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Permissible Product Hopping: Why A Per Se Legal Rule Barring Antitrust Liability Is Necessary To Protect Future Innovation In The Pharmaceutical Industry

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"The Sherman Act is indeed the 'Magna Carta of free enterprise,' but it does not give judges carte blanche to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."¹

Abstract

Pharmaceutical product hopping is a relatively new phenomenon in which a brand-name pharmaceutical company tactically reformulates a drug and patents the reformulation in an attempt to avoid competition by a generic competitor. When viewed in the context of the Hatch-Waxman framework, product hopping can effectively eliminate generic competitors from the market, thereby implicating § 2 of the Sherman Act. In addressing antitrust liability, this Note advocates a per se legal approach to product hopping so long as the hop is supported by a valid patent. Although some have argued that deference to the United States Patent and Trademark Office and the resultant presumption of validity for issued patents is undeserved, such deference is necessary to ensure a consistent approach to product hopping, to avoid type I errors that could trigger a chilling effect on pharmaceutical innovation, and to prevent additional litigation which would erode patent rights, diminish value, and delay innovation.

Introduction

From hypertension to HIV/AIDS, cancer to cystic fibrosis, innovation in the pharmaceutical industry has saved countless lives, contributed to an increase in life expectancy, improved quality of life, and resulted in fewer surgeries, hospital stays, and trips to the ER.² Put simply, innovative drug discovery "can mean an extra three months or five months or a year—another [holiday] with the family, another season to plant a garden, another passage in the life of a child."³ While the societal value of such innovation is priceless, the cost of developing new pharmaceuticals is enormous at more than \$1 billion per drug.⁴ The risk of failure is equally as high. Indeed, for every brand-name drug that makes it to market, 5,000 to 10,000 drug targets fail.⁵ Given the incredible upfront investment and attendant

¹ *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004).

² See PhRMA, *The Value of Medicine: Facts and Figures 2006*, Powerpoint Presentation (2005) at <http://www.phrma.org/files/Value%20of%20Medicine%202006.pdf> (last visited Oct. 19, 2008) (Recent findings by a Columbia University researcher indicate that new medicines generated 40 percent of the two-year gain in life expectancy achieved in 52 countries between 1986 and 2000. Also, between 1980 and 2000, the number of days Americans spent in the hospital fell by 56 percent. As a result, Americans avoided 206 million days of hospital care in 2000 alone.).

³ *Id.* at slide 7 (quoting Donna St. George, *The Washington Post*).

⁴ Although estimates differ, one source suggests that the cost of an approved pharmaceutical drug, including average launch costs, has gone up from \$1.1 billion in 1995-2000 to \$1.7 billion in 2000-2002. See Peter Landers, *Cost of Developing a Drug Increases to About \$1.7 Billion*, Bain & Company, 2003 study; *PAREXEL's Pharmaceutical R&D Statistical Sourcebook 2006/2007*, 107.

⁵ Accenture, *The Pursuit of High Performance Through Research and Development* 24 (2007).

risks, it is widely believed that without the protection of patents, brand-name drug companies would cease to invest in research and development of new drugs.⁶

Despite the critical social benefits provided by pharmaceutical innovation, there is a general consensus that prescription drugs are too expensive and that more generic alternatives are needed to reduce costs.⁷ Some critics have even portrayed pharmaceutical companies as villains raking in profits while average people cannot afford the drugs they need to live.⁸ In response to such criticism and in an attempt to reduce the cost of prescription drugs, the Hatch-Waxman Act was enacted in 1984 to “balance the benefits of patent protection for drug innovation against the benefits of lower prices from generic competition.”⁹ Despite its noble intent, the Act’s complex legislative framework, which governs the interaction between brand-name and generic drug companies, has led to a culture of patent litigation.¹⁰ As a result, brand-name drug companies, in an attempt to protect their patent rights, have been forced to engage in exclusionary tactics, such as reverse exclusionary agreements, authorized generics, and product hopping.¹¹

Pharmaceutical product hopping is a relatively new phenomenon which occurs when a brand-name drug company tactically reformulates a drug and patents the reformulation in an attempt to avoid competition by a generic competitor.¹² While this tactic would be of little consequence outside the Hatch-Waxman framework, inside the framework, it can effectively eliminate generic competitors from the market and, thus, implicates § 2 of the Sherman Act.¹³ In addressing liability under § 2, courts are once again faced with the onerous challenge of maintaining the delicate balance between patent and antitrust law.

Under the antitrust laws, there are three possible standards under which product hopping may be addressed: 1) per se illegal; 2) per se legal; or 3) rule of reason. One author advances a convincing argument that courts should first consider the timing of the product hop and then deem the product hop per se legal if the old formulation is left on the market, or apply the rule of reason if the old formulation is pulled off the market.¹⁴ Under the rule of reason, the product hop would be deemed per se illegal if the new formulation is not a significant improvement over the previous formulation.¹⁵ This argument, while persuasive and well supported, relies on the courts’ ability “to distinguish non-existent or trivial

⁶ David Schwartzman, *Innovation in the Pharmaceutical Industry* (1976).

⁷ Andrew A. Phillips, *Strengthening Pharmaceutical Patent Rights: Lowering the Cost of Prescription Drugs By Stopping the Reckless Patent Litigation Abuse of Generic Companies*, 13 Conn. Ins. L.J. 397, 399 (2006-2007).

⁸ *Id.* at 399.

⁹ Richard Gilbert, *Holding Innovation to an Antitrust Standard*, 3:1 Competition Policy International 68 (Spring 2007).

¹⁰ *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206 (2d Cir. 2006).

¹¹ Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, Mich. St. L. Rev. 631 (2007).

¹² See Herbert Hovenkamp, et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* (2002).

¹³ Alan Devlin, *supra* note 11 at 658.

¹⁴ *Id.* at 658-9.

¹⁵ *Id.* at 11 at 662.

improvements, on the one hand, from significant quality enhancements, on the other.”¹⁶ Reliance on the courts to make this determination is problematic because the patent laws already provide a comprehensive regulatory framework for determining whether a product improvement is sufficient for patent protection.¹⁷ This is of critical concern in the pharmaceutical industry where innovation is frequently and necessarily incremental and, to the lay judge or jury, may erroneously appear to be no better than the existing technology. Moreover, if product hopping becomes commonplace and ultimately leads to a long-term reduction in generic alternatives, the issue should be fixed at the statutory rather than the judicial level. For this reason, courts should apply a per se legal approach to product hopping so long as the new product is based on a valid patent. Under this approach, courts should defer to the decision of the United States Patent and Trademark Office (USPTO) in deciding the validity of an improvement patent. Doing so will ensure a consistent approach, avoid the likelihood of type I errors that could trigger a chilling effect on pharmaceutical innovation¹⁸, and prevent additional litigation which heightens the uncertainty of patent rights and ultimately diminishes value and delays innovation¹⁹.

In advocating a per se legal approach to product hopping it is important to acknowledge the counterargument that deference to the USPTO and the resultant presumption of validity for issued patents is undeserved. Indeed, some have argued that “rather than protecting accurate initial decisions from inefficient later meddling . . . [the presumption of validity] precludes what would often be a worthwhile second look at patent validity.”²⁰ While the USPTO is certainly burdened with an ever-increasing workload²¹, patent examiners, rather than judges and lay person juries, possess the technical expertise necessary to properly assess the merits of a patent application. Moreover, the presumption of validity does not prevent invalidation of wrongly granted patents. While the challenger is faced with proving invalidity via clear and convincing evidence²², this stringent standard provides the basis of strong patent rights essential to fueling innovation - especially in the pharmaceutical industry. The bottom line is that while the USPTO’s review process may, in some cases, be less than ideal, the benefits far outweigh the disadvantages.

Part I of this Comment addresses the tension between the Sherman and Patent Acts. The critical value of patents in the pharmaceutical industry is explained and advocated. Part II outlines the framework of the Hatch-Waxman Act and addresses the resultant culture of patent litigation and the exclusionary tactic of product hopping. Part III considers antitrust decision theory and suggests a

¹⁶ *Id.* at 661-62.

¹⁷ 35 U.S.C § 101, et. seq.

¹⁸ See Alan Devlin, *supra* note 11 at note 55. (Type I errors occur when pro-competitive business practices are struck down.).

¹⁹ *In re Tamoxifen*, *supra* note 10 at 203.

²⁰ Doug Lichtman & Mark Lemley, *Rethinking Patent Law’s Presumption of Validity*, 60 Stanford L. Rev. 45, 48 (2007).

²¹ Statistics show that in 2007, the USPTO received 484,955 new patent applications. See http://www.uspto.gov/go/taf/us_stat.pdf (last visited Dec. 17, 2008).

²² *Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1367 (Fed. Cir. 2000).

product hop supported by a valid patent on a new drug formulation, dosage, or format should be deemed per se legal - - even if the product hop ultimately harms consumers in the short-term by keeping a generic drug off the market. The benefits of a per se legal approach versus the rule of reason are discussed and the likely counterarguments addressed.

I. The Contentious Intersection of the Patent Act and Sherman Act

Patent rights are anchored in the Constitution and give Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries.”²³ A patent grants an innovator “the right to exclude others from making, using, offering for sale, or selling [an] invention”²⁴ for a period of 20 years from the date of application.²⁵ The Patent system “reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’”²⁶ Thus, the “‘embarrassment of an exclusive patent’ is a special legal privilege justified only [when] . . . ‘monopolies of invention’ serve[] the ‘benefit of society.’”²⁷

The goals of antitrust law, embodied in the Sherman Act, 15 U.S.C. § 1 *et seq.*, mirror those of patent law. Specifically, the Sherman Act, much like the Patent Act, strives to “stimulate competition and innovation.”²⁸ Despite these common goals, the two areas of law function in stark contrast to one another. While the Patent Act grants a limited monopoly, § 2 of the Sherman Act prohibits “monopoliz[ation], or attempt[s] to monopolize, or combin[ations] or conspire[acies] . . . to monopolize any part of the trade or commerce among the several states.”²⁹ Indeed, “a patent by its very nature is anticompetitive” and “an exception to the general rule against monopolies and the right of access to a free and open market.”³⁰

Certainly, this “tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the [Patent Act]”³¹ creates a nucleus of uncertainty in the pharmaceutical market. Brand-name, or innovator, pharmaceutical companies are faced with the impossible decision of either stringently protecting their patent rights or risking their investments in innovation to avoid antitrust litigation and treble damages. To fully appreciate the quandary faced by innovator pharmaceutical companies, it is helpful to first consider the unique role of patents in the pharmaceutical industry.

²³ U.S. Const. Art. I, § 8, cl. 8.

²⁴ 35 U.S.C. §154(a)(1) (2000).

²⁵ 35 U.S.C. §154 (2000).

²⁶ *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 481 U.S. 141, 147 (1989).

²⁷ Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent Privilege in Historical Context*, 92 Cornell L. Rev. 953, 954 (2007) (Citing Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in 13 *The Writings of Thomas Jefferson* 326, 334–35 (Andrew A. Lipscomb ed., 1903)).

²⁸ *In re Tamoxifen*, *supra* note 10 at 201.

²⁹ 15 U.S.C. §2 (2000).

³⁰ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 2008 WL 4570669, 6 (C.A.Fed. (N.Y.) 2008).

³¹ *In re Tamoxifen*, *supra* note 10 at 201.

A. Patent Protection and the Role of Patents in the Pharmaceutical Industry

1. Strong Patents Rights Are the Key to Pharmaceutical Innovation

In today's society, innovator pharmaceutical companies provide a key facet of future health and well-being. For example, there are presently more than 750 new medications in development for the treatment of cancer³², 277 for the treatment of heart disease and stroke³³, 92 for the treatment of HIV/AIDS³⁴, and countless others. Despite their significant societal contribution, pharmaceutical companies must fight to protect their intellectual property rights. Patents are crucial and relied upon heavily to protect the enormous upfront investment required to bring a new drug to market. Of critical importance is that, unlike electronics or other high-tech goods, pharmaceuticals are easily reverse engineered and, thus, easily copied and sold at considerably lower prices by a competitor who did not incur research and development costs.³⁵ Without patent protection, brand-name drug companies would likely cease to invest in research and development as they would be undercut in the market and fail to recoup their initial costs.³⁶ Innovation would be stymied and society would suffer as the pipeline of drugs to meet future healthcare needs would run dry. Put simply, 'the promise of the new biomedical sciences of the 21st century - is by no means a sure thing... If the needed R&D investments can't be covered or made less risky, they will slow down.'³⁷

Several issues unique to drug development explain the pharmaceutical industry's strong reliance on patent protection and the perceived link between patent protection and high priced pharmaceuticals. First, innovation comes with a hefty price. As noted previously, the average cost to bring a drug to market, including commercial costs, such as the preparation of marketing materials, is more than \$1 billion.³⁸ Indeed, in 2005 alone, US pharmaceutical companies spent approximately \$51.8 billion on research and development.³⁹ Second, much of the investment occurs up-front and, since only 1 out of every 5,000 to 10,000 targets makes it to market⁴⁰, the development process is incredibly risky. Third, given the enormous up-front investment, drug targets are generally patented early in the development process and lose an appreciable amount of the period of patent exclusivity. As it takes approximately 10 to 15 years to move a drug candidate through discovery and development⁴¹, most drugs are left with only

³² PhRMA, *Medicines in Development for Cancer*, 2008 Report at http://www.phrma.org/files/meds_in_dev/Cancer2008.pdf (last visited Oct. 19, 2008).

³³ PhRMA, *Medicines in Development for Heart Disease and Stroke*, 2007 Report at <http://www.phrma.org/files/Heart%202007.pdf> (last visited Oct. 19, 2008).

³⁴ PhRMA, *Medicines in Development for HIV/AIDS*, 2007 Report at <http://www.phrma.org/files/Meds%20in%20Development%20for%20HIV%20AIDS.pdf> (last visited Oct. 19, 2008).

³⁵ David Schwartzman, *supra* note 6.

³⁶ *Id.*

³⁷ Mark McClellan M.D., Ph.D., *Speech Before Drug Information Association*, Ottawa, Canada, Nov. 18, 2003.

³⁸ Peter Landers, *Cost of Developing a Drug Increases to About \$1.7 Billion*, Bain & Company (2003).

³⁹ Burrill & Company, *Analysis for PhRMA, Pharmaceutical Industry Profile 2* (2006).

⁴⁰ Accenture Report, *supra* note 5 at 24.

⁴¹ *Id.* at 15.

5 to 10 years of exclusivity which is far below the patent life inventors enjoy in other industries⁴². The result is that once a brand-name drug actually makes it to market, the pharmaceutical company must charge a price commensurate with its upfront investment and risk in order to recoup its costs and invest in future innovation.

B. The Societal Need for Access to More Generic Drugs

Given these unique issues, erosion of strong patent rights would undoubtedly immobilize pharmaceutical innovation. Despite this, critics of the pharmaceutical industry have blamed the current patent system for the high price of prescription drugs and pushed for regulations that facilitate entry into the market of generic alternatives.⁴³ Such critics' arguments are not without merit. To the contrary, arguments in favor of the need for more generic alternatives are incontrovertibly valid - especially considering the current healthcare crisis and aging baby-boomer population.

From individuals to corporations, to the Federal Government, the cost of prescription drugs is burdensome. Thus, faster access to more generic alternatives is the logical solution because "generics save consumers—and third-party payers—money."⁴⁴ A lot of money, in fact. A recent report indicates that "if consumers were to buy generic products whenever possible and no brand-name equivalents, [the] savings [would] be approximately \$17 billion" per year.⁴⁵ Savings on the corporate level are substantial as well. In December 2000, General Motors determined that "for each one percent increase in the use of generic drugs, GM can save \$3 million per year."⁴⁶

Based on these considerable benefits, it would seemingly make sense to provide consumers as many generic alternatives as possible. From a cost perspective, generic drugs unequivocally benefit society and would be an ideal solution to a critical healthcare problem. Unfortunately, the solution is not as simple as it appears. To fully appreciate the implications of generic drugs, one must view the issue in light of the trade-off between short-term and long-term benefits. In the short-term, consumers, corporations, and the government would benefit from greater access to less expensive prescription drugs. While billions of dollars would be saved, the key question is at what long-term cost. The answer is at the cost of reducing the profits of innovator pharmaceutical companies below the level necessary to induce investment in future research and development.

Loss of future innovation is a critical issue in any industry. However, it is of particular concern in the pharmaceutical industry because the vast majority of drug research and development costs in the United States are shouldered by brand-name pharmaceutical companies.⁴⁷ For example, in 2005,

⁴² Andrew A. Phillips, *supra* note 7 at 406.

⁴³ Alan M. Fisch, *Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 *Jurimetrics J.* 295, 296 (1994).

⁴⁴ Robin J. Strongin, *Hatch-Waxman, Generics, and Patents: Balancing Prescription Drug Innovation, Competition, and Affordability*, *National Health Policy Forum*, June 21, 2002.

⁴⁵ Robert Pear, *Administration Offers a Mixed View on Drug Imports*, *New York Times*, Oct. 22, 2004.

⁴⁶ Robin J. Strongin, *supra* note 44 at 8.

⁴⁷ Andrew A. Phillips, *supra* note 7 at 407.

pharmaceutical companies spent 78% more on drug discovery than the NIH.⁴⁸ Not surprisingly, pharmaceutical companies are thus the source of the majority of drugs approved by the FDA. The statistics are staggering. Between 1981 and 1990, the pharmaceutical industry developed 92.4% of approved drugs while the government and academia were responsible for a mere 4.6%.⁴⁹ Certainly, these statistics validate that, but for pharmaceutical companies' substantial investment in research and development, innovation in the drug market would be minimal and our culture of modern healthcare would be at risk. Moreover, any short-term cost savings garnered from more generic drugs would undoubtedly be obviated in the long-term by the need for incalculable government investment in drug discovery. Put simply, the enormous short-term savings reaped from more generic drugs come at a steep price and one we surely cannot afford.

II. The Hatch-Waxman Framework

The debate over generic drugs and the inherent benefits and risks associated therewith has been a key policy issue for more than twenty years. The issue was formally addressed in 1984, upon enactment of The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the "Hatch-Waxman Act."⁵⁰ With the noble goal of balancing the creation of incentives for research and development on the part of prospective patent holders with the consumer welfare-enhancing effects of the availability of generic substitutes, the Act paved the way for the generic drug industry.⁵¹

A. Generic Entry Barriers and the Hatch-Waxman Solution

Prior to enactment of the Hatch-Waxman Act, generic manufacturers were faced with two main entry barriers. First, generic manufactures were required to adhere to the same FDA approval process as brand-name manufacturers and had to file a New Drug Application (NDA) if they wished to market a generic equivalent of a brand-name drug already on the market. This process required the generic manufacturer to conduct a costly and comprehensive series of pre-clinical tests to determine the efficacy and safety of the drug.⁵² Essentially, the generic manufacturer had to repeat the same studies already conducted by the brand-name manufacturer. Second, if the generic manufacturer began such testing before the patents on the brand-name drug expired, it would be committing an act of patent infringement. Certainly, the cost to file an NDA and the delayed market entry prevented any meaningful participation by generic manufacturers.

The Hatch-Waxman Act eliminated both entry barriers and facilitated a robust market for generic drugs. Indeed, between 1984 and mid-2007, the use of generic drugs increased from 19% of all

⁴⁸ Joseph Loscalzo, M.D., Ph.D., *The NIH Budget and the Future of Biomedical Research*, 354 *New England Journal of Medicine* 1665, 1666 (April 20, 2006).

⁴⁹ Andrew A. Phillips, *supra* note 7 at 407.

⁵⁰ 21 U.S.C. § 355 (2000).

⁵¹ Speech by Rep. Henry Waxman, Generic Pharmaceutical Assoc., Jan. 28, 2003 at http://www.house.gov/waxman/news_files/news_statements_gpha.htm (last visited, Dec. 17, 2008).

⁵² See, e.g., *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230-31 (4th Cir. 2002)

prescriptions to 67%.⁵³ Through creation of the Abbreviated New Drug Application (ANDA), the Act hastened approval of generic drugs through a streamlined and less costly process. Under this process, so long as the generic drug is bioequivalent to its brand-name counterpart⁵⁴, the ANDA allows the generic manufacturer to rely upon the preclinical testing results submitted for the brand-name drug⁵⁵. Also, the FDA may now approve the generic drug for marketing prior to expiration of the brand-name drug's patents if the generic manufacturer makes one of four certifications.⁵⁶ Three certifications - - paragraph I, paragraph II, and paragraph III certifications - - apply to ANDA filings that do not challenge the patents still protecting the brand-name drug. The fourth, called a "paragraph IV certification," is of particular importance to the issues discussed herein because it allows a generic manufacturer to claim that the patents protecting the brand-name drug are either invalid or not infringed.⁵⁷

Although the Act provides considerable benefits to generic manufacturers, it does not render patent owners entirely defenseless.⁵⁸ Upon learning of a paragraph IV certification, the patent owner has forty-five days in which to sue the generic manufacturer for patent infringement.⁵⁹ If suit is brought within this timeframe, an automatic thirty month stay is triggered, during which time the FDA may not approve the generic drug.⁶⁰ As a result, a paragraph IV certification almost always leads to a lawsuit. To prevent this risk from deterring generic entry, the Act awards the first filer of a paragraph IV certification a 180 day period of exclusivity, during which other generic manufacturers are barred from marketing their version of the brand-name drug.⁶¹

B. The Resultant Culture of Litigation

Ultimately, because there is a massive asymmetry in the ratio of risk to reward available to brand-name and generic manufacturers respectively, this statutory framework creates an environment of litigation.

Unlike in a typical patent infringement suit where an alleged infringer enters the market after substantial investment in manufacturing and marketing, under the Hatch-Waxman framework, the patent holder is incentivized to bring suit before the alleged infringer has invested anything other than legal fees.⁶² Also, because of the timing of the lawsuit, the alleged infringer escapes liability for damages.⁶³ The potential benefits, in contrast, are enormous. For example, after successfully challenging Eli Lilly's Prozac patents, Barr Laboratories, during the 180 day exclusivity period, sold \$311 million of its generic

⁵³ PhRMA tabulation of 1984-2000 data: IMS Health, National Prescription Audit Plus TM, 2001; 2001-2007 data: IMS Data (through 2nd Quarter of 2007).

⁵⁴ 21 U.S.C. § 355(j) (2000).

⁵⁵ *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1325-26 (Fed. Cir. 2002).

⁵⁶ 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(III) (2000).

⁵⁷ 35 U.S.C. § 271(e)(2)(A) (2000).

⁵⁸ The patent owner is assumed to be the brand-name manufacturer.

⁵⁹ 35 U.S.C. § 355(j)(5)(B)(iii) (2000).

⁶⁰ *Id.*

⁶¹ § 355(j)(5)(B)(iv) (2000).

⁶² *In re Tamoxifen*, *supra* note 10 at 206.

⁶³ *Id.*

equivalent and produced earnings that were nearly \$3.00 per share higher than in the previous fiscal year.⁶⁴

In stark contrast, the risks to the patent holder are vast and the benefits few. If the patent holder loses the infringement suit, “it will be stripped of its patent monopoly.”⁶⁵ Indeed, collateral estoppel is of great concern to the patent holder because once a patent is invalidated, nonmutual issue preclusion prevents the patentee from ever asserting it again.⁶⁶ Moreover, the patentee stands to gain little from winning the suit other than continuation of the lawful monopoly over the manufacture and sale of the drug.⁶⁷ Even worse, because the Hatch-Waxman framework forces a premature patent infringement suit, the patent holder is denied any possibility for damages. Considering that the patent holder likely invested 10 to 15 years of research and development and more than \$1 billion to develop and market the drug⁶⁸ this result seems particularly inequitable.

Accordingly, the Act “creates a legal environment conducive to horizontal agreement and strategic interaction between incumbent, brand-name drug manufacturers, on the one hand, and potential competitors seeking to file ANDAs, on the other.”⁶⁹ Brand-name manufacturers, in an attempt to protect their patent rights, have been forced to employ strategies within the complex web of laws to deter entry by generic manufacturers.⁷⁰ The result has been the emergence of exclusionary tactics such as reverse exclusionary agreements, authorized generics, and product hopping.⁷¹ While reverse exclusionary agreements and authorized generics are of particular concern in the pharmaceutical industry, the scope of this Comment will address only product hopping.⁷²

C. Product Hopping as an Exclusionary Tactic

Product hopping occurs when a patentee switches the formulation of its patented drug as soon as a generic competitor’s ANDA is approved.⁷³ The Hatch-Waxman Act coupled with the FDA’s regulatory framework creates an ideal environment for this tactic because substitution of a generic for the brand-name drug is permitted only if the generic has been “AB-rated” by the FDA.⁷⁴ To be AB-rated, the generic drug must not only be bioequivalent to the brand-name drug, but also have the same form,

⁶⁴ A. Maureen Rouchi, *Beyond Hatch-Waxman*, Chemical & Engineering News, Sept. 23, 2002 at <http://pubs.acs.org/cen/coverstory/8038/8038biogenerics2.html> (last visited Oct. 24, 2008).

⁶⁵ *In re Tamoxifen*, *supra* note 10 at 208.

⁶⁶ See *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971).

⁶⁷ *In re Tamoxifen*, *supra* note 10 at 208.

⁶⁸ Peter Landers, *supra* note 38.

⁶⁹ Alan Devlin, *supra* note 11 at 639.

⁷⁰ *Id.* at 640.

⁷¹ *Id.* at 632. (The first manifestation of this practice has seen incumbents and potential entrants entering into so-called reverse exclusionary agreements. Subsequent practices involve such strategies as product hopping and authorized generics.)

⁷² For a detailed description of the antitrust issues related to reverse exclusionary agreements and authorized generics, see Alan Devlin, *supra* note 11 at 640-657 and 674-680.

⁷³ Alan Devlin, *supra* note 11 at 657.

⁷⁴ *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*, 432 F. Supp. 2d 408, 415 (D. Del. 2006).

dosage, and strength.⁷⁵ Thus, “an approved generic that is not AB-rated against a currently available branded drug . . . cannot be substituted for the branded drug and may only be sold, if at all, as a separately branded, rather than generic drug.”⁷⁶

Given this requirement, a brand-name manufacturer could effectively foreclose a generic competitor from entering the market by switching the formulation, dosage, or strength of its patented drug as soon as the generic competitor’s ANDA is approved.⁷⁷ The timing of the product hop is critical and determines whether the antitrust laws are implicated.⁷⁸ Specifically, if the brand-name manufacturer “product hops after an ANDA is filed by the generic manufacturer, but before the accuracy of the paragraph IV certification has been judicially determined, the FDA will be unable to grant authorization.”⁷⁹ The generic manufacturer is thus faced with two options: 1) enter the relevant market as a brand-name drug; or 2) restart the ANDA process based on the new version of the brand-name drug.⁸⁰ Certainly, these options provide no resolution. The first would be prohibitively expensive as the generic competitor would be required to file an NDA and conduct extensive preclinical testing. The second, while feasible, could result in a vicious cycle because, assuming the USPTO will grant an improvement patent, the brand-name manufacturer could reformulate its patented drug each time an entrant filed an ANDA.⁸¹ Regardless of the option pursued by the generic manufacturer, § 2 of the Sherman Act is implicated because the brand-name manufacturer perpetuates its monopoly,⁸² which ultimately harms consumers by simultaneously reducing consumer choice and increasing price.

III. The Pitfalls and Promises of Antitrust Decision Theory

The pertinent question is thus: how should courts address product hopping under the antitrust laws. There are three possible modes of analysis: 1) per se illegal; 2) rule of reason; and 3) per se legal. This author argues that a per se legal approach should be applied so long as the product hop is supported by a valid patent. At the other end of the spectrum is the per se illegal approach which is easily eliminated because a business practice may be condemned under this approach only if the challenged action has a “pernicious effect on competition and lack[s] any redeeming value.”⁸³ Applying such an approach to product hopping would induce consumer harm because product hops based upon valid improvements would be condemned and foreclose potentially valuable new drugs from the market. The rule of reason approach falls somewhere in the middle. Under this approach, which has been applied in recent cases and advocated by at least one antitrust scholar, “a court will conduct a case-specific

⁷⁵ *Id.* at 415.

⁷⁶ *Id.*

⁷⁷ Alan Devlin, *supra* note 11 at 657.

⁷⁸ *Id.* at 658.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.* at 657.

⁸² *Id.* at 660.

⁸³ *Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 289 (1985)

assessment of the facts to determine whether the relevant actions actually harmed consumers or not.”⁸⁴ Examination of two recent cases brings to light the promises and pitfalls of the rule of reason versus per se legal approach.

A. Recent Product Hopping Cases

1. *Walgreen Co. et al. v. AstraZeneca Pharmaceuticals* – The Case of Prilosec and Nexium

*Walgreen Co. v. AstraZeneca*⁸⁵ involved the well known heartburn drugs Prilosec and Nexium. The crux of plaintiffs’ claim was that AstraZeneca engaged in anticompetitive innovation in violation of § 2 of the Sherman Act by deliberately switching the market from Prilosec, which had generic competition, to a virtually identical drug, Nexium, which did not have generic competition.⁸⁶ The active ingredient in Nexium is an isomer of the active ingredient in Prilosec⁸⁷, meaning that the molecules that have the same molecular formula but different structural properties.⁸⁸ Put simply, the drugs are similar but have distinct effects on the body.⁸⁹ The plaintiffs asserted there was no pharmacodynamic reason the two drugs would interact with the body any differently and that by vigorously promoting Nexium over Prilosec, AstraZeneca undermined the market for Prilosec’s generic alternatives.⁹⁰ In addition, the plaintiffs alleged that AstraZeneca “engaged in prohibited exclusionary conduct when it introduced [an over the counter version of] Prilosec and obtained a grant of exclusivity for three years from the FDA.”⁹¹

Ultimately, the court held that AstraZeneca did not violate § 2 because the “fact that a new product siphoned off some of the sales from the old product, and, in turn, depressed sales of the generic substitutes for the old product does not create an antitrust cause of action.”⁹² AstraZeneca did not interfere with the plaintiffs’ right to compete because Prilosec was left on the market. The court concluded AstraZeneca’s conduct was procompetitive because they successfully advertised a new product, albeit to the disadvantage of plaintiffs.⁹³

2. *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.* – The TriCor Case

*Abbott v. Teva*⁹⁴ presents a similar series of facts; however, Abbott recently denied wrongdoing and settled the case for \$184 million.⁹⁵ Abbott, the manufacturer of TriCor, a fenofibrate drug used to treat high levels of triglycerides and high cholesterol, allegedly engaged in prohibited exclusionary

⁸⁴ Alan Devlin, *supra* note 11 at 634 (see *Standard Oil Co. v. United States*, 221 U.S. 1 (1911) (applying the rule of reason standard for the first time)).

⁸⁵ *Walgreen Co. et al. v. AstraZeneca Pharmaceuticals*, 534 F.Supp.2d 146 (D.D.C. 2008).

⁸⁶ *Id.* at 149.

⁸⁷ Richard Gilbert, *supra* note 9 at 69.

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Walgreen Co. v. AstraZeneca*, *supra* note 85 at 149.

⁹¹ *Id.*

⁹² *Id.* at 152.

⁹³ *Id.*

⁹⁴ *Abbott v. Teva*, *supra* note 74.

⁹⁵ See Tracy Staton, *Abbott to Pay \$184 Million in TriCor Settlement*, Nov. 11, 2008 at <http://www.fiercepharma.com/story/abbott-pay-184m-tricor-settlement/2008-11-21> (last visited Dec. 17, 2008).

conduct under § 2 of the Sherman Act when it changed the drug from a capsule to a patented, lower dosage tablet with a broader FDA indication that included the ability to increase good cholesterol levels.⁹⁶ Then, on a second occasion, Abbott, again based on a patent, offered a different, even lower dosage tablet based on a new composition of the active ingredient that could be absorbed into the bloodstream without being taken with food.⁹⁷ Unlike in *Walgreen Co. v. AstraZeneca* where AstraZeneca left the old formulation on the market, here, Abbott pulled the previous formulations off the market.⁹⁸ In both cases, Abbott also notified the National Drug Data File (NDDF), a private database that provides information about FDA approved drugs, that the previous formulations were obsolete, thus preventing pharmacies from filling prescriptions for TriCor with a generic alternative.⁹⁹ Generic manufacturers alleged that Abbott intentionally manipulated the Hatch-Waxman framework to monopolize the fenofibrate market by preventing pharmacies from filling prescriptions written for the new TriCor formulations with generic alternatives.¹⁰⁰

B. The Tradeoff Between Innovation and Antitrust

While there are several key issues in these cases, this Comment will focus mainly on the critical question of how much innovation is enough to prevent an antitrust violation. Addressing this question in the context of the pharmaceutical industry presents much complexity because “incremental . . . innovation[] in the form of supplementary approvals for new dosages, formulations, and indications account for a substantial share of drug utilization and associated economic and medical benefits.”¹⁰¹ Adopting a rule that would condemn such incremental innovation would be disastrous. Moreover, because “a monopolist is permitted, and indeed encouraged, by § 2 to compete aggressively on the merits, any success that it may achieve through ‘the process of innovation’ is clearly tolerated by the antitrust laws.”¹⁰² Thus, a per se legal rule against liability under the Sherman Act should be adopted when a product hop is supported by a valid patent.

1. Promises of the Per Se Legal Rule versus the Rule of Reason

The beauty of the per se legal approach is its simplicity. Rather than waste precious judicial resources and hefty discovery and litigation expenditures, as is necessary in applying the rule of reason, under this simplified test, a judge, upon deeming a product hop is based on a valid patent, would simply dismiss the matter. Predictability and simplicity would be greatly enhanced, type I errors avoided, and the Patent Act respected. For example, under the proposed per se legal approach, *Abbott v. Teva* and

⁹⁶ *Abbott v. Teva*, *supra* note 74 at 416.

⁹⁷ *Id.* at 418.

⁹⁸ *Id.* at 416, 418.

⁹⁹ *Id.* at 416.

¹⁰⁰ *Id.* at 418-19.

¹⁰¹ Ernst R. Berndt, et al., *The Impact of Incremental Innovation in Biopharmaceuticals*, 24(2) *Pharmacoeconomics* 69 (2006).

¹⁰² *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 281 (2d Cir. 1979).

Walgreen Co. v. AstraZeneca would have the same outcome. In both cases, patents supported the product hops. Thus, the conduct of both companies would be deemed per se legal.

a. The Rule of Reason's Overly Complex Formula

Opponents to this outcome, including the plaintiffs in *Walgreen Co. v. AstraZeneca* and *Abbott v. Teva*, argue in favor of the rule of reason because some product improvements are "strategic business decisions, intended to avoid competition on the merits, and thereby to protect an existing market position against otherwise foreseeable decline."¹⁰³ While in some cases their argument may hold true, approaching the issue of pharmaceutical product hopping under the rule of reason is simply too complex.

Under the rule of reason, a court, in addressing the question of how much innovation is enough to prevent antitrust violation, will conduct "a case-specific assessment of the facts to determine whether the relevant actions actually harmed consumers or not."¹⁰⁴ According to the Supreme Court, the rule of reason inquiry is "whether the challenged [conduct] is one that promotes competition or one that suppresses competition. . . ."¹⁰⁵ While a seemingly simple test on its face, application of the test is plagued with difficulties when coupled with the issues of pharmaceutical patents. Specifically, "a total [rule of reason] test would have to consider the impacts of innovation on the innovator and on other firms and consumers in the present and in the future, and should also account for the impacts of antitrust enforcement on future incentives to innovate."¹⁰⁶ Whether courts are in a position to conduct this complex analysis is clearly debatable.

Indeed, even economists faced with this question would likely be unable to render a synchronous decision about consumer welfare.¹⁰⁷ The rule of reason formula is simply too open ended because "when everything is relevant, nothing is dispositive."¹⁰⁸ For example, a court addressing the questions posed in the *Walgreen Co. v. AstraZeneca* and *Abbott v. Teva* cases would have to grapple with the fact that in both cases, the brand-name drug company was granted patents on improvements to its drugs and thus granted a permissible, short-term monopoly for their manufacture, use, and sale.¹⁰⁹ Since "even a monopolist, may, 'through technological innovation expand its market share, increase consumer brand identification, or create demand for new products'"¹¹⁰, determining whether such incremental innovation is too minimal to avoid antitrust violation is nearly impossible. By invalidating the patents, a court would benefit consumers and other firms in the short-term, but could stifle future innovation. The problem is

¹⁰³ Jay L. Himes & Saami Zain, *Anti-Competitive Innovation: Is There a Role for Antitrust in Evaluating Product Line Extensions*, American Conference Institute: Pharmaceutical Antitrust 14 (May 2007).

¹⁰⁴ Alan Devlin, *supra* note 11 at 634 (referring to *Standard Oil Co. v. United States*, 221 U.S. 1 (1911) (applying the rule of reason standard for the first time)).

¹⁰⁵ *National Soc'y of Professional Eng'rs v. United States*, 435 U.S. 679, 691 (1978).

¹⁰⁶ Richard Gilbert, *supra* note 9 at 53.

¹⁰⁷ Frank H. Easterbrook, *The Limits of Antitrust*, 63 Tex. L. Rev. 1, 11 (1984).

¹⁰⁸ *Id.* at 12.

¹⁰⁹ 35 U.S.C. § 154(a)(1); See generally Michael C. Smith, *Patent Litigation: A Changing Landscape*, 71 Tex. B.J. 42 (2008).

¹¹⁰ *Abbott v. Teva*, *supra* note 74 at 420 (quoting *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 546 (9th Cir. 1983)).

that the impact on future innovation is impossible to measure. Certainly, if economists would be unable to agree upon the economic outcome, how can we expect courts to do so?

b. A More Structured Rule of Reason Imposes Too Great a Burden on Patent Holders and Overshadows the Presumption of Patent Validity

One antitrust scholar advocates for application of a slightly modified rule of reason and argues that so long as the incumbent pharmaceutical company is prevented from withdrawing its original product from the market for a limited period of time, we should rely on the “court’s ability to distinguish non-existent or trivial improvements . . . from significant quality enhancements.”¹¹¹ This approach is well-supported because it makes at least one factor dispositive and seemingly solves the issues of consumer harm and harm to innovation. Specifically, by keeping its old product on the market, the incumbent manufacturer allows generic market entry and thus greater competition and consumer choice.¹¹² In addition, the incumbent would still be able to market its new product and potentially reap the benefits of its research and development efforts and upfront investment.¹¹³ Although convincing, this argument relies on the province of the courts to distinguish between trivial improvements and significant quality enhancements. This is troublesome because just like how courts are ill equipped to handle complex economic analyses¹¹⁴, so too are they ill equipped to handle complex analyses into whether a product improvement is trivial or significant.¹¹⁵

Even more concerning is this approach overshadows the rule that every patent enjoys a presumption of validity.¹¹⁶ By questioning patent validity, the rule of reason threatens future innovation by clouding the value of the intellectual property rights on which pharmaceutical companies have traditionally relied. This should be avoided and, instead, courts should apply simple presumptions that “structure antitrust inquiry” and, thus, “guide businesses in planning their affairs by making it possible for counsel to state that some things do not create risks of liability.”¹¹⁷ In the case of product hopping, one such presumption should be that any product hop based on a patent is per se legal. Since every patent

¹¹¹ Alan Devlin, *supra* note 11 at 662.

¹¹² *Id.* at 661.

¹¹³ *Id.*

¹¹⁴ See Frank H. Easterbrook, *supra* note 107 at 12.

¹¹⁵ Similar difficulties exist in other contexts. For example, the 9th Circuit’s subjective motivation test from *Image Technical Servs., Inc. v. Eastman Kodak Co.*, 125 F. 3d 1195, 1201 (9th Cir. 1997), was criticized by the Federal Circuit. See *In re Independent Service Orgs. Antitrust Litig.*, 203 F.3d 1322, 1327-28 (Fed.Cir. 2000) (“We see no more reason to inquire into the subjective motivation of Xerox in refusing to sell or license its patented works than we found in evaluating the subjective motivation of the patentee in bringing suit to enforce that same right. In the absence of any illegal tying, fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using or selling the claimed invention free from liability under the antitrust laws. We therefore will not inquire into his subjective motivation for exerting his statutory rights, even though his refusal to sell or license his patent invention may have an anti-competitive effect, so long as that anti-competitive effect is not illegally extended beyond the statutory patent grant.”)

¹¹⁶ 35 U.S.C. § 282 (2000).

¹¹⁷ Frank H. Easterbrook, *supra* note 107 at 14.

issued by the USPTO already carries a presumption of validity¹¹⁸ justified by the “complexities of patent law and the expertise of the patent office”¹¹⁹, this additional presumption is merely a natural extension.

c. Arguments Against the Presumption of Validity are Outweighed By the Benefits of Future Pharmaceutical Innovation

Despite the benefits of the presumption of validity, Doug Lichtman and Mark Lemley posit that the presumption should be weakened because the large number of patent applications, limited financial resources, and incomplete information make it impossible for the USPTO to thoroughly review applications and grant only those patents deserving of protection.¹²⁰ Their argument has merit as a high percentage of patents are invalidated during litigation¹²¹; however, it fails to acknowledge the unique intricacies of drug discovery such as the enormous upfront investment in research and development, early patenting of thousands of drug targets, and the high failure rate of testing. As discussed previously, because of this dimension of complexity, patent rights are critical to innovator pharmaceutical companies and even minimal weakening the presumption of validity will lead to increased uncertainty surrounding a pharmaceutical company’s ability to enforce its patents. Ultimately, societal harm will result as firms will decrease investment in innovation.

Lichtman and Lemley disagree and note that less certainty is unlikely to radically alter behavior because “success in the pharmaceutical industry . . . depends on other unavoidable uncertainties such as the uncertainty associated with FDA review and the . . . risk that, because of some unexpected side effect, a blockbuster drug will suddenly lose all of its value.”¹²² While such uncertainties are indeed unavoidable, their argument ignores the fact that the presumption of validity is a critical constant that allows pharmaceutical companies to withstand the risks posed by the FDA approval process and the ever looming possibility of adverse side effects. If companies were no longer assured their investment in new drug targets would be protected by a presumption of validity, the cumulative risks would simply be too great to bear. While the current USPTO patent review process and presumption of validity are far from perfect, they provide critical stability for the pharmaceutical industry which, in turn, fuels continued innovation. Overall, the benefits of the presumption of validity outweigh the harms and further confirm the need to apply a per se legal approach to product hopping.

d. A Per Se Legal Approach Defers to the USPTO and Facilitates Consistent Outcomes

Indeed, given the great complexity of pharmaceutical patents, it is reasonable to assume that understanding a pharmaceutical patent itself, much less whether it represents a significant improvement over the previous version of the drug requires, at a minimum, understanding of the relevant chemical sciences. For example, Abbott’s ‘670 patent, at issue in *Abbott v. Teva*, claims “an immediate-release

¹¹⁸ 35 U.S.C. § 282 (2000).

¹¹⁹ *Monroe Auto Equipment Co. v. Heckethorne Mfg. & Supply Co.*, 332 F.2d 406, 412 (6th Cir.).

¹²⁰ *Id.* at 47.

¹²¹ John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 200 (1998).

¹²² Doug Lichtman & Mark Lemley, *supra* note 20 at 58.

fenofibrate composition comprising: (a) an inert hydrosoluble carrier covered with at least one layer containing fenofibrate in a micronized form having a size less than 20 <<mu>>m, a hydrophilic polymer and a surfactant¹²³ The extreme technical content of this claim and others at issue in pharmaceutical product hopping cases, suggests that courts should defer to the USPTO's experienced examiners as they have the technical background to properly make such determinations whereas judges and juries may not. The bottom line is that the USPTO, rather than the courts, should decide whether a product improvement is enough to warrant the limited monopoly granted by a patent. This is easily accomplished under a per se legal approach.

Whether deference to the USPTO's technical savvy is justified is hotly debated. Lichtman and Lemley argue that although patent examiners have expertise in the relevant subject areas while judges and juries do not, the USPTO functions under such poor conditions that any advantages associated with expertise are overwhelmed by the disadvantages associated with insufficient funding and inadequate outsider information.¹²⁴ They argue a court-based review process is superior because more complete information results from the adversarial process and financial constraints are reduced because only a tiny fraction of issued patents warrant litigation.¹²⁵ While this argument correctly acknowledges the many challenges faced by the USPTO, Lichtman and Lemley again fail to fully appreciate the complexity of the drug discovery process and the challenges faced by innovator pharmaceutical companies. By failing to respect the decisions of the USPTO, patent rights are diminished leading to increased uncertainty and decreased innovation. Consequently, disadvantages that arise from deference to the USPTO are offset by the societal need for continual advances in pharmaceutical innovation.

Although the USPTO's review process may be imperfect, deference to the USPTO fosters consistency. Consistent decisions confirm the certainty of patent rights which, in turn, facilitate not only investment in innovation, but also decreased litigation costs. As discussed *supra*, the rule of reason requires an incredibly complex undertaking that courts are ill equipped to perform. In contrast to the predictable per se legal approach, the rule of reason is open ended and yields contradictory results. The problem with the rule of reason is that "any one factor might or might not outweigh another, or all of the others."¹²⁶ Such vagueness proffers no guidance to businesses planning their conduct and, in the context of litigation, leads to "ceaseless discovery."¹²⁷ Indeed, "litigation costs are the product of vague rules combined with high stakes, and nowhere is that combination more deadly than in antitrust litigation under the Rule of Reason."¹²⁸ Adding the question of how much innovation is enough in the context of pharmaceutical product hopping makes the combination even more lethal. The stakes are enormous

¹²³ U.S. Pat. No. 6,074,670

¹²⁴ Doug Lichtman & Mark Lemley, *supra* note 20 at 47.

¹²⁵ *Id.*

¹²⁶ Frank H. Easterbrook, *supra* note 107 at 12.

¹²⁷ *Id.*

¹²⁸ *Id.* at 13.

because on the one hand, brand-name pharmaceutical companies' patent rights and incentive to innovate are at risk, and on the other, consumer choice, decreased cost, and increased competition. The problem is that "in antitrust, there is no right answer"¹²⁹ and, thus, balancing the trade-off between "optimal incentives ex ante and optimal use of existing knowledge" is doomed to fail.¹³⁰

e. Adoption of a Per Se Legal Approach will Prevent Type I Errors

Failure to properly balance ex ante incentives with the optimal use of existing knowledge will undoubtedly lead to type I errors. Type I errors, which occur when procompetitive business practices are struck down¹³¹, are particularly egregious because "a practice once condemned is likely to stay condemned, no matter its benefits"¹³². Thus, if pharmaceutical innovation is condemned it is likely to stay condemned. Application of a per se legal approach when the product hop is supported by a patent avoids type I errors by deferring to the USPTO and respecting pharmaceutical companies' patent rights. If such a test is adopted, although some "socially undesirable practices may escape"¹³³, the risk of type I errors is minimal. To the contrary, under the rule of reason, the risk of type I errors is great because, as discussed above, the complexity of the test will lead to ineffective balancing of short-term and long-term benefits. To put this risk in perspective, consider the following hypothetical outcome of *Abbott v. Teva*.

If Abbott had not settled and its conduct was deemed exclusionary in violation of § 2 of the Sherman Act, Abbott and other pharmaceutical companies would undoubtedly alter their future conduct to avoid similar liability. Specifically, they would likely be overly cautious with respect to releasing products based on incremental innovation. This is troubling because incremental innovation can be procompetitive as it brings new drugs to market and benefits consumers by providing treatments for a greater array of diseases. For example, in *Walgreen Co. v. AstraZeneca*, there was some indication Nexium was useful for the treatment of esophageal and duodenal ulcers.¹³⁴ Similarly, in *Abbott v. Teva*, Abbott claimed the new TriCor formulations offered a lower dosage, the potential benefit for increasing good cholesterol, and the ability to be taken without food.¹³⁵ Because of the presence of valid patents on the Nexium and TriCor formulations, under the per se legal rule, it would be unnecessary to address whether or not these differences constitute improvements. The product hops would simply be deemed legal and incentives to innovate would be preserved. The same outcome would result for Nexium under the rule of reason because, since the old formulation was left on the market, it would be considered per se legal. Tricor is a different story. Since the previous TriCor formulations were pulled off the market, a court would have to assess whether the new formulation is a significant improvement over the previous.

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ Alan Devlin, *supra* note 11 at note 55 (referencing Richard A. Posner, *An Economic Approach to the Law of Evidence*, 51 Stan. L. Rev. 1477, 1504 (1999) (defining Type I and Type II errors)).

¹³² Frank H. Easterbrook, *supra* note 107 at 15.

¹³³ *Id.*

¹³⁴ Richard Gilbert, *supra* note 9 at 69.

¹³⁵ *Abbott v. Teva*, *supra* note 74 at 416.

Here, one could argue that TriCor's lower dosage means less medication for the liver to process and an easier, more convenient pill to swallow. While this may be a strong argument, some courts would likely reject it, deem TriCor per se illegal, and remove it from the market. Others might accept the criteria as sufficient and leave TriCor on the market. Supposing that TriCor indeed benefits at least some consumers, condemning it under the rule of reason would constitute a type I error and thus disincentivize investment in future innovation for fear similar products would be deemed illegal products hops.

Unlike the rule of reason, the per se legal rule eliminates the risk of type I errors. Although, this approach may permit some socially undesirable practices, such as decreased generic competition in the short-term, "errors on the side of excusing questionable practices are preferable" because "the economic system corrects monopoly more readily than it corrects judicial errors."¹³⁶ In addition, the "costs of monopoly wrongly permitted are small, while the costs of competition wrongly condemned are large."¹³⁷

f. Benefits of the Per Se Legal Approach Outweigh the Risks Posed by Type II Errors

Type II errors are also of concern in the context of product hopping. In contrast to type I, such errors constitute false positives and occur when patents are issued for compounds undeserving of patent protection. Under the per se legal approach, type II errors would undoubtedly exist because imperfections in the USPTO's review process, such as resource constraints, imperfect information, and the challenges of prior art searches lead to an increased incidence of type II errors.¹³⁸ Despite this, the consequences of type I errors are far more troublesome because they disincentivize incremental innovation while type II errors do not. Rather, allowing some undeserved patent rights, while potentially harmful to consumers in the short-term due to decreased generic competition and increased price, ultimately benefit consumers in the long-term by ensuring continued investment in innovation. While type II errors may be reduced by tightening the requirements of patentability, this strategy fails miserably in the context of pharmaceutical patents because, as discussed infra, incremental innovation is prominent in drug discovery and stricter patentability requirements foreclose future innovation.

Certainly, there is no perfect solution. Indeed, shifting deference away from the USPTO to the courts, as suggested by Lichtman and Lemley, is similarly riddled with type II errors. Specifically, the clear and convincing standard required to overcome the presumption of validity is stringent and favors patentability.¹³⁹ Also, jury trials favor patentability because jurors tend to favor inventors over infringers and are often swayed toward patentability by the technological "wow-factor".¹⁴⁰ The bottom line is when courts cannot reliably make determinations, a bright-line rule, such as the per se legal approach, will serve as the best heuristic.

¹³⁶ Frank H. Easterbrook, *supra* note 107 at 15.

¹³⁷ *Id.*

¹³⁸ Rochelle Cooper Dreyfuss, *Non-Obviousness: A Comment on Three Learned Papers*, 12 Lewis & Clark L. Rev. 431, 434 (2008).

¹³⁹ *Id.* at 434.

¹⁴⁰ *Id.* at 434-35.

g. A Per Se Legal Approach Respects the Current Legislative and Regulatory Framework and Fosters Incremental Pharmaceutical Innovation

The benefits of the per se legal approach to product hopping are clear. However, it is important to acknowledge the counterargument that the standard for granting improvement patents is too low¹⁴¹ and allows pharmaceutical companies to improperly manipulate the Hatch-Waxman framework to their advantage. While such arguments are not without merit, the USPTO, in granting improvement patents, is simply applying the statutory framework promulgated by Congress. Under the current Patent Act, an applicant is entitled to an improvement patent if that product is different from the original.¹⁴² Enhancement in product quality is not required. Despite this low threshold, the Patent Act prevents illusory product improvements because “one year after approval of the underlying patent, the ‘parent’ becomes part of the prior art.”¹⁴³ Thus, “mere reformulation is likely to founder on the novelty requirement.”¹⁴⁴

Moreover, due to the nature of drug discovery, the low threshold of patentability is critical to pharmaceutical patent rights because most pharmaceutical research and development is incremental. Opponents argue that incremental innovation provides little or no advantage, and therefore does not deserve patent protection. However, this position is misguided and demonstrates a lack of understanding of drug discovery because incremental innovation is the key to most major advances in the treatment and prevention of disease.¹⁴⁵

For this reason, there is a strong need for continued patent protection of drug compounds that are merely different, not necessarily an improvement, over their predecessors. This is the mainstay of incremental innovation because minor variations on previously known compounds may have surprising properties. However, given that drug compounds are necessarily patented early in the development process, the benefits of such properties may not emerge until much later. Thus, a low threshold of patentability is necessary and must focus on differences rather than improvements because the ability of innovator pharmaceutical companies to patent slightly different analogs of the same compound is what makes modern drug discovery possible. Without such protection, the considerable investment necessary to investigate those compounds would be outweighed by the risk of the patent being denied later in the process or competitors copying the compound. Put simply, increasing the threshold of patentability would halt pharmaceutical innovation as we know it.

¹⁴¹ See Alan Devlin, *supra* note 11 at 660.

¹⁴² See *Id.* at note 22 (The primary bar to patenting an improvement will be anticipation, but this only occurs if a single prior art discloses each and every element of the claimed invention. See Roger Schechter & John Thomas, Principles of Patent Law 77 (Thomson West 2d ed. 2004). See generally Arnold B. Silverman, The Relationship Between Basic and Improvement Patents, 47 J. Minerals, Metals, & Materials Soc’y 50 (1995), available at <http://www.tms.org/pubs/journals/JOM/matters/matters-9501.html>.)

¹⁴³ *Id.* at 660.

¹⁴⁴ *Id.*

¹⁴⁵ Glaxo Smith Kline, Press Release on Incremental Innovation, Jan. 2008 at <http://www.gsk.com/policies/GSK-public-policy-on-incremental-innovation.pdf> (last visited Dec. 17, 2008).

Given the critical need to meet future healthcare requirements, this is a risk we cannot afford to take. Courts must continue to respect the current state of the Patent Act and, thus, refrain from applying the rule of reason to invalidate even those patents granted for incremental innovation. While the USPTO's review process is imperfect and risks type II errors which could reduce consumer choice and increase prices, the long-term benefits of deferring to the USPTO and respecting the current presumption of validity far outweigh these short-term risks.

Finally, if pharmaceutical product hopping is, at some point, deemed an unforeseen consequence of the Patent Act's arguably low standard for grant of improvement patents or the Hatch-Waxman Act's 30 month stay provision, surely the proper forum to address this issue is Congress rather than the courts. Alternatively, "the FDA could develop policies to facilitate generic substitution and limit new drug approvals to drugs that meet a threshold level of utility."¹⁴⁶ Regardless, proponents of modification to the Patent Act or FDA regulations should err on the side of caution because increasing the statutory requirements for grant of improvement patents or allowing easier entry of generic drugs, much like the rule of reason, risks stifling future innovation.

Conclusion

In sum, the issue of pharmaceutical product hopping is complex and much is at stake for consumers and pharmaceutical companies - - brand-name and generic alike. The Patent Act, in combination with the Hatch-Waxman Act, exists to balance the delicate relationship between incentives for future pharmaceutical innovation and the need for additional generic alternatives. By adopting a *per se* legal approach when the product hop is supported by a valid patent, courts will respect the intricate statutory framework already in place and, at the same time, align short-term and long-term benefits. In doing so, courts will prevent harm to consumers and patent holders by facilitating more predictable outcomes and preventing type I errors that could suspend further innovation. While the USPTO's review process is imperfect and risks type II errors, the long-term benefits of a *per se* legal approach far outweigh the short-term disadvantages. The logical conclusion is that, in the context of pharmaceutical product hopping, the rule of reason is simply too complex and should be overlooked because by seeking "to embody every economic complexity and qualification, [it may], through the vagaries of administration, prove counter-productive, undercutting the very economic ends [it] seeks to serve."¹⁴⁷

¹⁴⁶ Richard Gilbert, *supra* note 9 at 74.

¹⁴⁷ Frank H. Easterbrook, *supra* note 107 at 16.