants were a violation of the Sherman Act.⁹⁴ In reaching its conclusion, the

⁸⁸ *Valley Drug Co.*, 344 F.3d at 1312.

⁸⁹ *Id.* at 1313. In dismissing the application of rule of reason analysis, the court held that what was instead required was an analysis of the extent to which antitrust liability might undermine innovation, or the extent to which the patent laws prevent antitrust liability for exclusionary agreements. *Id.* at 1311. The court did not further explain how this type of analysis should be distinguished from the rule of reason. *Id.*

⁹⁰ *Id.*

⁹¹ *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1294-99 (S.D. Fla. 2005).

⁹² *Id.* at 1299-1307.

⁹³ *Id.* at 1319-20.

⁹⁴ FTC Opinion, *supra* note 51, at 86.

Commission appeared to apply the rule of reason analysis, yet concluded, similarly to the Sixth Circuit, that the agreements were unlawful under the Sherman Act.⁹⁵ Schering-Plough later appealed the decision, and the Eleventh Circuit set aside and vacated the order, holding that the agreements did not violate the Sherman Act because they did not unreasonably restrain competition beyond the exclusionary effects of the patent.⁹⁶

Schering-Plough manufactured K-Dur 20, a prescription drug used to treat low potassium levels, usually to aid treatment of high blood pressure or congestive heart disease.⁹⁷ In August 1995, Upsher-Smith filed an ANDA for a generic version of K-Dur 20, and Schering sued for patent infringement, thereby triggering the thirty-month stay that would run until May 1998.⁹⁸ In June 1997, Schering and Upsher-Smith agreed to a settlement, wherein Upsher-Smith promised not to introduce any generic form of K-Dur 20 into the market until September 2001, infringing or non-infringing, and also agreed to license five Upsher-Smith products to Schering.⁹⁹ Even though Schering stated that it was not interested in paying Upsher-Smith to “stay off the market,” in return it agreed to pay them \$60 million.¹⁰⁰ The FDA approved Upsher-Smith’s ANDA in November 1998, but Upsher-Smith did not begin marketing its products per the agreement, so its 180-day exclusivity period did not begin to run and no other generic applicant could enter the market.¹⁰¹

In addition to Upsher-Smith’s request for generic approval, in December 1995, ESI Lederle filed an ANDA for its K-Dur 20 generic alternative and Schering sued ESI for patent infringement, again triggering the thirty-month stay.¹⁰² Ultimately, Schering and ESI agreed to settle in January 1998, at which time ESI agreed not to market any generic version of K-Dur 20 before January 2004 and

⁹⁵ *Id.*

⁹⁶ *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056, 1076 (11th Cir. 2005), *petition for cert. filed*, 74 U.S.L.W. 3130 (U.S. Aug. 29, 2005) (No. 05-273).

⁹⁷ *Id.* at 1058.

⁹⁸ *Id.* at 1058-59.

⁹⁹ *Id.* at 1059-60.

¹⁰⁰ *Id.* at 1060.

¹⁰¹ Chin & Walsh, *supra* note 6, at 305.

¹⁰² FTC Opinion, *supra* note 51, at 4.

Schering agreed to pay ESI \$30 million.¹⁰³

The FTC filed an administrative complaint against Schering, Upsher-Smith and ESI in April 2001, alleging that they had violated Section 5 of the FTC Act by entering into unlawful agreements to delay the introduction of low-cost generic drugs to the market.¹⁰⁴ In the initial decision, the Administrative Law Judge dismissed all charges, stating that the FTC had not met its burden of proving either invalidity of the Schering patent or non-infringement, without which it was not possible to conclude that the settlement agreements delayed generic entry to the marketplace. The Commission, holding that the complainants were not required to meet this burden, reversed on appeal and issued an order against Schering-Plough.¹⁰⁵ In its opinion, the FTC ordered Schering and Upsher-Smith to cease and desist from being parties to any agreement settling a patent infringement lawsuit where a generic manufacturer (1) received anything of value, and (2) agreed to suspend research, development, manufacturing or marketing of its product for any period of time.¹⁰⁶

Even though the FTC did not hold the agreements unlawful *per se*, it concluded that the “quid pro quo” for the payment was an agreement to defer the introduction of generic drugs to the market, and that such a delay would injure competition and consumers.¹⁰⁷ The Commission noted that a plaintiff may satisfy its burden of showing actual or likely market effects by looking at the facts of the case, without engaging in a full-blown market analysis.¹⁰⁸ In this case, the fact that the parties agreed to a deferred entry of a potential competitor that would have certainly reduced sales for Schering was sufficient to show the anticompetitive nature of the agreements.¹⁰⁹

¹⁰³ *Id.*

¹⁰⁴ *Id.* The complaint was filed against Schering-Plough Corporation, Upsher-Smith Laboratories, and American Home Products Corporation. ESI is a division of American Home Products. *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1062 (11th Cir. 2005), *petition for cert. filed*, 74 U.S.L.W. 3130 (U.S. Aug. 29, 2005) (No. 05-273).

¹⁰⁸ FTC Opinion, *supra* note 51, at 16 (citing F.T.C. v. Indiana Fed’n of Dentists, 476 U.S. 447, 460-61 (1986)).

¹⁰⁹ *Id.* at 20. The Commission pointed to Schering’s 1997 Operating Plan showing that Schering anticipate their sales to drop significantly if a competing generic drug were to enter the market. *Id.* Schering projected its K-Dur revenues to drop from \$190 million in 1997 to just \$70 million by 2001. *Id.* After the

Furthermore, the Commission stated that a presumptively legal patent does not confer the right to preclude generic entry, and the validity of the patent is not at issue if the settlement in question resulted in a later entry of the generic product.¹¹⁰

By applying a rule of reason analysis and examining the specific facts of the case, the FTC held that the agreements were in fact unlawful.¹¹¹ Interestingly, while the FTC clearly stated that the agreements were not unlawful *per se*, it is difficult to see how applying the Commission's reasoning to future cases could lead to any other finding than a violation of antitrust laws.¹¹²

IV. Horizontal Trade Agreements Between Pioneer Drug Manufacturers and Generic Competitors Should Be Considered Unlawful *per se*

A review of the Sixth Circuit *Cardizem* and Eleventh Circuit *Valley Drug* decisions, in conjunction with the FTC Schering-Plough opinion, highlights the mixed standards that the courts are applying to reverse payments resulting from patent infringement litigation under the Hatch-Waxman Act. On one hand, there is the notion that such agreements are *per se* violations of the Sherman Act and no further factual inquiry is required. On the other, there is the idea of applying a "rule of reason" analysis, which has been interpreted differently by various courts resulting in little guidance for those in the pharmaceutical industry.

The significance of this issue cannot be understated. In 2003, Americans spent \$179 billion on prescription drugs, representing roughly 1.5% of the Gross National Product, and just over ten percent of all health care expenditures.¹¹³ That number is projected to grow to \$480 billion by 2013.¹¹⁴ Furthermore, the effect of hindering a generic drug's entrance to the market has a significant impact on the consumer. As of 2004, forty-eight percent of all prescription drugs

settlement which deferred the introduction of a generic drug, Schering's next 1998 Operating Plan projected increased K-Dur sales through 2000. *Id.*

¹¹⁰ *Id.* at 30.

¹¹¹ *Id.* at 10.

¹¹² Chin & Walsh, *supra* note 6, at 307.

¹¹³ U.S. Census Bureau, *Statistical Abstract of the U.S.: 2006, Section 3 Health & Nutrition*, Tables 118 and 119, (2006) available at <http://www.census.gov/prod/2005pubs/06statab/health.pdf>.

¹¹⁴ *Id.*

sold were generic drugs, up from forty percent in 1995. Such an increase is not surprising considering the average cost of a brand-name drug prescription was ninety-six dollars in 2004 compared to just twenty-nine dollars for the generic equivalent.¹¹⁵ Despite the magnitude of some of these numbers and the impact on consumers of all ages and demographics, the Supreme Court has yet to grant certiorari and establish a standard for courts and professionals in the pharmaceutical industry to apply when considering a potential agreement in lieu of patent infringement litigation.

These types of agreements between pioneer and generic drug manufacturers should be considered unlawful *per se* for several reasons. First, this is a very specific situation that arises between the pioneer and generic manufacturers and would not require the courts to apply a sweeping *per se* standard to various areas of patent law analysis. Second, holding such agreements to be unlawful *per se* would eliminate the confusion clearly highlighted by the circuit split as well as reduce the costs associated with litigation. Third, and perhaps most importantly, applying a *per se* standard to non-compete agreements would be consistent with the intent behind the Hatch-Waxman Act as it would benefit consumers by facilitating the entry of generic drugs to the marketplace.

A. The *Per Se* Antitrust Analysis Would Be Limited to this Narrow Area of Patent Law

In general, courts are not eager to extend the reach of *per se* analysis because it makes a certain practice unlawful, regardless of the surrounding facts and circumstances specific to that case.¹¹⁶ However, in some limited circumstances *per se* analysis is not only appropriate, but also preferred because it provides a bright line rule for the courts and for parties who find themselves confronted with those limited circumstances. Furthermore, the Supreme Court has held that *per se* rules often still require an inquiry into market conditions before it is justifiable to apply a presumption of

¹¹⁵ *Id.* at Table 126 (citing Nat'l Ass'n of Chain Drug Stores, *Pharmacy Industry Profile* 2005).

¹¹⁶ *See, e.g.,* F.T.C. v. Indiana Fed'n of Dentists, 476 U.S. 447, 458-59 (1986) (“[W]e have been slow . . . to extend *per se* analysis to restraints imposed in the context of business relationships where the economic impact of certain practices is not immediate obvious”) (citation omitted); *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 723 (1988) (“We have said that *per se* rules are appropriate only for conduct that is manifestly anticompetitive”) (citation omitted).

anticompetitive conduct and pronouncement of *per se* analysis.¹¹⁷ In other words, a situation or practice needs to meet the specific behavior that has been deemed unlawful *per se*, and some form of inquiry into the facts at hand is necessary in order to do so. In regard to the types of agreements highlighted in the Sixth and Eleventh Circuit decisions, the courts would first have to come to the conclusion that such an agreement was a horizontal restraint of trade before applying the *per se* analysis.

By limiting the use of *per se* analysis to reverse payments agreed to between pioneer and generic drug manufacturers to delay the entry of a competing generic drug, this would not have the adverse effect of stifling innovation and the development of new products which is so important across multiple industries. Certainly, a major source of the tension between patent law and antitrust law is due to the recognition of the benefits of pharmaceutical innovation such as increased life expectancy, overall quality of life and economic growth.¹¹⁸ However, applying a *per se* analysis to this specific set of circumstances still allows and promotes continued research, development and ingenuity, because the vast majority of antitrust inquiries into patent law apply the rule of reason.¹¹⁹ As the FTC acknowledged in its Schering-Plough opinion, one must look at antitrust analysis as a continuum that ranges from *per se* condemnation of particularly anticompetitive conduct to a closer detailed and fact-finding approach toward more ambiguous behavior.¹²⁰ Non-compete agreements between the drug manufacturers are not ambiguous. As the Sixth Circuit held, there was “simply no escaping the conclusion” that the agreement not to compete was a horizontal agreement not to compete, something that has repeatedly been held by the Supreme Court as unlawful *per se*.¹²¹

¹¹⁷ Nat'l Collegiate Athletic Ass'n v. Board of Regents of Univ. of Okla., 468 U.S. 85, 103-04 (1984).

¹¹⁸ Stephen A. Stack, Jr., *Afterword: Some Further Observations on the "Pharmaceutical Wars,"* 71 ANTITRUST L.J. 705, 711 (2003).

¹¹⁹ Chin & Walsh, *supra* note 6, at 272. (discussing several types of agreements such as refusals to license, tie-ins, and patent pools and highlighting how a factual-based analysis is applied to determine antitrust liability. Factors that are typically reviewed include the business context of the transaction and the business reasons for the deal, market analysis, a review of the services and geographic areas that will be affected by the transaction, and the market share of the parties involved).

¹²⁰ FTC Opinion, *supra* note 51, at 7.

¹²¹ *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2002),

In regard to *per se* rules when considering antitrust liability, the Court has stated that:

Without the *per se* rules, businessmen would be left with little to aid them in predicting in any particular case what courts will find to be legal and illegal under the Sherman Act Congress . . . can, of course, make *per se* rules inapplicable in some or all cases, and leave courts free to ramble through the wilds of economic theory in order to maintain a flexible approach.¹²²

Should the Supreme Court choose to grant certiorari on this issue, adopting the *per se* standard of unlawfulness in regard to horizontal non-compete agreements between drug manufacturers would still leave endless “wilds” to ramble through in the context of intellectual property rights and antitrust law.¹²³

B. Establishing a Bright Line Rule Would Eliminate Confusion and Provide Guidance and Predictability to the Courts and the Pharmaceutical Industry

If the circuit split shows anything, it shows that there is confusion not only in terms of which type of analysis to apply, but that if anything but a *per se* analysis is used, courts are likely to reach very different results. The Eleventh Circuit in *Valley Drug* and in *Schering-Plough* repeatedly stated that rule of reason analysis was not appropriate for these types of agreements, then proceeded to “quintessentially apply” what appeared to be a rule of reason analysis.¹²⁴ If this is acceptable, what standard are the courts, attorneys and members of the pharmaceutical industry to follow? The FTC repeatedly stated its hesitancy to apply a *per se* standard, but in undergoing the same factual inquiry as the Eleventh Circuit came up with a completely different result and held the agreements to be

cert. denied sub nom., *Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004).

¹²² *U.S. v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972).

¹²³ See generally Chin & Walsh, *supra* note 6 (reviewing general principles of antitrust analysis of transactions involving intellectual property rights. In doing so, the authors refer to numerous types of transactions, and refer to a fact-specific analysis and a standard of reasonableness in regard to all transactions. The only reference to *per se* analysis is in regard to the circuit split at the focus of this article).

¹²⁴ *Id.* at 307-08.

unlawful.¹²⁵ Adopting a *per se* analysis as the appropriate standard with which to review non-compete agreements between generic and pioneer drug manufacturers would provide predictability for members of the pharmaceutical industry and guidance when faced with pending patent infringement litigation.

If the *per se* analysis were abandoned in favor of a more fact-based rule of reason inquiry, the likelihood of eliminating confusion and minimizing the cost of litigation would be low. As the Supreme Court has held, courts are not good at examining difficult economic problems.¹²⁶ Further, their inability to weigh, "in any meaningful sense, destruction of competition in one sector of the economy against promotion of competition in another," is one of the main reasons *per se* rules were formulated in the first place.¹²⁷ While it is unknown how the Supreme Court would rule on this particular issue, if the opinion of the FTC is of any influence, the Commission's comments in the Schering-Plough opinion certainly suggest a hesitancy to engage in full-blown market analysis to determine the potential anticompetitive effects of these kinds of agreements.¹²⁸

In addition to having to scrutinize the facts of the case and conduct market research that would accurately predict the anticompetitive effects of the agreement, courts would have to also try and determine the odds of ultimate success in the patent infringement litigation between the parties.¹²⁹ In other words, if it was likely that the court would find the patent invalid, or not infringed, then perhaps the agreement was more anticompetitive in nature than if the patent owner had a high likelihood of winning the infringement suit. The difficulties of playing this type of predictability game "cannot be underestimated" and are risky both in the cost and the inefficiency of trying to assign probabilities to litigation outcomes.¹³⁰ Because the courts are not skilled at this type of analysis, and the cost of doing so would be great, the *per se* analysis is a far better approach than the rule of reason which could entail risky speculation. The system should work as it was designed; if the patent owner has a valid claim, the suit should continue, and the

¹²⁵ FTC Opinion, *supra* note 51, at 86-87.

¹²⁶ *Topco Assocs., Inc.*, 405 U.S. at 610.

¹²⁷ *Id.* at 609-10.

¹²⁸ FTC Opinion, *supra* note 51, at 16-19.

¹²⁹ Stack, *supra* note 118, at 714.

¹³⁰ *Id.*

patent will protect the pioneer manufacturer. If the patent owner does not have a valid claim, the generic manufacturer should have a right to move forward with development and marketing of the new product to the consumer.

Finally, one could argue that under a *per se* analysis, there is the risk that an agreement would be condemned which, under the rule of reason analysis, would have otherwise been permitted. While this is a possibility, the reason why this specific type of agreement is analyzed under a *per se* analysis is because it so closely fits the mold of a horizontal restraint of trade that has repeatedly been held as a *per se* violation of the Sherman Act.¹³¹ Additionally, the Court has said that this risk has been recognized and tolerated as a necessary cost “[f]or the sake of business certainty and litigation efficiency.”¹³²

C. Holding These Agreements Unlawful *Per Se* Meets the Purpose of the Sherman Act and the Hatch-Waxman Act and Works Toward the Benefit of the Consumer

Not only would the *per se* analysis be limited to a specific type of agreement between competitors and eliminate confusion in the courts and the pharmaceutical industry, but it would also, possibly most importantly, reflect the intent of relevant legislation and protect the consumer. The purpose of the Hatch-Waxman Act was to make it easier to introduce lower-cost generic drugs into the market while continuing to encourage the pioneer drug manufacturers to make the necessary investments to research and develop new products.¹³³ The amendments to the Act that resulted from the Medicare Act of 2003 were implemented in order to make it even easier to allow generic drugs to enter the marketplace.¹³⁴ Applying a *per se* standard to these non-compete agreements certainly appears to be in line with the legislature’s consistent efforts toward facilitating generic entry into

¹³¹ See, e.g., *Nat. Soc’y of Prof. Engineers v. U.S.* 435 U.S. 679, 692 (1978) (“[A]n agreement that interferes with the setting of price by free market forces is illegal on its face.”) (citation omitted); *U.S. v. McKesson & Robbins, Inc.* 351 U.S. 305, 309-10 (1956) (“It has been held too often to require elaboration now that price fixing is contrary to the policy of competition underlying the Sherman Act and that its illegality does not depend on a showing of its unreasonableness, since it is conclusively presumed to be unreasonable”).

¹³² *Arizona v. Maricopa County Med. Soc’y.*, 457 U.S. 332, 344 (1982).

¹³³ Narinder Banait, *Authorized Generics: Antitrust Issues and the Hatch-Waxman Act*, MONDAQ BUS. BRIEFING, Nov. 4, 2005.

¹³⁴ *Id.*

the marketplace.

In addition to promoting the entry of generic drugs into the market, the *per se* standard would not significantly hinder the incentive for the pioneer manufacturers to develop new drugs. The Hatch-Waxman Act has been credited with greatly expanding consumer access to generic drugs, from roughly nineteen percent of the pharmaceutical market in 1984 to fifty-seven percent of the market in 2005.¹³⁵ Yet, while the generic drugs saw a significant increase in the percentage of drugs sold, pharmaceutical companies have continued to invest in science and new technology.¹³⁶ Prior to the enactment of the Hatch-Waxman Act, in 1980 pharmaceutical manufacturers spent a combined \$2 billion on the research and development of new drugs, and in 2004, that number was \$39 billion.¹³⁷ Applying a *per se* analysis to reverse payment agreements between competing drug manufacturers would unlikely have anywhere near the impact that the Hatch-Waxman Act had on increasing the percentage of generic drugs in the marketplace. It is therefore difficult to argue that applying such an analysis in a limited set of circumstances would stifle the investment and innovation so critical to the pharmaceutical industry.

Finally, those who oppose a *per se* analysis of non-compete agreements between pioneer and generic drug manufacturers may argue that the reverse payment agreements may actually benefit both companies financially, but the intent of Congress was not to make money for the pharmaceutical industry.¹³⁸ If the payment is part of a settlement, the patent owner wins because a defeat in the patent litigation could have a severe financial impact.¹³⁹ On the other side, if the generic manufacturer were to lose in litigation, they would have nothing to show for its efforts, whereas a settlement agreement might allow the generic competitor to reach an agreed-upon date for market entry, and would likely ensure compensation for the time that it

¹³⁵ See Pharmaceutical Research and Manufacturers of America (PHRMA), *Pharmaceutical Industry Profile 2005-2006* at 20, available at <http://www.phrma.org/files/AnnualReport20052006.pdf>.

¹³⁶ *Id.* at 14-15.

¹³⁷ *Id.* at 19.

¹³⁸ Sean R. Sullivan, *Where Antitrust Law and Patent Infringement Intersect: Clear Standards Needed in Hatch-Waxman Patent Litigation*, 232 LEGAL INTELLIGENCER, 100 (May 23, 2005).

¹³⁹ *Id.*

abstains from entering the market.¹⁴⁰ These are valid considerations from the business perspectives of the pharmaceutical companies, but while the two manufacturers would possibly be better off financially as a result of the agreement, it would make the consumers worse off, because their access to low-cost generic alternatives would be delayed. The purposes of the Sherman and Hatch-Waxman Acts were to increase competition and make generic drugs available to the consumer. Holding reverse payment agreements not to compete as *per se* violations of the Sherman Act is consistent with this intent.

V. Conclusion

In general, the ideals behind antitrust law and intellectual property rights or patent law do overlap in that they are in place to protect consumer welfare.¹⁴¹ However, enforcement of both types of law can lead to conflict in interpreting certain types of behavior, in particular in the pharmaceutical industry. In fact, the FTC has targeted the health care market because it has such a tremendous impact on consumers.¹⁴² The circuit split between the Sixth and Eleventh Circuits reflects the varying opinions in regard to the appropriate type of analysis when looking at agreements between pioneer and generic drug manufacturers arising from patent infringement litigation.

The Supreme Court has yet to grant certiorari in regard to this issue, but several notions suggest that the Sixth Circuit was correct in holding such agreements to be unlawful *per se* under the Sherman Act. The *per se* analysis would be limited to this particular type of scenario, members of the pharmaceutical industry would have a bright line rule to follow when considering the impact of such agreements, and the courts would not have to engage in a fact-finding economic analysis in order to try and predict the potential anticompetitive effects. Finally, the legislative intent behind the Hatch-Waxman Act and the Sherman Act would be upheld in that low-cost generic drugs would be released to the market in a timely manner, ultimately benefiting the consumer.

According to a survey conducted in 2000, over ninety percent

¹⁴⁰ *Id.*

¹⁴¹ Chin & Walsh, *supra* note 6, at 271.

¹⁴² Diane Green-Kelly, *FTC and U.S. Courts Raise Questions About Legality of Pharmaceutical Patent Suit Settlements*, MONDAQ BUS. BRIEFING, Sept. 10, 2004.

of Americans reported that they had taken prescription drugs, and more than half said that they took prescription drugs on a regular basis.¹⁴³ Among the elderly, eighty-two percent reported that they regularly relied on prescription drugs.¹⁴⁴ At the same time, twenty-five percent of Americans reported that their prescription drugs were not covered by their health insurance plans, and close to thirty percent reported that they had not filled a prescription because of the cost.¹⁴⁵ American drug prices remain the highest in the world, and despite Congress' efforts to facilitate the entry of low-cost generic drugs to the marketplace, there is still the potential for delay when a patent infringement suit arises and the pioneer and generic manufacturers agree not to compete. This is an important issue and allowing generic drugs to enter the marketplace quickly is best served by applying a *per se* analysis to horizontal non-compete agreements arising from patent infringement litigation.

¹⁴³ Harvard School of Pub. Health, Kaiser Family Foundation, & The NewsHour with Jim Lehrer, *Prescription Survey Summary* (2000), available at http://www.pbs.org/newshour/health/prescriptions/survey_summary.html.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*