BRAND-NAME DRUG MANUFACTURERS RISK ANTITRUST VIOLATIONS BY SLOWING GENERIC PRODUCTION THROUGH PATENT LAYERING

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INTRODUCTION

Patents on many blockbuster drugs will expire in the near future, opening up the doorways for generic production.[1] Brand-name drug companies lose an estimated half of their U.S. sales during the first six months of generic production alone.[2] In an effort to forestall large sales declines, some brand-name pharmaceutical companies are scrambling to delay generic production. One measure brand-name pharmaceutical companies often take to extend their monopolies is patenting additional features of the drug products or purified forms of the drugs.[3] A patent gives a pharmaceutical company the exclusive right to make, use, or sell the patented drug for twenty years.[4] When the patent expires generic companies are free to market the same drug, creating competition in the marketplace and lowering prices.

Although antitrust law prohibits anti-competitive behavior, patents are an exception to the rule against monopolies.[5] Patent holders are given a legally enforceable monopoly for the twenty-year

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[1] National Institute for Health Care Management Issue Brief, *Prescription Drugs and Intellectual Property Protection*, *available at* http://www.nihcm.org (Aug. 2000) (on file with the author) [hereinafter NIHCM Issue Brief].

[2] Gardiner Harris & Chris Adams, *Drug Manufacturers Step Up Legal Attacks That Slow Generics*, WALL ST. J., July 12, 2001, at A1.

[3] *See infra* PART IV for further discussion.

[4] 35 U.S.C. § 154(a)(2) (1994).

[5] Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965) (quoting Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945)). Patents provide great public benefits by encouraging investment in innovation, but patents also provide antitrust concerns. David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD DRUG L.J. 321, 327 (2000).

life of the patent.[6] A patent holder, however, may violate antitrust laws when the patent is used to obtain increased market power beyond that intended by Congress.[7] Despite the perceived conflict between patent and antirust law, the two areas are truly complementary.[8] Both are directed towards the promotion of innovation, enterprise, and competition.[9] Patents provide incentives for pharmaceutical companies to create new drugs because the absence of competition during the patent period allows pharmaceutical companies to charge high prices.[10]

The Federal Trade Commission ("FTC") recently took action against a series of agreements between brand-name pharmaceutical companies and generic manufacturers that sought to use the Hatch-Waxman Act[11] 180-day exclusivity provision to block the entrance of other generic manufacturers into the market.[12] Generic

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[6] Melissa K. Davis, Note and Comment, *Monopolistic Tendencies of Brand-Name Drug Companies In the Pharmaceutical Industry*, 15 J.L. & COM. 357, 361-62 (1995).

[7] DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW: CASES AND MATERIALS 1111 (2d ed. 2001).

[8] Anne K. Bingaman, Address at the Federal Circuit Judicial Conference (transcript), *available at* http: //www.usdoj.gov/atr/public/speeeches/94-06-16.txt (July 15, 1994) (on file with the author).

[9] *Id.*

[10] *ABC NEWS: Bitter Medicine: Pills, Profits and the Public Health*, ABC TELEVISION BROAD., May 29, 2002, LEXIS, News Library, Transcripts File [hereinafter *Bitter Medicine*].

[11] 35 U.S.C. § 156 (2002).

[12] James Langenfeld, *Antitrust: New Economy, New Regime Second Annual Symposium of the American Antitrust Institute: Intellectual Property And Antitrust: Steps Toward Striking A Balance*, 52 CASE W. RES. L. REV. 91, 105 (2001). The FTC recently challenged three agreements between brand-name pharmaceutical companies and generic drug manufacturers where the brand-name company paid the generic manufacturer to delay entry into the market. The Federal Trade Commission, *Prepared Statement Before the Committee On the Judiciary United States Senate, available at* http://www.ftc.gov/os/2001/05/pharmtstmy.htm (May 24, 2001) (on file with the author).

Under the Hatch-Waxman Act, generic manufacturers are given incentive to challenge a patent holder by awarding the first generic manufacturer to submit an Abbreviated New Drug Application (ANDA), a 180-day exclusivity period whereby it is protected from competition by subsequent generic applicants. 21 U.S.C. § 355(j)(5)(B)(iv) (1994). The period does not begin until either the generic manufacturer markets the drug, or when a court renders a decision holding the patent invalid or not infringed. *Id.* Thus, if a brand-name company and the first generic company to file an ANDA settle a patent dispute and enter into an agreement to forestall generic production, other generic manufacturers are prevented from marketing their generic versions indefinitely. The Federal Trade Commission, *Prepared Statement Before the Committee on Commerce, Science, and Transportation United States Senate, available at* http://www.ftc.gov/os/2002/04/pharmtestimony.htm#N_39_ (April 23, 2002) (on file with the author). The Greater Access to Affordable Pharmaceuticals Act (GAAP), however, which was passed in the Senate on July 31, 2002, would amend the Hatch-Waxman Act so that generic and brand-

manufacturers, Congress, and the public have accused brand-name pharmaceutical companies of attempting to forestall generics from entering the market by filing frivolous drug patents, a practice the FTC has recently begun to review.[13]

The pharmaceutical industry is the most profitable industry in the country, with the top ten companies earning more than thirty-seven billion dollars in profits in 2001.[14] Although pharmaceutical companies' earnings are high, one study indicates that it costs an average of eight hundred million dollars to get one new drug to the market.[15] Thus, it is not difficult to see why pharmaceutical companies want to hold on to their monopolies on profit-producing drugs.

This Comment examines patent prosecution tactics used by brand-name pharmaceutical corporations to extend their drug monopolies and discusses whether these tactics rise to the level of antitrust violations. Part I provides an overview of patent law in the pharmaceutical industry and the role of the Hatch-Waxman Act. Part II provides a general overview of antitrust law. Part III describes the patent prosecution tactics used by some brand-name pharmaceutical companies to extend their monopolies. Specifically, Part III.A describes the approach of patenting metabolites[16] created by the

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name companies that enter into agreements to keep the generics off the market, will not prohibit other generic companies from marketing the drug. S. Res. 812, 107th Cong. (2002) (enacted). One of the Act's purposes is "to ensure fair marketplace practices and deter pharmaceutical companies (including generic companies) from engaging in anticompetitive action or actions that tend to unfairly restrain trade." *Id.*

[13] In February 2001, the FTC announced its intention to collect information about brand-name pharmaceutical companies' orange book listings to investigate generic competition development under the Hatch-Waxman Act. Federal Trade Commission Agency Information Collection Activities; Submission for OMB Review; Comment Request, 66 Fed. Reg. 12512 (Feb. 27, 2001). To date no action has been taken against the pharmaceutical industry for frivolous patent listings. *Id.* This study will provide the FTC with information about "concerns that manufacturers of pioneer drugs are listing additional patents shortly before the expiration of previously listed patents . . . ." The Federal Trade Commission, *Prepared Statement Before the Committee on the Judiciary United States Senate, available at* http://www.ftc.gov/os/2001/05/pharmtstmy.htm (May 24, 2001) (on file with the author).

[14] *Bitter Medicine*, *supra* note 10.

[15] *Id.* Tufts University found that it costs $800 million in drug development to get one new drug on the market. *Id.* However, pharmaceutical industry critics argue that the drug companies have yet to reveal any detailed reports of their research costs and that this number is used by the pharmaceutical industry for political purposes. *Id.*

[16] Metabolites are molecules that are formed in the body from the breakdown of an ingested drug. Mylan Pharm., Inc. v. Thompson, 139 F. Supp. 2d 1, 9 (2001).

breakdown of a drug in the body.[17] Part III.B explains the approach of double patenting drugs.[18] Part III.C describes the approach of patenting polymorphic forms of already patented drugs.[19]

This Comment concludes that brand-name pharmaceutical companies are likely to be immune from Sherman Act Section 2 claims under the Noerr-Immunity doctrine, even if their intent was to extend the scope of their monopolies through patent evergreening.[20] This Comment recommends both legislative changes to the Hatch-Waxman Act and the institution of guidelines for listing a patent in the Orange Book.[21] This Comment calls for review of both the protection the Federal Circuit[22] gives patent holders and the Patent and Trademark Office's procedures.

I. PATENT LAW IN THE PHARMACEUTICAL INDUSTRY AND THE HATCH-WAXMAN ACT

For the past twenty years, the pharmaceutical industry has been the most lucrative industry in the United States, due in part to its power to control prices derived from intellectual property protection.[23] Prescription drug sales have increased dramatically in recent years.[24] In 2000, prescription drug expenditures in the United States were over $130 billion, representing an almost twenty percent

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[17] The patenting of metabolites is one method that has been used by some pharmaceutical companies to extend the lives of their exclusivity periods. *Id.*

[18] The practice of double patenting involves obtaining multiple patents on one single compound where the two patents are not distinct. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 967 (2001).

[19] Some drug compounds exist in multiple forms called polymorphs. Pharmaceutical companies have been successful in patenting different polymorphic forms of certain drugs. *See* Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (1997).

[20] Evergreening is the strategy of obtaining additional patents on specific features of a drug product or a purified form of the drug to extend the monopoly on a drug when the patent is close to expiration. NIHCM Issue Brief, *supra* note 1.

[21] The Orange Book, or the Approved Drug Products with Therapeutic Equivalence Evaluations, lists all FDA approved drugs and their related patents. *See* 21 U.S.C. § 355 (1994).

[22] The Court of Appeals for the Federal Circuit (CAFC) was created in 1982 as a forum for patent appeals to reduce patent litigation forum shopping. CHISUM ET AL., *supra* note 6, at 24-25. The court has exclusive jurisdiction over patent appeals set forth under 28 U.S.C. § 1295(a) (1994). *Id.* at 25. The court consists of twelve circuit judges. *Id.* at 26.

[23] NIHCM Issue Brief, *supra* note 1.

[24] National Institute for Health Care Management Research and Educational Foundation, *Prescription Drug Expenditures In 2000: The Upward Trend Continues* (2000), *available at* http://www.nihcm.org (last visited Nov. 1, 2002) (on file with the author).

increase from 1999.[25] In light of this rapid rise in prescription drug expenditures, there is renewed public attention on patent laws, drug regulations, and the tactics employed by brand-name drug companies to forestall generic drug entry into the market.[26]

The United States Constitution Article I, Section 8, Clause 8 authorizes Congress to grant patents.[27] A patent provides a monopoly in an invention for a limited period of time, including the exclusive rights to make, use, and sell the invention.[28] Thus, patents are an exception to the rule against monopolies[29] and to the right to a free and open market.[30] A United States patentee receives a patent for twenty years from the date of filing.[31] Once granted, a patent provides the patent holder with the right to exclude others from using the invention.[32] Anyone who "without authority makes, uses, offers to sell, or sells any patented invention within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."[33]

Patents provide great incentive for brand-name pharmaceutical companies to conduct research because patent rights eliminate competition during the patent period, enabling patent holders to charge a premium for their drugs.[34] Because of the high costs of research and development, the pharmaceutical industry views patents as an especially important form of motivation.[35] Thus, it is advantageous for a pharmaceutical company to obtain as many

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[25] *Id.*

[26] *Id.*

[27] *See* U.S. CONST. art. I, § 8 ("The Congress shall have the power . . . to promote the progress of science and useful arts by securing for times to authors and inventors the exclusive right to their respective writings and discoveries."). The Supreme Court explained the purpose of patents as public franchises given to inventors as compensation for their time and expense in creating new and useful improvements for the benefit of the public. Seymour v. Osborne, 78 U.S. 516, 533 (1870).

[28] Davis, *supra* note 6, at 361-62.

[29] Section 2 of the Sherman Antitrust Act provides that "every person who shall monopolize, or attempt to monopolize . . . shall be deemed guilty of a felony." 15 U.S.C. § 2 (1994).

[30] Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965) (quoting Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945)).

[31] 35 U.S.C. § 154(a)(2) (1994). The patent gives its owner a monopoly on the invention that expires twenty years from the date of the patent application. *Id.*

[32] Special Equip. Co. v. Coe, 324 U.S. 370, 378 (1945).

[33] 35 U.S.C. § 271(a) (1994).

[34] *See* NIHCM, *supra* note 1.

[35] Evan Ackiron, *The Human Genome Initiative and the Impact of Genetic Testing and Screening Technologies: Note and Comment: Patents for Critical Pharmaceuticals: The AZT Case*, 17 AM. J.L. MED. 145, 149 (1991).

patents as possible. Patent holders can obtain numerous patents on a single drug including: formulation, composition, methods of manufacture, and method of use patents.[36] A patent holder may increase the term of its monopoly by filing additional patents at a time later than the original filing.[37]

To obtain a patent, the inventor must file an application with the Patent Office.[38] The applicant must claim that the invention is novel, useful, and nonobvious.[39] Although the patent process is *ex parte*, a patent has a presumption of validity.[40] As a protection, applicants have the duty of absolute candor to the Patent Office and must disclose all material information.[41] Absolute candor requires, however, only that applicants provide the Patent Office with prior art[42] of which they have knowledge.[43] There is no affirmative duty to research and supply additional information.[44] Further, reviews of

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[36] Terry G. Mahn, *Symposium Issue - Striking The Right Balance Between Innovation And Drug Price Competition: Understanding The Hatch-Waxman Act: The Hatch-Waxman Act During Patent Prosecution and Beyond*, 54 FOOD DRUG L.J. 233, 234 (1999).

[37] *See id.* "If there are multiple NCEs [new chemical entities] developed during the drug development stage, the patent strategy should be to file for separate patents for each NCE." *Id.* at 234. New chemical entities include isomers, crystalline forms, metabolites, and polymorphs. *Id.*

[38] 35 U.S.C. §§ 1-376 (1988). The Patent Office has the power to grant patents pursuant to the Patent Act. *Id.* The Patent Office is officially known as the Patent and Trademark Office (PTO).

[39] 35 U.S.C. §§ 101-103 (1988).

[40] 35 U.S.C. § 282 (1988). The only participants in patent prosecution are the applicant and the patent examiner. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1499 (2001).

[41] 35 U.S.C. § 115 (1988).

[42] "Prior art is the set of circumstances set forth in [35 U.S.C. §102] AND NOTHING MORE. Prior art may be an act—an offer for sale, a use, and a prior invention – or it may be a document—a prior foreign patent or publication, or it may be a U.S. patent." PLI'S EXAM FOCUS PATENT BAR REVIEW, STUDY GUIDE (2002) (emphasis in original). 35 U.S.C. section 103 provides that "[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art . . . ." 35 U.S.C. § 103. Section 102 (a), (e), and (g) are the prior art subsections. Application of Bass, 474 F.2d 1276, 1290 (1973). Section 102 provides that "[a] person shall be entitled to a patent unless-(a) the invention was known . . . by others . . . or described in a printed publication . . . before the invention by the applicant, or (e) the invention was described in- (1) an application for patent, or (2) a patent granted on an application for patent" or (g) another inventor establishes that the invention was made by the other inventor. 35 U.S.C. § 102 (1994).

[43] Lemley, *supra* note 40, at 1499-1500. The examiner has the responsibility of reviewing the application and researching the prior art to decide whether the claims in the patent application should be rejected. *Id.*

[44] *Id.*

patent applications are not extensive.[45] The examiner only spends an average total of eighteen hours over the course of the two to three year prosecution of each application.[46] As such, examiners often overlook the most relevant prior art.[47] The result is that many of the patents issued would have been rejected if given greater review.[48] Further, a large percentage of patents that are eventually litigated to judgment are invalidated.[49]

Pharmaceutical research typically involves years of experiments in human cell models and in animals prior to human experimentation.[50] If this extensive preclinical research is successful, the company files an Investigational New Drug application ("IND") with the Food and Drug Administration ("FDA") requesting approval to initiate human experiments.[51] Pharmaceutical companies generally file patents during preclinical testing[52] of the drug, prior to the filing of an IND with the FDA.[53] If the company deems a drug to be safe and efficacious after clinical trials, a New Drug Application (NDA) is filed with the FDA requesting approval to market the drug.[54] The NDA must contain the drug's safety and effectiveness data, information on the manufacturing process; and information on packaging, labeling and marketing of the drug.[55] The NDA must also include a list of all the patents covering the pioneer drug that might be infringed if a generic drug was marketed prior to the patent

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[45] *Id.* at 1500.

[46] *Id.*

[47] *Id.* at 1528.

[48] Lemley, *supra* note 40, at 1528. A more comprehensive examination process might deter the filing of some frivolous applications because of the increased likelihood that it would be rejected. *Id.* at 1508.

[49] John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AM. INTELL. PROP. L. ASS'N Q.J. 185, 205 (1998).

[50] William M. Brown, *A "Highly Artificial Act of Infringement," Indeed, But It Can Still Cost You Attorneys' Fees . . . Comment on* Yamanouchi v. Danbury, 33 UWLA L. REV. 117, 124 (2001).

[51] Gerald J. Mossinghoff, *Symposium Issue - Striking The Right Balance Between Innovation And Drug Price Competition: Understanding the Hatch-Waxman Act: Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD DRUG L.J. 187, 192 (1999).

[52] Preclinical testing involves assessing a drug's potential utility in animal models and in vitro assays. Brown, *supra* note 50, at 125. If the drug is determined to be safe and efficacious during preclinical testing the drug is then tested in humans. *Id.* Testing in humans is called clinical trials. *Id.* If testing in humans shows the drug is safe and efficacious, a new drug application is made to the FDA. *Id.*

[53] Mossinghoff, *supra* note 51, at 192.

[54] Brown, *supra* note 50, at 125.

[55] 21 U.S.C. § 355(b), (c)(2) (1994).

expiration.[56] If the FDA approves the NDA, all the patents on the drug that are listed in the NDA will be published in the Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.[57] The FDA does not make an independent determination as to whether the patents listed in the NDA actually cover the pioneer drug, but instead relies on a signed declaration from the applicant.[58]

Generally, the patent is issued years before FDA approval of the drug.[59] However, under the Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Act Amendments to the Federal Food Drug and Cosmetic Act, the patent holder can apply for an extension on the patent term to regain time that was lost in regulatory review of the drug.[60]

Generic companies duplicate pioneer prescription drugs by using the same active ingredients found in the pioneer drugs but with different inactive ingredients.[61] The Hatch-Waxman Act governs FDA approval of generic drugs.[62] If the generic drug is the bioequivalent[63]

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[56] Brown, *supra* note 50, at 125.

[57] 21 C.F.R. § 314.53(b) (1994). The Approved Drug Products with Therapeutic Equivalence Evaluations is commonly known as the Orange Book. It lists all FDA approved drugs and their related patents. 21 U.S.C. § 355(j)(7)(A)(iii) (1994). The FDA obtains this information from the NDA applicant. 21 U.S.C. § 355(b)(1) (1994).

[58] Brown, *supra* note 50, at 125-26. The FDA lists almost any patent submitted with the NDA in the Orange Book. It avoids patent disputes and does not change the listings in the Orange Book for patents in dispute. 21 C.F.R. § 314 (1994).

[59] Mossinghoff, *supra* note 51, at 192.

[60] 35 U.S.C. § 156 (1984) [hereinafter the Hatch-Waxman Act or "the Act"].

[61] United States v. Generix Drug Corp., 460 U.S. 453, 454-55 (1983).

[62] 21 U.S.C. § 355 (j)(2)(A)(vii) (1994).

[63] Bioequivalence is defined as "the absence of significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. § 320.1(e) (1994). When two compounds act on the body with the same strength and similar bioavailability they are bioequivalents. *See* THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed. 2000), *available at* http://www.dictionary.com/search?q=bioequivalent&r=67 (on file with the author). Thus, bioequivalent drug products are "pharmaceutical equivalent or pharmaceutical alternative products that display comparable bioavailability when studied under similar experimental conditions." U.S. Food and Drug Administration Center for Drug Evaluation and Research, *Food and Drug Administration Center for Drug Evaluation and Research Approved Drug Products with Therapeutic Equivalence Evaluations Preface*, *available at* http://www.fda.gov/cder/ob/docs/preface/ecpreface.htm (last visited February 12, 2002) (on file with the author). Bioavailability is a measure of the compounds potential for entry into the human receptor. Danny D. Reible, *Definition of Bioavailability*, *available at* http://www.hsrc.org/hsrc/html/ssw/bioavailability.pdf (on file with the author).

of the approved drug, generic applicants are required only to submit an Abbreviated New Drug Application ("ANDA") that relies on the FDA's findings of safety and efficacy of the pioneer drug.[64] This enables generic applicants to forego expensive clinical testing.[65]

The generic applicant must provide a patent certification upon submission of an ANDA certifying that (i) there are no patents on the drug, (ii) the patent expired, (iii) the patent will expire prior to the date on which the generic drug will be marketed, or (iv) the patent is invalid or will not be infringed by the generic version.[66] The applicant must submit this certification for each patent on the pioneer drug that is listed in the Orange Book.[67] Thus, under the Act, generic companies may seek approval of patented drugs prior to their patent expirations if one of the following conditions is met: 1) they are certifying that the patent will expire prior to the sale of the generic drug, 2) the patent is invalid, or 3) the patent will not be infringed by generic manufacture.[68] Submitting a generic application for a drug claimed in a patent, however, is itself an act of patent infringement.[69]

Paragraph IV certification[70] requests immediate FDA approval of the ANDA prior to the expiration of a listed patent, and therefore, constitutes infringement.[71] The generic company filing an ANDA containing paragraph IV certification must notify the patent holder

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[64] 21 U.S.C. § 355 (j)(2)(A)(vii) (1994).

[65] *Id.*

[66] *Id.*

[67] Brown, *supra* note 50, at 129-30.

[68] 21 U.S.C. § 355(j) (1994). The Hatch-Waxman Act not only allows a generic company to file an ANDA prior to expiration of the pioneer drug patents, but it encourages generic companies to challenge pioneer patents by providing a 180-day exclusivity period to the first generic manufacturer. 21 U.S.C. § 355(j)(5)(B)(iv) (1994).

[69] 35 U.S.C. § 271(e)(2) (1994).

[70] Paragraph IV certification provides that the pioneer drug "patent is invalid or will not be infringed by generic manufacture, use or sale of the drug." 21 U.S.C. § 355(j)(2)(A)(vii) (1994).

[71] Brown, *supra* note 50, at 130. "It shall be an act of infringement to submit an application under . . . the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent, . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C.A. § 271(e)(2)(A) (West 1994); *see also* Yamanouchi v. Danbury, 231 F.3d 1339, 1346 (Fed. Cir. 2000) (explaining that a generic company's submission of an ANDA constitutes an act of infringement when the purpose of the submission is to get approval to market or manufacture the pioneer drug).

of its request.[72] The patent holder may bring an infringement suit against the generic manufacturer based on the filing of the ANDA.[73] If the action is brought within a forty-five day period the Hatch-Waxman Act requires that the FDA halt approval of the ANDA until the earlier of either the passage of thirty months or the successful resolution of the patent infringement suit.[74]

The Hatch-Waxman Act provides incentive for generic companies to challenge a patent holder by awarding the first generic manufacturer to submit an ANDA a 180-day exclusivity period whereby it is protected from competition by subsequent generic applicants.[75] This period begins either on the day the applicant commercially markets the drug or on the day a decision of a court is rendered holding the patent invalid or not infringed, whichever is earlier.[76]

Some brand-name pharmaceutical companies have manipulated the Hatch-Waxman Act to delay generic production.[77] Although the Act requires NDA applicants to list in the Orange Book all patents for an approved drug product that might be infringed upon by a generic company marketing the drug, it provides no mechanism for regulating the patents that are listed.[78] When an ANDA applicant files paragraph IV certification claiming a listed patent to be invalid, a brand-name patent owner can automatically delay approval of the ANDA for thirty months simply by instituting an infringement action against the generic ANDA filer.[79] Furthermore, the Hatch-Waxman

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[72] 21 U.S.C. § 355(j)(2)(A)(vii) (1994).

[73] 35 U.S.C. § 271 (e)(2) (1994). A patent holder has an automatic cause of action for infringement when a generic manufacturer certifies that a patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(ii) (1994).

[74] 21 U.S.C. § 355(j)(2)(A)(vii) (1994). Under the GAAP, however, only the alleged infringement of patents that are listed within thirty days of the time of approval of the brand-name drug will trigger an automatic thirty-month stay of the generic. S. Res. 812, 107th Cong. (2002) (enacted). Brand-name companies will have to obtain court ordered preliminary injunctions to delay generic approval of any patents listed after the thirty-day period. *Id.*

[75] 21 U.S.C. § 355(j)(5)(B)(iv) (1994). Under the GAAP, however, if a generic and a brand-name company contract to keep the generic off the market, other generic companies will not be prevented from bringing their generic versions to the market. S. Res. 812, 107th Cong. (2002) (enacted).

[76] 21 U.S.C. § 355(j)(5)(B)(iv)(I)-(II) (1994).

[77] Alfred B. Engelberg, *Special Patent Provisions For Pharmaceuticals: Have They Outlived Their Usefulness? A Political, Legislative And Legal History of U.S. Law And Observations For The Future*, 39 J.L. & TECH. 389, 415 (1999).

[78] *Id.* at 414-15. However, under the GAAP generic companies can seek the de-listing of frivolous patents, but listings are not otherwise regulated. S. Res. 812, 107th Cong. (2002) (enacted).

[79] Engelberg, *supra* note 77, at 414-15.

Act even allows for the NDA holder to receive this automatic thirty-month stay of generic approval if they list a patent on the eve of ANDA approval.[80] "Not surprisingly, the opportunity to extend market exclusivity by merely listing a patent in the Orange Book . . . encouraged brand-name drug companies to seek, obtain, and, ultimately list a great variety of patents of little scope or merit except for their ability to delay legitimate competition."[81]

The FDA approved nearly 900 new drug applications during the 1990s.[82] Approximately one third of those were for new molecular entities,[83] while about one half were merely for new formulations or new combinations of already approved active ingredients.[84] Moreover, most approved drug products have more than one corresponding patent listed in the Orange Book and some have as many as five or six listed patents.[85]

These efforts by the pharmaceutical giants to use patents to stop generic production are successful regardless of the ultimate outcome because, each time an action is filed, the generic version is delayed.[86]

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[80] *Id.*; *see also* Mylan Pharm., Inc. v. Thompson, 139 F. Supp. 2d 1, 16 (2001) (noting that merely twelve hours before Bristol-Myers Squibb's patent on the administration of buspirone to treat anxiety disorders was to expire, the PTO issued Bristol-Myers Squibb a patent on the method of use of a metabolite produced by the administration of buspirone which the FDA listed in the Orange Book). *See generally infra* PART III. Under the GAAP brand-name pharmaceutical companies can only receive an automatic thirty-month stay for patents listed within thirty days of approval of the brand-name drug. S. Res. 812, 107th Cong. (2002) (enacted). Any late listed patents can only be used to delay generics by receiving a preliminary injunction from a court. *Id.*

[81] Engelberg, *supra* note 77, at 415.

[82] *See* NIHCM Issue Brief, *supra* note 1.

[83] New Molecular Entities are compounds never sold before in the US. *Id.*

[84] *Id.*

[85] Engelberg, *supra* note 77, at 415.

[86] *See* The Federal Trade Commission, *Prepared Statement Before the Committee on Commerce, Science, and Transportation United States Senate, available at* http://www.ftc.gov/os/2002/04/pharmtestimony.htm#N_39_ (April 23, 2002) (on file with the author). Under the Hatch-Waxman Act when a brand-name company brings an infringement suit against a generic company, it is automatically granted a thirty-month stay during which the generic is prohibited from going to market until the infringement issue is resolved in the generic company's favor. *Id.* However, if the GAAP passes in the House and is signed into law by President Bush, then this automatic thirty-month stay will only be available for patents listed in the Orange Book within thirty days after approval of the brand-name drug. S. Res. 812, 107th Cong. (2002) (enacted). Nevertheless, brand-name companies can still delay generic production under the GAAP by alleging patent infringement for patents listed in the Orange Book more than thirty days after the brand-name drug is approved by obtaining a preliminary injunction. *Id.* Any delay in generic production is likely to be profitable for the brand-name company. *See* Steve Seidenberg, *The Battle Over Drug Patents*, 24 NAT'L. L.J. 43 (2002), *available at* http://www.nlj.com/special/

Even if pioneer companies just delay generic production, as opposed to keeping generics off the market by a finding of patent validity, they have achieved a monopoly for that extended period.

II. OVERVIEW OF ANTITRUST LAW

Patents alone do not turn patentees into prohibited monopolists.[87] Nonetheless, patent holders are not immune from antitrust liability.[88] The improper exercise of patent rights can result in antitrust violations.[89]

A. Basis for an Antitrust Claim and Standing to Bring an Action

Section 2 of the Sherman Act prohibits monopolization, attempts to monopolize, and conspiracies to monopolize.[90] To state a claim for monopolizing under Section 2, a plaintiff must show "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[91] The relevant market includes both the product market and the geographic market.[92] To demonstrate attempted monopolization a plaintiff must show "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous

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071502patents.shtml (last visited Nov. 1, 2002)(on file with the author). For instance, while Bristol-Myers Squibb delayed the generic sales of Buspirone through the patent infringement suit, the company earned an estimated two million dollars a day in sales. *Id.*

[87] Abbot v. Brennan, 952 F.2d 1346, 1354 (Fed. Cir. 1991). Professor Edmund Kitch argues that it is a common misconception that patents lead to an economic monopoly. Edmund W. Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, 53 VAND. L. REV. 1727, 1730 (2000). Kitch suggests that the literature has often stated patents confer an economic monopoly on their owners, but that this is only a true statement if the patent claims cover the entire relevant market. *Id.*

[88] CHISUM ET AL., *supra* note 7, at 1111.

[89] *Id.* For instance, an antitrust violation can occur when a patentee knowingly uses fraud to obtain a patent and subsequently brings a claim for infringement of the fraudulently procured patent. Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965). Another example of when a patent holder may violate antitrust laws is when the patentee brings an infringement suit that is a "sham" to interfere with a competitor's business. Eastern R.R. Presidents Conference v. Noerr Motor Freights, Inc., 365 U.S. 127, 144 (1961).

[90] 15 U.S.C. § 2 (2002).

[91] United States v. Grinell Corp., 384 U.S. 563, 570-71 (1966).

[92] *Id.* at 571. In patent cases the geographic market is nationwide. *Id.* The determination of the product market depends on the ability of consumers to obtain substitute products. *Id.*

possibility of achieving monopoly power."[93] Monopoly power is defined as "the power to control prices or exclude competition."[94] A majority market share may imply the existence of monopoly power.[95]

Under Section 4 of the Clayton Act[96], private plaintiffs injured in business by violation of antitrust laws have standing to bring an antitrust action.[97] The Federal Circuit approved the following criteria to determine whether a claimant possesses antitrust standing:

> (1) whether there is a causal connection between an antitrust violationand harm to the plaintiff and the defendants intended to cause that harm;(2) whether the nature of the plaintiff's alleged injury was of the typethe antitrust laws were intended to forestall; (3) the directness or indirectness of the asserted injury; (4) whether the claim rests on some abstract or speculative measure of harm; and (5) the strong interest in keeping the scope of complex antitrust trials within judicially manageable limits, avoiding both duplicative recoveries and the complex apportionment of damages.[98]

Generic companies have succeeded in asserting these antitrust violations. When the manufacturer of a generic form of Paclitaxel[99] filed an ANDA, Bristol-Myers Squibb, the brand-name pharmaceutical company, brought suit for patent infringement.[100] The generic manufacturer then filed an antitrust action against Bristol-Myers Squibb.[101] The United States District Court for the District of New Jersey concluded that the generic manufacturer had "standing to bring their Sherman Act claims."[102] The court found that Bristol-Myers Squibb's infringement litigation caused the generic manufacturer's injuries by preventing the generic manufacturer from obtaining FDA approval of its generic paclitaxel.[103]

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[93] Spectrum Sports, Inc., v. McQuillan, 506 U.S. 447, 456 (9th Cir. 1993) (holding that the defendant patent holders were not liable for attempted monopolization because there was no proof of a dangerous probability that defendants would monopolize a particular market and no evidence of defendants' specific intent to monopolize).

[94] *Grinnel*, 384 U.S. at 571 (quoting United States v. Du Pont & Co., 351 U.S. 377, 391 (1956)).

[95] *Id.*

[96] 15 U.S.C. §§ 12-19, 21-27; *see also* 29 U.S.C. §§ 52-53 (2002).

[97] 15 U.S.C. § 15(a) (2002).

[98] Bristol-Myers Squibb Co. v. Ben Venue Labs., 90 F. Supp. 2d 540, 543 (2000).

[99] Paclitaxel is a drug used to treat cancer. *Id.* at 541.

[100] *Bristol-Myers Squibb Co.*, 90 F. Supp. 2d at 546.

[101] *Id.*

[102] *Id.*

[103] *Id.* at 544-45.

B. Noerr-Pennington Immunity and the Exceptions

Even though a plaintiff may have standing to allege an antitrust violation, a defendant may be protected from suit by the First Amendment guarantees to the right to petition for legislative, executive, administrative or judicial action.[104] Thus, where the alleged anticompetitive conduct arises from the initiation of an infringement action, a form of petitioning, the First Amendment and antitrust laws collide.[105] The Supreme Court first articulated the protection from antitrust liability for anticompetitive activity that results from exercising the right to petition in *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*,[106] and *United Mine Workers v. Pennington*.[107] The protection is known as Noerr-Pennington immunity.[108]

In *Eastern Railroad Presidents Conference,* the Supreme Court considered whether the Sherman Act applied to the railroads' effort to influence legislation.[109] The railroads were campaigning for state laws for truck weight limits.[110] The truckers alleged that the railroads "had conspired to restrain trade in and monopolize the freight business in violation of §§ 1 and 2 of the Sherman Act."[111] The Court found that even if the railroads' intent was to monopolize the market, there was no violation of the Sherman Act because the action of petitioning the government is lawful.[112] The Court stated that to find otherwise would deprive the public of the right to petition the government for matters in which they are interested.[113] The Court held that the Sherman Act is not applicable to activities that are limited to soliciting the government because the right to petition the government is a right granted by the Constitution.[114] Noting that

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[104] U.S. CONST. amend. I.

[105] Raymond Ku, *Antittrust Immunity, The First Amendment and Settlements: Defining the Boundaries of the Right to Petition*, 33 IND. L. REV. 385, 385-86 (2000) (arguing that the right to petition is not sufficient to justify antitrust immunity).

[106] 365 U.S. 127 (1961).

[107] 381 U.S. 657 (1965).

[108] *See Eastern R.R. Presidents Conference*, 365 U.S. 127; *see also United Mine Workers*, 381 U.S. 657.

[109] *Eastern R.R. Presidents Conference*, 365 U.S. at 129.

[110] *Id.* at 131.

[111] *Id.* at 129.

[112] *Id.* at 139.

[113] *Id.*

[114] *Eastern R.R. Presidents Conference*, 365 U.S. at 145. The Noerr-Pennington doctrine was articulated in *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). The First Amendment grants citizens the right to petition the government and the

such political activity provides the government with valuable information in a democratic society, the Court held that the Sherman Act could not be used as a means for retaliatory antitrust lawsuits filed in response to citizens petitioning the government.[115] The Court, however, carved out an exception to antitrust immunity, stating that application of the Sherman Act to a petitioning situation that is merely an attempt to interfere with a competitor's business would be justified.[116]

Four years later in *United Mine Workers*, the Supreme Court extended antitrust immunity from petitioning the legislature to lobbying the executive branch.[117] Large coal miners and the United Mine Workers persuaded the Secretary of Labor to raise the minimum wage and convinced the Tennessee Valley Authority to purchase coal only from miners paying the higher wage.[118] The Court stated, "[j]oint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition. Such conduct is not illegal, either standing alone or as part of a broader scheme violative of the Sherman Act."[119] Thus, even if the sole intent is to eliminate competition, there is no Sherman Act violation because the act of petitioning the executive branch is immunized.

Furthermore, in *California Motor Transport Co. v. Trucking Unlimited*,[120] the Supreme Court held that the Sherman Act could not be construed to limit access to the courts.[121] California intrastate truckers tried to acquire operating rights while the interstate truckers instituted state and federal procedures before the Interstate Commerce Commission to prevent the acquisition of those rights.[122] Explaining that the right to petition extends to all three branches of government, the Court extended the Noerr-Pennington immunity doctrine to actions that involve petitioning the courts and administrative agencies.[123] The Court noted, however, the exception carved out in *Eastern Railroad Presidents Conference* making the doctrine

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Sherman Act should not restrict this right. *Eastern R.R. Presidents Conference*, 365 U.S. at 137-38. However, there is an exception for sham petitioning. *Id.* at 144.

[115] *Eastern R.R. Presidents Conference*, 365 U.S. at 137-38.

[116] *Id.* at 144.

[117] *Mine Workers*, 381 U.S. at 657.

[118] *Id.* at 660-61.

[119] *Id.* at 670.

[120] 404 U.S. 508 (1972).

[121] *Id.* Noerr-Pennington immunity extends to petitioning activity before administrative agencies and the courts. *Id.* at 510-11.

[122] *Id.* at 509.

[123] *Id.* at 510.

inapplicable to litigation "that is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor."[124] The Court concluded that "illegal and reprehensible practice which may corrupt the administrative or judicial processes" would not fall "under the umbrella of 'political expression.'"[125]

1. The Sham Litigation Exception

In *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*,[126] the Supreme Court defined the sham exception to Noerr-Pennington immunity.[127] To show that the lawsuit is a sham, the antitrust plaintiff must demonstrate that the "lawsuit [is] objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" and that the lawsuit was initiated with bad faith to interfere directly with the business relationships of a competitor.[128] The Court stated that the economic motivation behind bringing the suit was irrelevant because the suit was objectively reasonable.[129] Thus, if it is shown that the suit is not objectively baseless, the defendant's motivation is immaterial even if the motivation is to monopolize the market.[130]

2. The Walker Process Fraud Exception

Another exception to Noerr-Pennington immunity exists when a party knowingly and willfully makes fraudulent representations to the government.[131] In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*,[132] the issue was whether "maintenance and enforcement of a patent obtained by fraud on the Patent Office may be the basis of an action under Section 2 of the Sherman Act."[133] The

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[124] *Id.* at 511 (quoting *Eastern R.R. Presidents Conference*, 365 U.S. at 144).

[125] *California Motor Transport*, 404 U.S. at 513.

[126] 508 U.S. 49 (1993).

[127] *Id.*

[128] *Id.* at 60-61. Proof of sham litigation deprives the antirust defendant of Noerr-Pennington immunity. *Id.* at 61. The plaintiff still has the burden of establishing the other elements of the antitrust claim. *Id.*

[129] *Id.* at 65-66.

[130] Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1072 (Fed. Cir. 1998).

[131] *Walker Process Equip., Inc.,* 382 U.S. at 174-78. The Supreme Court held that a party that had engaged in alleged antitrust violations through a patent infringement suit based on a patent obtained through fraud was not protected from antitrust liability by Noerr-Pennington immunity. *Id.*

[132] *Id.*

[133] *Id.* at 173.

Supreme Court stated that if it were proved that Food Machinery obtained their patent through "knowing and willful misrepresentations to the Patent Office," they would be subject to antitrust claims and the shield of Noerr-Pennington immunity would not longer protect them.[134] Conversely, evidence of Food Machinery's good faith would serve as a complete defense to the antitrust claim.[135]

Thus, inappropriate use of patent rights can result in the violation of antitrust laws.[136] Patent misuse occurs when a patent holder leverages his patent to obtain greater market power than intended by grant of the patent.[137] In *Walker Process Equipment, Inc.*, the Supreme Court established that engaging in patent misuse and obtaining a patent by fraud is a violation under Section 2.[138] Patent misuse occurs when a patent holder brings a suit for the infringement of a patent that was knowingly obtained fraudulently.[139]

In *Bristol-Myers Squibb Co. v. Ben Venue Laboratories*,[140] the District Court of New Jersey stated that "antitrust liability under Section 2 of the Sherman Act may arise when a patent has been procured by knowing and willful fraud, the patentee has market power in the relevant market, and has used its fraudulently obtained patent to restrain competition."[141] Thus, to state a claim for *Walker Process* fraud, the generic company must show that the brand-name patentee "1) knowingly and willfully made a fraudulent omission or misrepresentation; 2) with clear intent to deceive the patent examiner; [and] 3) the patent would not have issued but for the misrepresentation or omission."[142]

In *Nobelpharma AB v. Implant Innovations*,[143] the United States Court of Appeals for the Federal Circuit held "that whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of

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[134] *Id.* at 177.

[135] *Id.*

[136] CHISUM ET AL., *supra* note 7, at 1111.

[137] RICHARD RAYSMAN ET AL., INTELLECTUAL PROPERTY LICENSING: FORMS AND ANALYSIS § 6.03(4) (2001).

[138] 382 U.S. 172, 177-78 (1965). The Court held that a party, who monopolizes the market through a patent infringement suit based on a patent that had been obtained through fraudulent representations to the Patent Office, could violate § 2 of the Sherman Act if all the elements necessary to satisfy the statute were present. *Id.* at 174-78.

[139] *Walker Process Equip., Inc.*, 382 U.S. at 177-78.

[140] 90 F. Supp. 2d 540 (D.N.J. 2000).

[141] *Id.* at 542 (quoting C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1367 (Fed. Cir. 1998)).

[142] *Bristol-Myers Squibb Co.*, 90 F. Supp. 2d at 542.

[143] 141 F.3d 1059 (1998).

its immunity from the antitrust laws is to be decided as a question of Federal Circuit law."[144] The court in *Nobelpharma AB* distinguished between inequitable conduct and *Walker Process* fraud.[145] *Walker Process* fraud requires a showing that there was a clear intent to deceive the patent examiner, and without such misrepresentation, the patent would not have issued.[146] Inequitable conduct, however, is lesser misconduct that serves as a defense to a patent infringement claim but does not expose the patent holder to antitrust liability.[147] "[*W*]*alker Process* antitrust liability is based on the knowing assertion of a patent procured by fraud on the [Patent and Trademark Office (PTO)]. [It is] very specific conduct that is clearly reprehensible."[148] To prove *Walker Process* fraud there must be evidence of "a clear intent to deceive the examiner and thereby cause the PTO to grant an invalid patent."[149]

Thus, a patent holder can lose Noerr-Pennington immunity, and be subject to antitrust liability in two ways.[150] First, if the patent was procured through knowing and willful fraud, and if the patent infringement plaintiff was aware of the fraud when bringing the suit, the patent holder will be striped of immunity.[151] Second, "if the patent infringement suit was a mere sham . . . namely that it was objectively baseless and subjectively motivated by a desire to impose collateral, anti-competitive injury rather than to obtain a justifiable legal remedy" the patent infringement plaintiff will lose Noerr-Pennington immunity.[152]

III. PATENT PROSECUTION TACTICS USED TO EXTEND DRUG MONOPOLIES

By 2005, patents will expire on brand-name prescription drugs

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[144] *Id.* at 1068.
[145] *Id.* at 1069.
[146] *Id.* at 1071.
[147] *Id.* at 1070.
[148] *Id.* at 1071.
[149] *Nobelpharma AB*, 141 F.3d at 1070.
[150] *In re: Buspirone Antitrust Litig.*, 185 F. Supp. 2d at 369.
[151] *Id.*
[152] *Id.*

with combined U.S. sales of approximately $20 billion.[153] In order to protect these profits, brand-name pharmaceutical companies have been using patent law to extend their monopolies.[154] For example, companies have sought patents on the purified forms of drugs obtained through manipulation of the compound's molecular structure.[155] This strategy of obtaining additional patents on specific features of a drug product, or a purified form of the drug, to extend the monopoly on a drug when the original patent is close to expiration is called "evergreening."[156]

"One [tactic] that has attracted increasing attention is the development of 'cleaned-up' versions of old drugs, called single isomers."[157] Often drugs exist in both active and inactive forms, and the elimination of the inactive component may increase a drug's potency or reduce side effects.[158] With a new patent on the single isomer form of a drug and large-scale advertising campaigns promoting the advantages of the new version, brand-name companies can lessen profit losses due to generic production of the old drug.[159] The FTC reviewed Eli-Lilly's introduction of the single isomer version of Prozac, Prozac Jr., without finding any antitrust violations.[160]

Generic companies, consumers, and the media have accused pharmaceutical companies of filing frivolous patents in order to prolong litigation.[161] Under current drug-patent law, the FDA must halt generic approval for thirty months when there is a patent

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[153] NIHCM Issue Brief, s*upra* note 1.

[154] Davis, *supra* note 6, at 357.

[155] NIHCM Issue Brief, *supra* note 1.

[156] *Id.*

[157] David Pilling & Richard Wolffee, *Drug Abuses: As Pharmaceutical companies go to extraordinary lengths to protect expiring patents, regulators are starting to pay close attention*, FINANCIAL TIMES, April 20, 2000, *available at* http://globalarchive.ft.com/gl. . ./article.html?id=000420000245&query= pharmaceutical+patent (on file with the author).

[158] *Id.*

[159] *Id.*

[160] *Id.* Sepracore, a company that develops Improved Chemical Entities (ICE) to help brand-name pharmaceutical companies battle generic manufactures, developed a single isomer form of Prozac. Brian Graney, *Score One for Sepracore*, *at* http://www.fool.com/news/2000/sepr000413.htm (April 13, 2000) (on file with the author). Prozac Jr., (R)–fluoxetine, is a single isomer form of Prozac that is more effective and has less side effects. *Id.* Sepracore developed and patented (R)-fluoxetine and licensed it to Eli Lily. *Id.* Instead of completely losing their market share to generic manufacturers, Lily can use (R)-fluoxetine to segment the market. *Id.* The FTC closed its investigation of Prozac Jr., finding that the introduction of the ICE is not anticompetitive. *Id.*

[161] Pilling & Wolffee, *supra* note 157. Some patents accused of being frivolous have included patents on innovation in the shape or color of the pill. *Id.*

dispute.[162] Thus, a brand-name pharmaceutical company may obtain a "frivolous" patent on some part of drug production, drug storage, packaging, administration of the drug, or action in the body to delay generic drug production and gain extensions on their monopolies.[163]

A. Metabolite Patent

"A metabolite is a new molecule that is created after an existing pharmaceutical agent breaks down in the body."[164] Some pharmaceutical companies have attempted to extend their patent protection on certain brand-name drugs by patenting the metabolite of the drug. However, in *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*,[165] the Court of Appeals for the Federal Circuit concluded that a patent on a drug's metabolite does not claim the drug itself.[166] The claim of the patent defines the invention and thus the patent owner's property rights.[167] Merely claiming the drug's metabolite, a chemically distinct compound, does not claim the actual drug product.[168] Therefore, the patent for the drug's metabolite is not necessarily a patent for the actual drug.

In a remarkable attempt to delay generic production, Bristol-Myers Squibb received a patent on the metabolite produced by the breakdown of their anti-anxiety drug, BuSpar®, one day before the patent on the active ingredient expired.[169] Under the current Hatch-

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[162] 21 U.S.C. § 355(j)(2)(A)(vii) (1994).

[163] Robert Langreth & Victoria Murphy, *Perennial Patents*, FORBES, Apr. 2, 2001, *available at* http://www.forbes.com/forbes/2001/0402/052_print.html (on file with the author). For example, Pfizer obtained a new patent on Neurontin, a popular epilepsy drug, whose patent expired in 2000. *Id.* The new patent is for "a way to formulate the drug to prevent degradation." *Id.* While courts determine the validity of the new patent, analysts estimate Pfizer will gain another $1.5 billion in Neurontin sales. *Id.*

[164] Mylan Pharm., Inc. v. Thompson, 139 F. Supp. 2d 1, 9 n.6 (2001).

[165] 109 F.3d 756 (Fed. Cir. 1997).

[166] *See id.* Hoechst's patent claimed "1-hydroxy-tacrine and a method of treating patients in need of memory enhancement." *Id.* at 757. 1-hydroxy-tacrine is the metabolite formed by the break down of tacrine hydrocholoride. *Id.* The patent did not, however, claim tacrine hydrochloride, the active ingredient in a drug used to treat Alzheimer's disease. *Id.* The court noted that Hoechst might be entitled to exclude others from administering tacrine hydrocholoride to patients because tacrine hydrochloride is metabolized into 1-hydroxy-tacrine in the body. *Id.* at 759. *See* Zenith Labs v. Bristol-Myers Squibb, 19 F.3d 1418, 1422 (Fed. Cir. 1994) (indicating that patent infringement may arise if the administered drug is metabolized in vivo into the patented product).

[167] *Hoechst-Roussel Pharm., Inc.*, 109 F.3d at 759.

[168] *See id.*

[169] Langreth & Murphy, *supra* note 163.

Waxman scheme,[170] FDA approval of the generic production of BuSpar® was put on hold until it could be determined whether the patent was valid and whether generic production would produce the metabolite.[171] Bristol-Myers Squibb argued that ingestion of a generic would produce the metabolite.[172]

Bristol-Myers Squibb first patented buspirone,[173] the active ingredient in BuSpar® for the treatment of anxiety in 1980.[174] Because FDA approval was not granted until 1986, Bristol-Myers Squibb received a two-year patent term extension, and thus, their patent was set to expire in 2000.[175] Mylan Pharmaceuticals (Mylan) submitted an ANDA to market a generic buspirone under paragraph III certification,[176] stating that it would not market the generic until Bristol-Myers Squibb's patent expired.[177] It was "tentatively approved" with final approval contingent on expiration of the patent.[178] Bristol-Myers Squibb, however, obtained another patent on BuSpar® on the last day of the patent term.[179] Due to the new patent, Mylan could not receive final approval to market its generic buspirone.[180] Bristol-Myers Squibb indicated to the FDA that the new patent was "a method of use patent."[181]

Mylan argued that the patent was improperly listed in the Orange Book because the patent did not '"claim the drug' or a 'method of using' the drug for which Bristol had obtained FDA approval," and that the patent did not meet the requirement that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of

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[170] If the GAAP was enacted into law Bristol-Myers Squibb would not receive an automatic thirty month stay for its late listed patent, but would have to seek a court ordered preliminary injunction to halt distribution of the generic. S. Res. 812, 107th Cong. (2002) (enacted).

[171] *Mylan Pharm, Inc.*, 139 F. Supp. 2d at 9.

[172] *Id.*

[173] Buspirone is the active ingredient of Bristol-Myers Squibb's brand-name drug BuSpar®, a medication used to treat generalized anxiety disorder. *Id.* at 7.

[174] *Id.*

[175] *Id.* at 7-8.

[176] Under the Hatch-Waxman Act generic applicants must certify that they are not infringing any patents by submitting an ANDA. 21 U.S.C. § 355(b)(2)(A)(iii) (1994). Under paragraph III certification, the generic ANDA applicant states that the patent(s) listed for the pioneer drug will expire on a specific date. *Id.*

[177] *Mylan Pharm., Inc.*, 139 F. Supp. 2d at 8-9.

[178] *Id.* at 9.

[179] *Id.*

[180] *Id.*

[181] *Id.* In a press release Bristol-Myers Squibb stated, "the [new] patent covers 'a method of use of a metabolite produced by the administration of buspirone.'" *Id.*

the drug."[182] Subsequently, the court enjoined Bristol-Myers Squibb to request that the FDA de-list the metabolite patent from the Orange Book, and the FDA was ordered to approve Mylan's ANDA for the generic BuSpar®.[183]

In response to Bristol-Myers Squibb's action, Mylan and various other generic drug makers and purchasers of buspirone brought suit against Bristol-Myers Squibb claiming anticompetitive conduct related to the use and sale of buspirone.[184] In the consolidated multidistrict litigation, Bristol-Myers Squibb moved to dismiss all of the antitrust claims.[185] Bristol-Myers Squibb argued that its actions in listing of the buspirone metabolite patent in the Orange Book and bringing the subsequent patent infringement suits against the generic manufacturers of buspirone were protected from Sherman Act claims under the Noerr-Pennington doctrine.[186] The court found that Noerr-Pennington immunity did not apply to the listing of the buspirone patent in the Orange Book because it is not an act of petitioning the government.[187] Because the FDA is required to publish submitted patent information, and thus the "FDA's actions are non-discretionary and do not reflect any decision as to the validity of the representations in an Orange Book listing" the court concluded that the act does not constitute petitioning.[188] The court further stated that Bristol-Myers Squibb's patent infringement actions may fall under the Noerr-Pennington doctrine, but noted that even if Noerr-Pennington immunity did apply, the plaintiffs' facts were sufficient to establish the Walker Process fraud and "sham" litigation exceptions to immunity.[189] The court noted, "neither the Supreme

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[182] *Mylan Pharm, Inc.*, 139 F. Supp. 2d at 19 (citing 21 U.S.C. §§ 355(b)(1), (c)(2)).

[183] *Id.* at 29.

[184] In re: Buspirone Antitrust Litig., 185 F. Supp. 2d 363, 365-67 (S.D.N.Y. 2002).

[185] *Id.* at 367.

[186] *Id.* at 367-68.

[187] *Id.* at 369-70.

[188] *Id.* at 371.

[189] *Id.* at 373. Specifically, the plaintiffs alleged that the manufacturer defrauded the FDA by submitting the patent to the FDA claiming it covered approved uses of buspirone knowing the statements were false. *In re: Buspirone Antitrust Litig.*, 185 F. Supp. 2d, at 373. Bristol-Myers Squibb indicated to the FDA that their patent does not just claim the metabolite, but also claims a method of use for buspirone. *Mylan Pharm., Inc.*, 139 F. Supp. 2d at 10. There was no objective basis for Bristol-Myers Squibb to claim their metabolite patent claimed the use of buspirone because it would have been invalid if it did. *Id.* at 9. In a separate companion opinion granting summary judgment in favor of the generic manufacturers on patent infringement claims brought against them by Bristol-Myers Squibb, the court found that the metabolite patent does not claim buspirone, and if it did it would be invalid under 35

Court nor the Court of Appeals for the Federal Circuit has addressed whether the Walker Process exception would apply to a fraudulent listing of a patent in the Orange Book along with subsequent lawsuits seeking to exploit the listing for anticompetitive advantage."[190] The Court, however, "accept[ing] the material facts alleged in the complaint as true and constru[ing] all reasonable inferences in the plaintiffs' favor," denied the defendant's motion to dismiss based on Noerr-Pennington immunity.[191] The court found that the plaintiffs pled sufficient facts that, if proven, would establish Walker Process fraud, and that there was no objective basis for Bristol-Myers Squibb's claim that the metabolite patent claimed buspirone, thus stripping Bristol-Myers Squibb of immunity.[192]

In an analogous case, Astrazeneca, another pharmaceutical innovator company, sued generic companies for patent infringement for filing ANDAs seeking approval to market generic versions of Astrazeneca's gastric acid inhibitor, Prilosec.[193] The court granted summary judgment to the generic manufacturers.[194] The court concluded that administration of the generic does not infringe the patent on the metabolite even though its active ingredient is converted into the metabolite in the body.[195]

Astrazeneca's patent that covered the active ingredient of Prilosec, omeprazole, expired in October 2001.[196] Astrazeneca, however, also holds a patent on "sulphenamides and the administration of sulphenamides for the treatment of inflammatory diseases of the human gastrointestinal tract" that will not expire until May 2005.[197] Astrazeneca claimed that ingestion of the generic

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U.S.C. section 102(b) for violating the on sale bar. *In re: Buspirone Patent Litigation*, 185 F. Supp. 2d 340, 359 (S.D.N.Y. 2002). The on-sale bar renders unpatentable inventions '"patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."' *Id.* at 359 (quoting 35 U.S.C. § 102(b)). It is undisputed that buspirone has been sold commercially in the United States since 1986 as BuSpar®. *Id.* at 57. Further, Bristol-Myers Squibb even admitted to the PTO that its metabolite patent did not cover Buspirone. *Mylan Pharm., Inc.*, 139 F. Supp. 2d at 9.

[190] In re*: Buspirone Antitrust Litig.*, 185 F. Supp. 2d at 373.

[191] *Id.* (quoting Gant v. Wallingford Bd. of Educ., 69 F.3d 669, 673 (2d Cir. 1995).

[192] *Id.* at 373.

[193] *In re* Omeprazole Patent Litig., No. 1291, 2001 U.S. Dist. LEXIS 7103, 1 (S.D.N.Y. May 29, 2001).

[194] *Id.* at 38.

[195] *Id.* at 37.

[196] *Id.* at 3-4.

[197] *Id.* at 4. Sulphenamides are a class of chemical compounds that are used to treat inflammatory diseases of the gastrointestinal tract. In re *Omeprazole Patent Litig.*,

manufacturer's omeprazole would infringe their sulphenamide patent because ingestion of omeprazole causes sulphenamide production in the body.[198] The court found that "by claiming patent protection for sulphenamides formed in vivo after the oral administration of omeprazole, [Astrazeneca] has merely attempted to patent the unpatentable, 'a scientific explanation for the prior art's functioning.'"[199] The court held that the defendants, generic manufacturers, did not infringe Astrazeneca's patent on sulphenamide "because any claim to sulphenamides produced in vivo upon the oral administration of omeprazole is inherently anticipated by prior art."[200]

Existing case law has established that a metabolite patent does not claim the precursor drug from which the metabolite is formed when administered.[201] If brand-name companies list these metabolite patents in the Orange Book and subsequently institute patent infringement actions against generic ANDA filers, the Noerr-Penington doctrine may still shield brand-name companies from antitrust liability unless generics can prove that either the Walker Process fraud or "sham" litigation exception applies. However, following the holding of *In re: Buspirone Antitrust Litigation*,[202] it appears that generic companies may be able to meet the difficult standards of proving Walker Process fraud or "sham" litigation when brand-name pharmaceutical companies rely on metabolite patents to assert that generic manufacturers are infringing their brand-name drug patents.

B. Double Patenting

Another way that pharmaceutical companies have been able to extend a patent term is through obviousness-type double patenting. Although double patenting is prohibited, if a pharmaceutical company is successful in obtaining a double patent it can extend its monopoly at least until the patent is found invalid.[203] In some cases, delay of a generic for only a few months may result in millions more

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No. 1291, 2001 U.S. Dist. LEXIS at 4.

[198] *Id.*

[199] In re *Omeprazole Patent Litig.*, No. 1291, 2001 U.S. Dist. LEXIS at 36 (quoting Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347 (1999)). In vivo means in the body, thus when sulphenamides are formed in vivo they are formed upon the ingestion of omeprazole.

[200] *Id.* at 37-38.

[201] *Hoechst-Roussel Pharm., Inc.*, 109 F.3d at 759.

[202] 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

[203] Seidenberg, *supra* note 86.

dollars worth of profits to a company.[204]

The obvious-type double patenting doctrine is a court-made prohibition of patent-term extension through subsequent patent claims that are not distinct from claims in a prior patent.[205] The court first analyzes the claims in both patents for differences, and then determines if the differences are patentably distinct.[206] A subsequent claim that "is obvious over, or anticipated by, the earlier claim, is not patentably distinct and thus invalid for obvious-type double patenting."[207]

Barr Laboratories ("Barr") filed an ANDA with paragraph IV certification for fluoxetine hydrochloride, the active ingredient in Eli Lilly & Co.'s ("Lilly") antidepressant drug Prozac.[208] Lilly brought a subsequent infringement action alleging that Barr infringed Lilly's patents for the drug.[209] Barr argued that Lilly's second patent, which would have extended its monopoly for three extra years, was invalid for double patenting.[210] The Court of Appeals for the Federal Circuit agreed and held that the patent was invalid for obviousness-type double patenting.[211]

The earlier Lilly patent claimed "a method for treating anxiety in a human by administering an effective amount of fluoxetine or a pharmaceutically-acceptable salt thereof," and the second patent claimed "a method of blocking the uptake of serotonin by brain neurons in animals by administering the compound fluoxetine hydrochloride."[212] The court found that people ordinary skilled in the art know "that fluoxetine hydrochloride is a pharmaceutically-acceptable salt of fluoxetine."[213] Furthermore, all evidence demonstrated that "blocking serotonin uptake by use of fluoxetine hydrochloride is an inherent characteristic of the administration of fluoxetine hydrochloride for any purpose, including the treatment of

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[204] When Bristol-Myers Squibb was able to delay the generic version of BuSpar® in only several months they earned $200 million in profits on the sale of the brand name drug. *Bitter Medicine*, *supra* note 10.

[205] Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 967 (Fed. Cir. 2001).

[206] *Id.* at 968.

[207] *Id.*

[208] *Id.* at 958. Under paragraph IV certification the generic manufacturer certifies that it is not infringing the pioneer drug's patent(s) because the patent(s) is invalid or will not be infringed by generic manufacture, use, or sale of the pioneer drug. 21 U.S.C. § 355(b)(2)(A)(iv) (1994).

[209] *Eli Lilly & Co.*, 251 F.3d at 958.

[210] *Id.*

[211] *Id.* at 958-59.

[212] *Id.* at 968-69.

[213] *Id.* at 969.

anxiety."[214] Because the second patent described the method through which fluoxetine hydrochloride worked, it was not patentably distinct from the prior patent.[215]

In March of 2000, SmithKline Beecham[216] ("SmithKline") obtained an additional patent on Augmentin®, U.S. Patent Nos. 6,218,380 (the "380 patent"), potentially extending its monopoly on the antibiotic until 2017.[217] SmithKline holds the patent on the active ingredient, amoxycilin.[218] The newly granted U.S. patent covers additional features of the drug such as an acid that inhibits degradation of the active ingredient.[219] Teva Pharmaceuticals, a generic drug manufacturer, sought summary judgment alleging that its proposed generic would not infringe SmithKline's 380 patent because the patent is invalid on the grounds of obviousness-type double patenting.[220] The court found that the 380 patent appears to be a rewording of the previous patent, U.S. Patent Number 4,529,720 (the "720 patent"), and thus, the two patents are not patentably distinct.[221] Therefore, the court invalidated the 380 patent for obvious type double patenting.[222]

Although a finding of obvious-type double patenting will render invalid a patent that is not patentably distinct from an earlier patent, a brand-name company that succeeds in obtaining a double patent will have extended its monopoly under the current Hatch-Waxman scheme by halting FDA approval of a generic ANDA until the patent is found to be invalid.[223] If brand-name companies list these double patents in the Orange Book and subsequently institute patent infringement actions against generic ANDA filers, the Noerr-Pennington doctrine may shield the brand-name companies from antitrust liability unless the generics can succeed at proving Walker Process fraud or "sham" litigation.[224]

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[214] *Id.* at 970.

[215] *Eli Lilly & Co.*, 251 F.3d at 971.

[216] SmithKline Beecham Corporation is now GlaxoSmithKline.

[217] Pilling and Wolffee, *supra* note 157.

[218] *Id.*

[219] *Id.*

[220] Geneva Pharm., Inc. v. Glaxosmithkline PLC, 189 F. Supp. 2d 377, 379-81 (E.D.Va. 2002).

[221] *Id.* at 384-85.

[222] *Id.*

[223] Seidenberg, *supra* note 86.

[224] *Id.*

C. Polymorph Patent

Pharmaceutical compounds may crystallize in different forms called polymorphic forms.[225] Some pharmaceutical companies have attempted to extend their patent protection on certain drugs by patenting the polymorphs of those drugs.[226]

Glaxo alleged that generic production of Zantac®, an anti-ulcer medication by Novopharm, would infringe its patents on ranitidine hydrochloride, the active ingredient in Zantac®.[227] Glaxo has three patents on ranitidine hydrochloride, which crystallizes into two distinct forms.[228] The patent that "discloses a method of making ranitidine hydrochloride and claims the compound per se" expired in July 1997.[229] Glaxo scientists later discovered that ranitidine hydrochloride crystallizes into a form preferable to the first known crystalline form, which was referred to as Form 1.[230] They called the new form Form 2.[231] Form 2 and the process for making Form 2 were patented in two separate patents that would expire in 2002 and 2004, respectively.[232] Novopharm filed an ANDA in 1991 seeking to market Form 2.[233] Glaxo brought suit against Novopharm for infringement under 35 U.S.C. § 271(e)(2), but Novopharm challenged the validity of the Form 2 patent. Novopharm alleged the original patent disclosed the method of making ranitidine hydrochloride and claimed the compound anticipated the Form 2 patent's claims.[234] The district court, however, rejected Novopharm's "anticipation defense."[235]

In 1994, Novopharm filed another ANDA to market Form 1 certifying that it would not infringe the Form 2 patent, and it did not intend to market Form 1 until the Glaxo patent expired.[236] Glaxo sued Novopharm for infringement of its patent on the process of

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[225] Allen G. Mitchell, *Racemic Drugs: Racemic Mixture, Racemic Compound, or Pseudoracemate?*, J. PHARMACY & PHARM. SCI., *available at* http://www.ualberta.ca/~csps/JPPS1(1)/A.Mitchell/racemicview.htm (last visited Oct. 30, 2002) (on file with the author). Polymorphism is defined as the ability of a compound to crystallize in multiple forms. *Id.*

[226] *See* Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (1997).

[227] *Id.* at 1563-64.

[228] *Id.* at 1564.

[229] *Id.*

[230] *Id.*

[231] *Id.*

[232] *Glaxo, Inc.*, 110 F.3d at 1564.

[233] *Id.*

[234] *Id.*

[235] *Id.*

[236] *Id.*

making Form 2.[237] Novopharm's ANDA permitted the product "to have a Form 1 [ranitidine hydrochloride] purity as low as 90%" with impurities that may include Form 2.[238]

Glaxo, however, was not able to establish that Novopharm's Form 1 ranitidine hydrochloride generic would contain Form 2.[239] Thus, the court found that "Glaxo failed to prove that Novopharm's product would contain Form 2 ranitidine hydrochloride . . . [and] also failed to prove that Novopharm was using a process claimed in the [Form 2 process] patent."[240]

Nonetheless, it appears that patenting different polymorphic forms of patented drugs may be a legitimate way for brand-name companies to extend their monopolies.[241] If brand-name companies can establish that generic manufacturers are producing drugs that contain the patented polymorphs they can prohibit generics from producing these drugs because doing so would constitute infringement.[242] A generic manufacturer, however, may produce a generic version of a drug in a polymorphic form for which the patent has expired.[243]

IV. ANALYSIS

Patent "evergreening" is a popular practice among brand-name pharmaceutical companies. Still, the unclear distinction between brand-name companies' aggressive, pro-active behavior and anti-competitive behavior can lead to antitrust challenges by generic companies and the federal government.[244]

Generic pharmaceutical companies sued for patent infringement for filing ANDAs will likely have standing to bring claims against their brand-name challengers under Section 2 of the Sherman Act. Generic manufacturers can assert that the brand-name companies violated Section 2 of the Sherman Act by monopolizing or attempting to monopolize the market for their brand-name drugs.[245] Generics can allege that the brand-name companies achieved

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[237] *Id.*

[238] *Glaxo, Inc.*, 110 F.3d at 1564.

[239] *Id.* at 1571.

[240] *Id.*

[241] *Id.*

[242] *Id.*

[243] *Id.*

[244] Peter O. Safir, *Current Issues in the Pioneer Versus Generic Drug Wars*, 50 FOOD & DRUG L.J. 335, 335 (1995), *available at* http://www.fdii.org/pubs (on file with the author).

[245] *Bristol-Myers Squibb Co.*, 90 F. Supp. 2d at 542.

monopoly power in the market for their drugs because of their predominant market share.[246] Generics can also assert that the brand-name companies violated Section 2 by willfully seeking to maintain their monopoly power.[247]

Under the Noerr-Pennington immunity doctrine, however, brand-name pharmaceutical companies are likely to be immune from Sherman Act Section 2 claims for bringing patent infringement suits against generic companies who file ANDAs. Patents are presumed valid for the duration of the lawsuit until invalidated by the court.[248] Therefore, brand-name companies are operating within the rights granted to them through grant of the patent. Under the patent grant, brand-name companies have the right to exclude generics from producing and selling their patented drugs.[249] Because the brand-name companies have patent protection, the lawsuits alleging patent infringement are unlikely to be found to be objectively baseless and thus, generics will not be able to successfully allege the "sham" litigation exception to Noerr-Pennington immunity.

Generic companies can allege that brand-name companies have committed Walker Process fraud by using fraud to procure their patents. Nevertheless, generic companies will face challenges in showing that the brand-name patentee "1) . . . knowingly and willfully made a fraudulent omission or misrepresentation; 2) with clear intent to deceive the patent examiner; 3) where the . . . 'patent would not have issued but for the misrepresentation or omission.'" [250]

It is clear that brand-name companies have used the clause in the Hatch-Waxman Act requiring the FDA to freeze approval of a generic ANDA for thirty months or until the patent infringement suit is resolved in court to delay generic production and extend their monopolies on money-making drugs.[251] The Greater Access to Affordable Pharmaceuticals Act ("GAAP") purports to close this loophole in the Hatch-Waxman Act by removing the thirty-month statutory preliminary injunction for any drug patent listed in the Orange Book more than thirty days after approval of the brand-name

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[246] *See Grinnel Corp.*, 384 U.S. at 571.

[247] *Id.* at 570-71.

[248] 35 U.S.C. § 282 (1988).

[249] Special Equip. Co. v. Coe, 324 U.S. 370, 378 (1945). The patent gives its owner a monopoly on the invention that expires twenty years from the date of the patent application. 35 U.S.C. § 154(a)(2) (1994).

[250] *Bristol-Myers Squibb Co.*, 90 F. Supp. 2d at 542 (quoting Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1069 (Fed. Cir. 1998)).

[251] Engelberg, *supra* note 77, at 415.

drug.[252] The GAAP was passed in the Senate on July 31, 2002.[253] Under the GAAP, in the case of late listed patents, brand-name companies can seek a court-granted preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement.[254]

Elimination of the thirty-month injunction, however, is not likely to be enough to halt any anti-competitive behavior. A presumption of validity is given to patents and the burden is on the challenger of the patent to show that a patent is invalid by clear and convincing evidence.[255] Furthermore, courts grant preliminary injunctions against alleged patent infringers when (1) it is reasonably likely that the patent holder will be successful on the merits, (2) there is a possibility of irreparable harm, (3) the balancing of hardships faced by the parties weighs in the patent holders favor, and (4) the injunction will not likely have an adverse impact on the public interest.[256] Further, "it is often assumed that infringement of a valid patent would result in irreparable harm."[257] Thus, it is likely that removal of the thirty-month statutory injunction will not remedy the existing situation because brand-name pharmaceutical companies can still delay generic production with the grant of a preliminary injunction by merely making a showing to the court that the patent could be valid.

The Federal Circuit gives great weight to patent holders. Patents are presumed valid and patent invalidity can only be demonstrated with clear and convincing evidence.[258] The patent process, however, is *ex parte*; the company seeking the patent provides the information.[259] Also, patent examiners do not spend a lot of time reviewing applications and prior art, and often miss relevant prior art.[260] The Patent and Trademark Office ("PTO") approves approximately seventy-percent of the massive amount of patent

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[252] S. Res. 812, 107th Cong. (2002) (enacted).

[253] *Id.*

[254] *Id.*

[255] Engelberg, *supra* note 77, at 422; *see also* Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986, 996 (9th Cir. 1979).

[256] Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 681 (Fed. Cir. 1990); s*ee also* Engelberg, *supra* note 77, at 422.

[257] Engelberg, *supra* note 77, at 422.

[258] Lemley, *supra* note 40, at 1528.

[259] Langenfeld, *supra* note 12, at 106.

[260] Lemley, *supra* note 40.

applications it reviews.[261] The PTO should revise its procedures so that close scrutiny is given to all patent applications. The PTO should also take competition into account when reviewing applications and frivolous applications should be denied. In addition, a more careful analysis should be given to the review of any application and all relevant prior art when an applicant seeks to obtain an additional patent on a pharmaceutical product that would extend the initial patent holders' monopoly beyond the expiration of the original patent. Therefore, PTO procedures should be reviewed in an attempt to increase competition and deter pharmaceutical companies from engaging in anti-competitive behavior by manipulating intellectual property rights.

In addition, the Orange Book alone provides an opportunity for a brand-name drug patent holder to extend its market exclusivity.[262] There are no guidelines for listing patents in the Orange Book and no mechanism for removing them.[263] Thus, the Orange Book itself encourages brand-name pharmaceutical companies to procure frivolous patents. Guidelines for regulating listings in the Orange Book should be established to prevent the listing of frivolous patents.[264] Such guidelines should provide specifically for any listing that extends a brand-name pharmaceutical company's monopoly beyond the expiration of the initial patent to be scrutinized.

Furthermore, any new legislation should impose a meaningful penalty upon companies that are found to have deliberately forestalled generic production by filing frivolous patents. Under the current scheme even if a frivolous patent is subsequently found invalid, the patent holder will have successfully forestalled generic production, at least until the infringement suit is determined. With some blockbuster drugs generating approximately $1,100,000 per day per drug,[265] the present system provides a mechanism for anti-competitive behavior where economic incentive clearly exists.

CONCLUSION

Patients' rights groups argue that these extensions of drug

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[261] Langenfeld, *supra* note 12, at 108.

[262] *See* discussion *infra* PART I.

[263] Engelberg, *supra* note 77, at 414-15.

[264] If enacted into law, the GAAP will provide generic companies with the ability to challenge these listings and seek de-listing of inappropriately listed patents. S. Res. 812, 107th Cong. (2002) (enacted).

[265] Terry G. Mahn, *Symposium Issue - Striking The Right Balance Between Innovation And Drug Price Competition: Understanding The Hatch-Waxman Act: The Hatch-Waxman Act During Patent Prosecution and Beyond*, 54 FOOD DRUG L.J. 233 (1999).

patents hurt consumers and the health care system by creating monopolies. Pharmaceutical companies, however, are using the current United States patent laws to obtain these patents. Further, patent law is designed to promote scientific research and innovation and these patents are being used to develop innovative prescription drugs that will ultimately benefit patients. Although both sides have strong policy arguments, it appears that the current scheme favors brand-name pharmaceutical companies by allowing them to use loopholes in the laws to extend their patent terms, while protecting them from antitrust liability under the Noerr-Pennington doctrine.