

REGAINING THE BALANCE OF HATCH-WAXMAN IN THE FDA GENERIC APPROVAL PROCESS: AN EQUITABLE REMEDY TO THE THIRTY-MONTH STAY

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I. INTRODUCTION

Approximately 150 brand name pharmaceutical drugs, or one-third of all prescription medicines in the United States worth more than thirty billion dollars in annual sales, will lose their existing patent protection by the year 2005.¹ As pioneer drug manufacturers begin to face an unprecedented number of blockbuster patent expirations, new strategies have emerged that use the Food and Drug Administration ("FDA") guidelines' interaction with the patent laws to effectively extend this profitable period at the expense of generic drug manufacturers. Though legislation was previously enacted to balance the competition between pioneer manufacturers and manufacturers of generic drugs, this balance has been destroyed in favor of the pioneer manufacturers, signaling the need for reform.

The present imbalance, as well as the legislative solution which this Note will advocate, is best understood against a backdrop of the FDA's drug approval procedures. When a new pioneer drug is ap-

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1. See Theresa Agovino, *FTC Studies Drug Patents Worth Millions in Sales*, THE TIMES UNION (Albany), Jan. 27, 2002, at E3; Frank Scussa, *Patent Games*, MED AD NEWS, June, 2002, at 1; cf. Ralph G. Schroeder and Paul Papas, *Protecting the Balance of Hatch-Waxman: Understanding the Industry's New Dynamics for the 21st Century*, 56 FOOD & DRUG L.J. 19, 24 (2001) (valuing the worth of expiring patents at \$19 billion). The top twenty of these drugs represent over one-fifth of the United States' total drug sales in 1998, or over \$19 billion. *Id.* at 24.

proved by the FDA, the FDA publishes a list of any patents covering the new drug. Prior to obtaining FDA approval for a new generic drug product, the generic drug company must certify that its product does not infringe the listed patents protecting the pioneer drug which it imitates. The most frequent result is that the generic manufacturer faces a great burden in proving, ultimately before a finder of fact, that its new drug does not infringe.

Procedurally, a pioneer company is given the right to reject a generic manufacturer's contention that its drug does not violate the patents that it has listed with the FDA for its pioneer drug. Upon the pioneer company's filing of a patent infringement action in district court, a thirty-month stay is triggered whereby the generic manufacturer is blocked from receiving FDA approval and entering its generic product on the market. The activation of this stay is intended to protect the pioneer company in lieu of an action for patent infringement and a resulting decision. Because the FDA is powerless to evaluate the applicability of patents to the drugs it approves, there is no barrier to the submission and listing of patents by the pioneer company, regardless of their applicability to a pioneer drug. Likewise, upon the pioneer company's contention that such a patent would be infringed by a generic, the FDA has no ability to review the merits and must automatically activate the thirty-month stay against generic approval.

As time is money in the pharmaceutical industry, a generic manufacturer would do best to bring an action immediately upon the activation of the thirty-month stay in hopes of quickest resolution. The options would appear to be either a declaratory judgment action for removal of the pioneer company's listed patent, whose presence is blocking the generic's approval, or to seek a declaratory judgment against patent infringement by the generic manufacturer.

In a critical decision, the United States Court of Appeals for the Federal Circuit announced in *Mylan Pharmaceuticals, Inc. v. Thompson*² that a direct action for removing a pioneer company's patent from its pioneer drug listing, regardless of its lack of applicability to the pioneer drug, would not stand.³ Short of patent infringement litigation brought by either party, there is no recourse from the thirty-month stay on generic approval. As there is no rebalancing of the parties' interests until after such litigation is completed, the posture of the FDA's approval regime thus greatly

2. 268 F.3d 1323 (Fed. Cir. 2001).

3. *See id.* at 1333.

favors the pioneer company and may unnecessarily delay the availability of generics to the American public.

This Note begins in Part II and Part III by providing an historical and statutory overview of legislation enacted specifically to balance the competing forces between generic and pioneer companies, as well as a brief overview of both the pioneer and the generic drug approval processes. Parts IV, V, and VI address the reasoning of the United States Court of Appeals for the Federal Circuit's holding in *Mylan v. Thompson*, the *Mylan*-patent-delisting cause of action, and alternative solutions to the destruction of this balance posed by both the Federal Circuit and by the current Congress. In Part VII the effectiveness of antitrust and unfair competition causes of action in the drug patent context will be analyzed. This Note argues in Part VIII that the best solution to regain the critical balance is not any of these existing proposals, but rather one that deters pioneer companies from listing with the FDA those patents which do not apply to their drugs for the sole purpose of blocking generic competition. The thirty-month FDA administrative stay on generic approval will be compared to the consequences of a legal injunction. This Note concludes by analyzing and advocating a requirement that pioneer companies post a bond upon triggering the thirty-month stay in their favor, akin to the bond requirement imposed by the federal rules prior to obtaining injunctive relief.

II.

THE OVERLAP OF THE PATENT LAWS AND THE FDA DRUG APPROVAL REGIME

A U.S. patent holder is granted a monopoly over his invention for twenty years following the date of filing his patent,⁴ whereby he may enjoin all others "from making, using . . . or selling" his patented invention.⁵ In the case of pharmaceutical drugs, twenty full years of exclusivity normally are not enjoyed due to the lengthy amount of time a pharmaceutical company must spend conducting FDA-mandated clinical trials. Prior to 1984, generic drug companies had to conduct these same new drug clinical trials, and thus the time to generic availability was equally protracted.⁶ The Federal

4. See 35 U.S.C. § 154(a)(2) (2000).

5. See 35 U.S.C. § 154(a)(1) (2000).

6. Prior to the enactment of the Hatch-Waxman Act of 1984, discussed *infra*, a generic drug approval procedure existed only for drugs approved by the FDA prior to 1962. See H.R. REP. 98-857, pt. 1, at 1 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647.

Circuit decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.* aptly demonstrated many of the problems plaguing the drug approval regime at that time.⁷

In *Roche v. Bolar*, Roche's pioneer drug patent was set to expire on January 17, 1984.⁸ Anticipating this date as well as a possible two-year delay in obtaining FDA generic approval on Roche's established drug, Bolar proceeded to order one of Roche's patented chemical compounds from overseas in order to "obtain stability data, dissolution rates, [and conduct] bioequivalency studies, and blood serum studies" as necessary precursors to its new drug application.⁹ Roche brought suit. The Federal Circuit held the Roche patent infringed, and that the "use" of a patented drug in conducting mandatory FDA approval tests did not differ from a violative "use" under the patent laws.¹⁰

Roche v. Bolar illustrates that prior to 1984, a generic manufacturer could not begin to make, use, or sell a drug until all of the patents covering the drug had expired, even if that use was related to expediting the availability of generic drugs *after* the date of the patent's expiration. The law functionally lengthened the period of exclusivity of the patent holder, as generic manufacturing and testing were not legal until the actual date of the patent's expiration.¹¹

7. 733 F.2d 858, 860 (Fed. Cir. 1984).

8. *Id.*

9. *Id.*

10. See *supra* note 5 and accompanying text. The defense of experimental use is a recognized exception to patent infringement whereby an accused infringer may "use" the invention only if that use was for particular non-commercial, experimental purposes. See 35 U.S.C. § 271(e)(1) (2000). Though Bolar attempted to assert that its use of the drug pertained to a "true scientific inquiry," the Federal Circuit held the experimental use defense to be "truly narrow" and refused to "expand it" in Bolar's circumstances. See *Roche*, 733 F.2d at 863. The Court's reasoning was that Bolar's intended experimental use was "solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.*

11. One could argue that pioneer drug companies needed this stringent protection. Patent applications for pharmaceutical drugs are often filed as soon as possible following the discovery of therapeutic use, which is before a drug's clinical testing period, in order to preserve the inventor's rights. The date of the patent application "is presumed to be the date of invention" for the purposes of establishing priority of invention. See DONALD S. CHISUM, 3 CHISUM ON PATENTS § 10.03[1][c][i] (perm. ed. 2002). "An inventor always bears the burden of proving an earlier date of invention by showing either an earlier actual reduction to practice or an earlier conception and diligence to reduction to practice." *Id.* Because of this burden, patent applications are submitted at the earliest date possible to establish priority, and in the case of pioneer drugs or drug methods, at a time usually preceding clinical testing and clinical trials.

Further, the law did no justice to the view that generic drugs should be made available to the American public as soon as possible.

III. THE COMPROMISE OF THE HATCH- WAXMAN ACT¹²

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as “The Hatch-Waxman Act,” was enacted to overrule *Roche v. Bolar* and to strike a balance between these competing forces.¹³ First, the Act included a patent term restoration provision that allowed for a pioneer company to gain an extended patent term.¹⁴ This statutory patent term restoration made up for some of the profit-making time lost by pioneer companies to FDA trials. To the benefit of generic manufacturers, and with the needs and pro-generic views of the American public in mind, generic drug applications prior to the expiration of the pioneer company’s patents for drugs were authorized.¹⁵ The introduction of these two provisions served as “a new incentive for increased expenditures [devoted] to research and development,”¹⁶ while cre-

12. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

13. The Federal Food, Drug, and Cosmetic Act (“FFDCA”) gives the FDA the authority to regulate the production, distribution, and sale of drugs in the United States. See 21 U.S.C. §§ 321–97 (2000). The Hatch-Waxman Act was enacted as an amendment in part of the FFDCA, and modifies the Patent Act at 35 U.S.C. §§ 271(e), 156 (2000) and 21 U.S.C. § 355(j) (2000).

14. See 35 U.S.C. § 156 (2000). The total patent life may not exceed a maximum of five years beyond the date of expiration of the original patent term, or extend beyond fourteen years from the drug’s approval date however. See 35 U.S.C. §§ 156(c), (d)(5)(E)(i). The patent term restoration application must satisfy certain criteria:

(1) [T]he term of the patent has not expired . . . (2) the term of the patent has never been extended . . . (3) an application for extension is submitted by the owner of the record of the patent or its agent . . . (4) the product has been subject to a regulatory review period [such as with the FDA] before its commercial marketing or use . . . (5) [for human drugs,] the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing use of a product manufactured under which such regulatory review period occurred [or for recombinant DNA technology,] the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent. 35 U.S.C. § 156(a)(1)–(5). The patent term restoration application must be submitted within 60 days of the product’s approval. See 35 U.S.C. § 156(d)(1).

15. See 35 U.S.C. § 271(e)(1).

16. See H.R. Rep. 98-857, pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

ating a unique approval procedure for generic drugs that would expedite generic's approval and availability.¹⁷

The mechanics of pioneer drug approval remained unchanged with the passing of Hatch-Waxman. In order for a company to market a pioneer drug in the United States, the company must prepare, file, and have approved a new drug application ("NDA") with the FDA.¹⁸ The approval of an NDA for the pioneer drug is a condition precedent to generic approval.

The NDA must contain: reports of investigations demonstrating the new drug's safety and effectiveness; a list of the components of the drug; a statement of the composition of the drug; a description of the methods, facilities, and controls used in the drug's manufacture, processing, and packaging; samples of the drug or its components; and, samples of the labeling proposed to be used for the drug.¹⁹ Importantly, the NDA must also include information on any patents claimed for the drug or method of using the drug, and for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.²⁰ The Hatch-Waxman Act provided that the FDA must publish any and all of such received patent information, and soon thereafter an FDA publication, "Approved Drug Products with Therapeutic Equiva-

17. *See id.*

18. *See* 21 U.S.C. § 355(b)(1).

19. *Id.*

20. *See id.*; 21 C.F.R. § 314.53(c)(2) (2002). Information on process patents may not be submitted, but information on drug substance, drug product, and method of use patents may be. *See* 21 C.F.R. § 314.53(c)(2). Only those drug product patents that claim a product that is the subject of a pending or approved application, or drug substance patents that claim substance that is a component of such a product, are to be included. *See* 21 C.F.R. § 314.53(b). Likewise, information on method of use patents can be submitted if they claim indications or other conditions of use of a pending or approved application. *Id.*

If an applicable patent is obtained by the pioneer company later on, and while the drug enjoys exclusivity from another patent, the pioneer company may submit the new patent information to the FDA for listing within thirty days of the new patent's issue. *See* 21 U.S.C. § 355(c)(2). It is equally important that these later-issued method-of-use patents fulfill the statutory requirement that they claim indications or other conditions of an already approved use for the drug. *See Mylan v. Thompson*, 139 F. Supp. 2d 1, 23 (D.D.C. 2001) (stating that for a new patent "to be properly filed with the FDA and listed in the Orange Book . . . [the patent] must cover the same method of [use of the pioneer drug] as is currently approved"). As discussed *infra*, the FDA is without the authority to monitor the content of the submitted patent information; it must take the submissions at face value and publish the patent information.

lence Evaluations,” commonly referred to as the “Orange Book,” was created for this purpose.²¹

According to Hatch-Waxman’s “safe harbor” provision, a generic manufacturer becomes able to make and use pharmaceuticals in violation of a pioneer company’s patent on a drug, as long as that use is reasonably related²² to obtaining federal approval to market pharmaceutical or veterinary products.²³ In other words, the generic manufacturer may develop its version of a drug within a “safe harbor,” or without fear of being sued by the pioneer company for patent infringement.

21. See 21 U.S.C. § 355(j) (7) (A) (iii). The Orange Book is available online at <http://www.fda.gov/cder/ob/default.htm> (last visited Nov. 20, 2002).

22. The issue of what types of activities may be construed to be “reasonably related” to obtaining FDA approval has been heavily litigated. The Federal Circuit’s interpretation has been exceptionally liberal in this respect, holding that § 271(e)(1)’s safe harbor protects uses that are objectively reasonably related to gathering information for FDA submission. See *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1280–81 (N.D. Cal. 1991), *aff’d*, 991 F.2d 808 (Fed. Cir. 1993); see also Brian D. Coggio & Francis D. Cerrito, *The Safe Harbor Provision of the Hatch-Waxman Act: Present Scope, New Possibilities, and International Considerations*, 57 FOOD & DRUG L.J. 161 (2002) (discussing the broad reach of the safe harbor throughout ANDA jurisprudence).

Based on this expansive reading, courts have held a broad array of activities protectable by the safe harbor provision, including: using the drug to raise capital, obtaining foreign patents, selling the drug to international distributors, demonstrating the drug publicly, advertising the product or its clinical trials, arranging foreign import of the drug, and a variety of other activities within the public realm. See Brian D. Coggio & Francis D. Cerrito, *The Application of the Patent Laws to the Drug Approval Process*, 52 FOOD & DRUG L.J. 345, 346–48 (1997) (collecting cases) [hereinafter *Application of the Patent Laws*]. Broad readings of “objectively reasonably related” have also resulted in the safe harbor’s protection even where the information gathered is not included in the final submission. See *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 109 (D. Mass. 1998); accord *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, No. Civ.A. 97-10814-WGY, 2001 WL 1512597, at *6 (S.D.N.Y. Nov. 28, 2001). The Federal Circuit has noted, in the context of commercial uses, that “even if the activities serve other purposes, it is irrelevant since the plain language of the statute has the word ‘uses’ and not ‘purposes.’” Shashank Upadhye, *Understanding Patent Infringement Under 35 U.S.C. § 271(e): The Collisions Between Patent, Medical Device and Drug Laws*, 17 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 11 (2000).

23. See *Application of the Patent Laws*, *supra* note 22, at 345. Specifically, the “safe harbor” provision states that:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1) (2000).

In addition to the safe harbor, generic manufacturers also gained the benefit of an expedited approval process under Hatch-Waxman. The Act provides that once a generic manufacturer is ready to seek FDA approval, it may file an abbreviated new drug application (ANDA) with the FDA.²⁴ The ANDA must contain information to show that the generic version of the drug is essentially equivalent to the previously approved drug.²⁵ Under Hatch-Waxman, a company is thus able to gain approval for a generic drug without conducting its own independent clinical trials. Instead, the generic manufacturer must only demonstrate bioequivalence to a previously approved drug, thereby relying in part upon previously conducted research.²⁶

There is no limit as to how many ANDAs the FDA may approve for a generic drug, assuming that for each, all of the statutory qualifications are met. However, the Hatch-Waxman Act affords the first ANDA applicant a 180-day period of market exclusivity.²⁷ Thus to stimulate generic drug availability, the first generic applicant is awarded a brief generic monopoly wherein no additional ANDAs may be approved.²⁸ This 180-day period is not triggered until the first ANDA applicant actually begins commercial marketing of the drug.²⁹

This pro-generic ANDA-approval provision was compromised by giving pioneer companies the ability to initiate a thirty-month stay on ANDA approval. Under the Act, the ANDA applicant must submit a patent certification if there are patents listed in the Orange Book for the approved drug that it imitates. The ANDA applicant may submit a "Paragraph II" certification, by which it certifies that it is not seeking approval prior to the expiration of any patents

24. See 35 U.S.C. § 355(j)(2)(A); *infra* note 25.

25. Specifically, the ANDA must contain the following information: that the conditions of use proposed in the new drug's labeling have been previously approved for the listed drug; the active ingredient(s) is (are) the same as the listed drug; the dosage, route of administration, and strength are the same; bioequivalence exists between the new and listed drug; and the labeling is the same except for changes due to different manufacturing companies. See 21 U.S.C. § 355(j)(2)(A)(i)-(v). Like the NDA, the ANDA must also provide a full list of the drug's components, a statement of its complete composition, description of the methods, facilities, and controls, samples as required, and samples of labeling. See 21 U.S.C. § 355(j)(2)(A)(vi).

26. See 21 U.S.C. §§ 355(j)(2)(A)(iv), 355(j)(8)(B).

27. See 21 U.S.C. § 355(j)(5)(B)(iv).

28. *Id.*

29. *Id.*

listed for the pioneer drug in the Orange Book.³⁰ Otherwise, the ANDA applicant must submit a “Paragraph IV” certification, by which it certifies that any listed patents are invalid or not infringed by the manufacture, use, or sale of the generic drug.³¹

The filing of the Paragraph IV certification may constitute patent infringement.³² After making a Paragraph IV certification to the FDA, the ANDA applicant is required to give notice to the patent holder (the pioneer company).³³ After receiving notice, the pioneer company has forty-five days to file a patent infringement action in federal court.³⁴ Upon filing an infringement suit, a thirty-month stay is triggered under which without a court judgment,³⁵ the FDA may not proceed to process and approve the ANDA application.³⁶

Interestingly, the statutory scheme does not allow for Orange Book listing for patents covering antibiotic medications, thus elimi-

30. See 21 U.S.C. § 355(j)(2)(A)(vii)(II). As discussed *supra*, if the ANDA applicant does not seek approval prior to the expiration of the pioneer drug’s patents, it remains within the safe harbor of § 271(e)(1). There is a great motivation to seek pre-expiration approval, however, as the economic rewards for such a seemingly brief period are quite significant.

31. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Alternatively, if there are no patents listed for an approved drug, the ANDA applicant may submit either a “Paragraph I” certification, certifying that patent information has not been filed, or a “Paragraph III” certification, whereby the ANDA applicant certifies that it will not market its generic drug until the date of expiration of the pioneer company’s patent. See 21 U.S.C. §§ 355(j)(2)(A)(vii)(I), (III).

32. See 35 U.S.C. § 271(e)(2) (2000); see also *Am. Bioscience v. Thompson*, 269 F.3d 1077, 1079 (D.C. Cir. 2001).

33. See 21 U.S.C. § 355(j)(2)(B)(i)(I).

34. See 21 U.S.C. § 355(j)(5)(B)(iii). In the unlikely event that no action is brought within this time, the ANDA would be made effective immediately. *Id.*

35. The FDA has stated that for the purposes of sections 355(j)(5)(B)(iii)(I) and (iv), the word “court” will be interpreted by the FDA to mean “the first court that renders a decision finding the patent at issue invalid, unenforceable, or not infringed.” See *Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act* (Mar. 2000), attached as Exhibit B to Alvin J. Lorman, *FDA/Patent Law Intersection: What’s New With Hatch-Waxman*, in INTELL. PROP. ANTITRUST 2001, at 364 (PLI Pat., Copyright, Trademarks, & Lit. Prop. Course, Handbook Series No. G0-00R6, 2001). If a district court renders such a decision, the stay will be lifted and the ANDA may be approved on the date of the district court’s decision; if a court of appeals reverses, the FDA may then reverse its approval of the ANDA. See *id.*

36. See 21 U.S.C. § 355(j)(5)(B)(iii). It is significant to note that Congress originally contemplated the creation of an 18-month stay, which was ultimately further compromised by increasing the duration to thirty months. See *id.*; H.R. REP. NO. 98-857, pt. 2, at 9–10, reprinted in U.S.C.C.A.N. 2686, 2693–94 (1984) (discussing the creation of the 18-month stay).

nating the need for a generic manufacturer to file a Paragraph II or IV certification.³⁷ In the case of antibiotics therefore, there can be no thirty-month stay on approval by the FDA, and generic production of antibiotics is promoted by the statutory scheme of Hatch-Waxman.³⁸

For a time, the compromises of the Hatch-Waxman Act adequately balanced three powerful and dynamic competing forces in the American pharmaceutical industry. Generic companies benefited by the introduction of the “safe harbor” provision, the “Abbreviated” NDA regime, and the 180-day exclusivity period awarded to the first ANDA applicant. Pioneer companies were compensated with patent restoration provisions and the ability to initiate the thirty-month stay in the event of an infringement dispute. And finally, the American public was assured that generic drug approval could be expedited in many cases.

In recent times, however, the delicate balance between pioneer companies and generics has been destroyed. As demonstrated though the events of recent litigation involving the popular anti-anxiety drug BuSpar,³⁹ the pioneer company’s ability to trigger the thirty-month stay against production and sale of generic non-antibiotic drugs is greatly abused and weighs the balance greatly in favor of pioneer companies.

37. To quote the statutory provision:

(2) EXCEPTION.—The following subsections of section 505 (21 U.S.C. 355) shall not apply to any application for marketing in which the drug that is the subject of the application contains an antibiotic drug and the antibiotic drug was the subject of any application for marketing received by the Secretary of Health and Human Services under section 507 of such Act [21 U.S.C. 357] before the date of the enactment of this Act [Nov. 21, 1997]:

(A)(i) Subsections . . . (j)(2)(A)(vii), (j)(2)(A)(viii), (j)(2)(B) . . . and (ii) The third and fourth sentences of subsection (b)(1) (regarding the filing and publication of patent information) . . .

See Pub. L. No. 105-115, Title I, § 125(d), 111 Stat. 2327 (1997).

38. This Note shall therefore focus only on the imbalance caused by the pioneer company’s ability to initiate the thirty-month stay against non-antibiotic drugs, and not discuss antibiotics further but merely note that these drugs belong to a different legislative class.

39. BuSpar is marketed and manufactured by Bristol-Myers Squibb, and its sales generate approximately \$700 million per year. See Scott Hensley & Andrew Caffrey, *Bristol-Myers Falls as U.S. States Sue*, *ASIAN WALL ST. J.*, Dec. 14, 2001, at 7.

IV.

MYLAN V. THOMPSON⁴⁰A. *The District Court Decision*—Mylan I

On March 13, 2001, the United States District Court for the District of Columbia granted plaintiff Mylan Pharmaceuticals, Inc. (“Mylan”)⁴¹ its request for a preliminary injunction, enjoining defendant Bristol-Myers Squibb (“BMS”)⁴² to request the de-listing of a patent from the FDA’s Orange Book.⁴³ This was the first court to directly order the delisting of a patent from the Orange Book.⁴⁴

40. 139 F. Supp. 2d 1 (D.D.C. 2001) [hereinafter “Mylan I”], *rev’d*, Mylan Pharm., Inc. v. Thompson, 268 F.3d 1323 (Fed. Cir. 2001) [hereinafter “Mylan II”].

41. Though the district court stated that Mylan is the largest generic drug manufacturer in the United States, more recent reports state that Mylan is second to Watson Pharmaceuticals. *See Mylan I*, 139 F. Supp. 2d at 8; Pamela Gaynor, *Mylan Builds \$600 Million ‘Kitty’: Generic Drug Maker Looks for Acquisitions*, PITTSBURGH POST-GAZETTE, Mar. 6, 2002, at C1; Gardiner Harris, *Judges’ Comments Hint Mylan Investors May Be In For a Nasty Surprise*, PITTSBURGH POST-GAZETTE, Aug. 21, 2001, at E2. Over 80% of Mylan’s revenues come from the sale of generic drugs. *See Lawsuits Hurt Mylan Customers, CEO Says*, CHARLESTON GAZETTE, July 28, 2001, at 11A. Though Mylan’s stock price varied greatly in 2001, Mylan executives’ projected earnings for 2002 are 2% higher than last year’s estimate. *See Gaynor, supra*. Additionally, Mylan has amassed \$600 million in cash and is currently looking to increase its assets by acquiring other drug companies. *Id.*

42. BMS is one of the nation’s leading pharmaceutical manufacturers. BMS lost close to a billion dollars last year in its investment in a now flailing biotech company, and saw revenues decline 51% and 91% respectively on its top drugs BuSpar and cancer drug Taxol in 2001. *See Theresa Agovino, Expensive Deals, Lawsuits Cloud Bristol’s Future*, EVANSVILLE COURIER & PRESS, Jan. 26, 2002, at B6. Despite this, BMS’s net income increased 11% to \$5.24 billion in 2001, and its 2001 revenues increased to \$19.1 billion, though company officials expect 2002 to be a less profitable year. *Id.*

43. *See Mylan I*, 139 F. Supp. 2d at 29–30.

44. Though the *Mylan* Court was the first to approach the direct de-listing cause of action, the Federal Circuit has addressed the de-listing issue through a more indirect mechanism. In *Abbott Laboratories v. Novopharm Ltd.*, the Federal Circuit affirmed an order by the United States District Court for the Northern District of Illinois, which required that Abbott, the patentee, remove its principal patent from its Orange Book listing. 104 F.3d 1305, 1306 (Fed. Cir. 1997). Specifically, the court found that Abbott’s listing of a second patent for its popular hypertension drug was improper, because that patent had expired in 1995 and was not eligible for a term extension under the Uruguay Round Agreements Act. *Id.* at 1308–09. The defendants Novopharm and Geneva Pharmaceuticals, Inc. successfully moved for summary judgment that the patent had expired. *Id.* at 1307. Most interestingly, the district court ordered that Abbott request removal from the Orange Book with the FDA, noting that its judgment “ha[d] little effect without the change in listing.” *Id.* The Federal Circuit agreed with this analysis, and affirmed the order noting both that “[the district court] took the least intrusive action to

The dispute concerned BMS's anti-anxiety drug BuSpar, whose active ingredient is the compound buspirone hydrochloride.⁴⁵ BMS was granted a patent in 1980 covering the treatment of anxiety with buspirone.⁴⁶ BMS's term of exclusivity was set to expire at 11:59 p.m. on November 21, 2000.⁴⁷ As the FDA had "tentatively approved" Mylan's ANDA on a generic version of buspirone tablets,⁴⁸ a shipment of Mylan's generic product was set on trucks and set to ship beginning at 12:00 a.m. on November 22, 2000.⁴⁹

Just twelve hours prior to the expiration of BMS's exclusivity period, however, BMS was issued another patent, U.S. Patent No. 6,150,365 ("the '365 patent"),⁵⁰ "which [BMS] immediately delivered to the FDA for listing in the Orange Book [for BuSpar]."⁵¹

seek to enforce its judgment" in ordering Abbott to remove its listing and that "[w]hether the FDA would honor [Abbott's] request and whether it would approve [Novopharm and Geneva's] new drug applications was left to the FDA to determine." *Id.* at 1309.

45. Buspirone hydrochloride "is an Antianxiety agent . . . useful in treating the elderly, alcoholics, or people with a history of addiction," see <http://www.psyweb.com/Drughtm/buspar.html> (last visited Nov. 20, 2002), as it "is not chemically or pharmacologically related to the benzodiazepines, barbiturates, or other sedative/anxiolytic drugs." See <http://www.rxlist.com/cgi/generic/buspir.htm> (last visited Nov. 20, 2002).

46. U.S. Patent No. 4,182,763 (issued Jan. 8, 1980).

47. See *Mylan I*, 139 F. Supp. 2d at 8. Though receiving the buspirone patent in 1980, BMS obtained FDA approval for its product in 1986 and received a two-year extension to compensate for the delays in FDA approval. See *id.* at 7-8; see also *supra* note 14. BMS was later granted a six-month extension of exclusivity under the "pediatric exclusivity provisions of the FFDCA, 21 U.S.C. § 355a." *Id.* at 8. Under these provisions, a six-month extension of exclusivity may be granted following the expiration of a patent for a listed drug if pediatric studies are completed in accordance with a request by the Secretary. See 21 U.S.C. §§ 355a(a)(2)(B) (2000).

48. Because Mylan's ANDA contained a Paragraph III certification, which stated that it would not market its generic drug until the expiration of BMS's main '763 patent, the final approval of the ANDA was only contingent on the expiration of BMS's exclusivity period on November 22, 2000. See *Mylan I*, 139 F. Supp. 2d at 8.

49. See *id.*; see also *Lawsuits Hurt Mylan Customers, CEO Says*, *supra* note 41.

50. The Patent and Trademark Office ("PTO") issued the '365 patent so close to this deadline as the result of an expedited patent prosecution. See *Mylan I*, 139 F. Supp. 2d at 8 n.4. BMS filed the application on June 6, 2000, and gained "expedited issuance of the '365 patent by filing a 'petition to make special'" with the PTO. *Id.* As per BMS's request, the '365 patent was issued prior to November 22, 2000, though barely so. *Id.* Meanwhile, fifty million generic pills manufactured by Mylan were packed into cases in a Chicago warehouse awaiting approval—which never arrived. See Robert Langreth & Victoria Murphy, *Perennial Patents*, FORBES, Apr. 2, 2001, at 52.

51. See *Mylan I*, 139 F. Supp. 2d at 8.

The '365 patent had only one claim, and that was to a method of using a metabolite of buspirone to treat anxiety in mammals.⁵² The "11th-hour patent"⁵³ was immediately listed in the Orange Book, successfully preventing Mylan's scheduled shipment.⁵⁴

Mylan filed a Paragraph IV certification, and filed suit in federal court in the District of Columbia, naming both the FDA and BMS as defendants.⁵⁵ The district ruled in favor of Mylan, holding that "the stringent standard for obtaining a mandatory preliminary injunction" requiring de-listing of the '365 patent from the Orange Book was met.⁵⁶ The court found that Mylan was likely to succeed on the merits because the '365 patent did not "claim" a method of using BuSpar as per the statutory language of 21 U.S.C. § 355(b)(1); thus its generic did not infringe.⁵⁷ This holding was in conformity with the Federal Circuit's decision in *Hoechst-Roussel*

52. "A 'metabolite' is a new molecule created after an existing pharmaceutical agent breaks down in the body." *Id.* at 9 n.6. The active metabolite described in the '365 patent is "6-Hydroxy-8-[4-[4-(2-pyrimidinyl)-piperazinyl]-butyl]-8-azaspiro[4.5]-7,9-dione." *Id.* "A striking characteristic of degradative metabolism," that is, the body's breakdown of substances, "is that it converts a large number of diverse substances . . . to common [metabolites]." DONALD VOET & JUDITH G. VOET, *BIOCHEMISTRY* 414 (2d ed. 1995). As discussed *infra*, the Federal Circuit has clearly held that metabolite patents do not "claim" the listed drug.

53. The "11th-hour patent" terminology emerged in the media aftermath of *Mylan I* primarily to implicate improper, rather than proper, last minute patent listing. See, e.g., *BuSpar Case Seen as Catalyst for Pro-Generic Legislation*, *GENERIC LINE*, July 13, 2001, available at 2001 WL 15571243; *Analysts See Brand Makers Avoiding 11th-Hour Patents*, *GENERIC LINE*, Sept. 7, 2001, available at 2001 WL 15571290 (stating that analysts are beginning to respond to the regulators' view that 11th-hour patent filings are often ploys).

54. Mylan was then faced with the situation where it would have had to file a Paragraph IV certification, serve BMS with notice, and wait the 45 days to receive notice of patent infringement suit.

55. Danbury Pharmacal, Inc. ("Danbury"), another generic manufacturer with a pending ANDA for buspirone, "filed suit in the U.S. District Court for the District of Maryland. Like Mylan, Danbury sought an injunction ordering the de-listing of [BMS's] '365 patent from the Orange Book." *Mylan I*, 139 F. Supp. 2d at 10 & n.9. In its suit, Danbury named FDA commissioner Jane Henney as the sole defendant. *Id.* Danbury (by its owner Watson Pharmaceuticals, Inc.) lost its Maryland case on January 18, 2001. *Id.*; see also *Watson Pharm., Inc. v. Henney*, 194 F. Supp. 2d 442 (D. Md. 2001). Affirming the "ministerial" role of the FDA in patent disputes, the court ruled that it was "not the business of the FDA or of this [c]ourt . . . to adjudicate the merits of the scope and/or validity of the claims covered by the '365 patent." *Mylan I*, 139 F. Supp. 2d at 11 (citing *Watson* at 446).

Interestingly, Watson Pharmaceuticals, Inc. later reached a settlement with BMS resolving all of its disputes regarding buspirone for \$32 million. See *Reinventing Companies*, *MED AD NEWS*, June, 2002, at 37.

56. See *Mylan I*, 139 F. Supp. 2d at 29.

57. See *id.* at 18-19; see also text accompanying *supra* note 20.

Pharmaceuticals, Inc. v. Lehman,⁵⁸ which held that metabolite patents do not “claim” a method of using a drug.⁵⁹

Critically, the district court proceeded to analyze Mylan’s claim without analysis of whether Mylan had a valid cause of action for de-listing in the first place.⁶⁰ The court made its finding that BMS’s patent was likely improperly listed in the Orange Book while seemingly ignoring BMS’s argument that the FDCA does not allow for a private right of action for de-listing Orange Book patents.⁶¹ In granting Mylan’s preliminary injunction, generic BuSpar was

58. 109 F.3d 756 (Fed. Cir. 1997). The *Hoechst-Roussel* court held that “Congress chose to require that the patent, itself, claim the FDA-approved product or its use” and that Congress did not intend “claims” to have anything other than its “ordinary meaning from the patent law.” *Id.* at 761.

59. The *Mylan* court first found that the ‘365 patent did not claim the administration of buspirone, because BMS surrendered that subject matter during the patent’s prosecution. *See Mylan I*, 139 F. Supp. 2d at 15. Further, the court found that BMS did not refute Mylan’s showing that even if the administration was covered, the ‘365 patent did not cover the same method of using BuSpar that was approved by the FDA. *See id.* at 15. The district court concluded that Mylan was likely to succeed on the merits as suggested by the Federal Circuit. *See id.* at 29.

60. The court found that Mylan’s case met the “controversy” requirements of the Declaratory Judgment Act, and that jurisdiction existed under federal patent laws. *See id.* at 14–15. The test that the court used to determine whether a “controversy” exists in a patent case was twofold:

(1) whether the defendant’s acts create a “reasonable apprehension” on the part of the plaintiff that it will face an infringement suit or whether “the acts of the defendant indicate an attempt to enforce its patent;” and (2) whether acts of the plaintiff might subject it or its customers to a suit for patent infringement.

Id. Mylan was found to satisfy both factors of the test. *Id.*

The court further stated that jurisdiction existed because the suit was a “patent case” that inherently “arises under” federal patent laws. *See id.* at 16–17. It made this finding first by noting that the well-pleaded complaint rule must be applied, “not to the declaratory judgment complaint, but to the action that the declaratory defendant would have brought.” *Id.* at 16. The court then applied the following string of reverse logic: the action BMS would have brought was a claim for infringement of the ‘365 patent; a claim for infringement clearly “arises under” federal patent laws; thus, jurisdiction was proper. *Id.* at 14–16.

Although the court found that Mylan would not suffer irreparable harm if the injunction was not granted, it found that the lack of likely harm to BMS did not weigh heavily against injunctive relief, and further that the public interest in promoting generic access to buspirone outweighed any harm to industry incentives to develop new drug treatments in this case. Because the district court found that Mylan made “such a strong showing on three of the four preliminary injunction factors,” it granted the requested relief. *Id.* at 29.

61. *See id.* at 14.

cleared for market entry four months after BMS's buspirone patent had expired.⁶²

B. The Federal Circuit's Reversal—Mylan II

The Federal Circuit overruled the district court's decision on the basis that "improper listing" in the Orange Book is not a recognized defense to patent infringement.⁶³ Interestingly however, the court also stated that "[a]lthough this issue may be akin to an estoppel defense or an unenforceability defense for a patentee's inequitable conduct in prosecuting a patent in the Patent and Trademark Office, Mylan has not asserted any such link."⁶⁴ In addition, the court stated that the proposed Greater Access to Affordable Pharmaceuticals Act of 2001,⁶⁵ then and currently pending before Congress, "appears to recognize Mylan's cause of action."⁶⁶ This reinforced the Federal Circuit's conclusion that the cause of action was not available to Mylan.⁶⁷ Noting that "Congress only envisioned that recognized defenses could be raised in declaratory judgments in patent infringement actions,"⁶⁸ the court characterized Mylan's suit as an improper attempt to create a private "de-listing" cause of action under the FFDCA and reversed in favor of BMS.⁶⁹

62. See *supra* note 35 and accompanying text.

63. *Mylan II*, 268 F.3d 1323, 1331 (Fed. Cir. 2001). The Federal Circuit, like the district court, applied the well-pleaded complaint rule for analyzing a declaratory judgment action, which looks to the "action that the declaratory defendant would have brought" to determine which federal law is the basis of the action. *Id.* at 1330 (quoting *Speedco, Inc. v. Estes*, 853 F.2d 909, 912 (Fed. Cir. 1988)); see also *supra* note 57.

64. *Mylan II*, 268 F.3d at 1331.

65. S. 812, 107th Cong. (2001).

66. *Mylan II*, 268 F.3d at 1333.

67. See *id.*

68. *Id.* at 1332. After first making the mistake of filing its declaratory judgment action within the 45-day prohibited period imposed by 21 U.S.C. § 355(j)(5)(B)(iii), Mylan then provoked the court's holding by arguing that its claim was not an "action" with respect to § 355. *Id.* at 1331–32. The court balked: "An attempt, by ingenious pleading, to escape one principle of law by making it appear that another not truly appropriate rule is applicable appears to have been attempted." *Id.* at 1332–33 (quoting *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993)).

69. The Federal Circuit noted that its "conclusion that a declaratory judgment action to 'de-list' is unavailable under the patent laws does not preclude its jurisdiction [under 28 U.S.C. § 1338]." Jurisdiction was extended to Mylan's well-pleaded complaint because it established that relief depended on a resolution of a question of federal patent law. *Id.* at 1333 n.3.

C. Finally—Resolution on the Merits

While Mylan had filed its declaratory judgment suit in district court following the listing of the '365 patent, BMS filed a patent infringement suit in the United States District Court for the Southern District of New York against Mylan for its Paragraph IV certification.⁷⁰ When this suit, later entitled *In re Buspirone Patent Litigation*, was filed, the thirty-month stay was again triggered against Mylan.⁷¹

The district court granted a motion for summary judgment by Mylan and co-defendants, finding that the '365 patent does not cover uses of buspirone and that Mylan's ANDA and Paragraph IV certification did not infringe. The court found that the language of the '365 patent's claim supported the construction that buspirone was not covered,⁷² and further that the prosecution history of the '365 patent "le[ft] no doubt that the '365 [p]atent does not cover the use of buspirone."⁷³ Because of this, the district court here, like the district court in *Mylan I*, found that the '365 metabolite patent did not "cover" uses for BuSpar approved by the FDA.⁷⁴

Interestingly, not only did BMS lose on its infringement claim, but the court in *In re Buspirone Patent Litigation* also stated that the

70. See *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 340, 343 (S.D.N.Y. 2002) [hereinafter "*Buspirone I*"]. BMS's suit also named Watson Pharmaceuticals as co-defendants. Though both Mylan's suit and BMS's suit were filed within the forty-five day period imposed by 21 U.S.C. § 355(j)(5)(B)(iii), only BMS's action during this time period was proper. See *supra* note 68.

71. See *Buspirone I*, 185 F. Supp. 2d at 343. Likewise, Watson Pharmaceuticals's ANDA was also stayed. *Id.* It is unclear from the record, however, what effect this had on Mylan or overall generic buspirone availability, as the generic first hit the shelves in March 2001 after the United States District Court for the District of Columbia's decision in *Mylan I*. Though the FDA had the authority to reverse its ANDA approval after *Mylan II*, *supra* note 35, it is unclear whether it actually did so in light of the court's statement in *Buspirone I* that a stay was again triggered.

72. The court rejected BMS's interpretation that the claim referring to the systemic administration of a "dose" of the metabolite was the same as claiming a dose of buspirone into the body, because the specification in the '365 patent did not indicate any specialized meaning for "systemic administration," rather the "term . . . has a common and well-understood meaning in the medical community." See *Buspirone I*, 185 F. Supp. 2d at 353.

73. *Id.* at 355. The court found that BMS had clearly applied for a patent where the metabolite covered uses for buspirone (treating anxiety), but that "any reasonable view of the subsequent [prosecution] history indicates that [BMS] gave up a claim to the disputed uses of buspirone." *Id.* In the application that resulted in the '365 patent, BMS was found to have "clearly narrowed" its application by deleting all references to a use of "buspirone," because every time a use of "buspirone" had been made in an application, that application was rejected by the patent examiner. *Id.* at 357.

74. *Id.* at 359.

'365 patent would have been invalid if construed to cover buspirone as BMS wanted.⁷⁵ The court agreed with Mylan that according to the undisputed facts, the basic criteria for establishing invalidity would have been met because the '365 patent violated the on-sale bar.⁷⁶

V.

LISTING & LITIGATING—THE BALANCE OF EQUITIES HAS BEEN DESTROYED

What is plainly apparent from the two federal court decisions is that the '365 patent did not belong listed in the Orange Book in the first place, and it is quite possible that BMS knew it.⁷⁷ Aside from attorney's fees in defending Mylan's action in the district court for the District of Columbia and initiating and prosecuting its claims against Mylan in the Southern District of New York,⁷⁸ BMS lost nothing by the improper listing.⁷⁹ However, it gained \$100 million in sales by having its exclusivity wrongfully extended, even

75. *Id.* at 360.

76. The on-sale bar states:

A person shall be entitled to a patent unless . . . the invention was 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.

35 U.S.C. § 102(b) (2000).

The court stated that because buspirone has been on the commercial market since 1986 for treating anxiety—that is, since BMS received its FDA approval for BuSpar—and was thus “ready for patenting” in 1986, the “basic elements of an on-sale bar” would be present if the '365 patent were construed to claim a use for buspirone. *See Buspirone I*, 185 F. Supp. 2d at 359. Thus, under BMS's proposed claim construction, the '365 patent would be invalid. *Id.* 361.

77. In light of the Federal Circuit Court's apparently straightforward holding in *Hoechst-Roussel*, 109 F.3d 756 (Fed. Cir. 1997), it is unlikely that the applicability of the metabolite patent was vague. *See supra* note 58.

78. Aside from the four patent infringement claims brought by BMS in the Southern District of New York, that court also received twenty-two consolidated antitrust actions brought by Mylan, Danbury, and Watson regarding its monopoly on buspirone. *See In re Buspirone Antitrust Litig.*, 185 F. Supp. 2d 363, 365 (S.D.N.Y. 2002) [hereinafter “Buspirone II”]; *see also infra* notes 126–31 and accompanying text.

79. This is aside from public rapport, of course. The Stop Patient Abuse Now! (“SPAN”) organization, a coalition of over 125 organizations representing seniors, consumers, and patients, has become involved in “public campaigns” against BMS for “prop[ping] up high prices for its profits.” *See* www.spancoalition.org/index.htm (last visited Nov. 20, 2002). SPAN has diligently embarked on exposing BMS's “Strategy Of Deceit” in delaying availability of BuSpar, the cancer drug Taxol, and other drugs through media releases and demonstrations. *See id.*

while the four-month wrongful extension of BMS's exclusivity "reportedly cost consumers at least \$100 million."⁸⁰

Though the buspirone litigation only took four months away from Mylan and other ANDA applicants, in many cases the entire thirty-month stay will expire before a solution is achieved.⁸¹ It is also possible, absent a finding that the pioneer company does not comply with 35 U.S.C. § 355(j) (5) (B) (iii) to "reasonably cooperate in expediting the action," for a pioneer company to obtain a second thirty-month stay upon the listing of an additional patent.⁸²

80. See Scussa, *supra* note 1, at 54; cf. *BuSpar Ruling Casts Pall Over Brand Efforts to Protect Markets*, *GENERIC LINE*, Mar. 6, 2002 (\$160 million gained); Langreth & Murphy, *supra* note 50 ("analysts estimate that each year the generic [buspirone] is blocked, [BMS] gains at least \$350 million in revenues").

81. When Hatch-Waxman was first proposed, Congress reported that "the median time between the filing and disposition of a patent suit was 36 months [And] [o]ver ten percent of [those] cases took more than 77 months." See H.R. REP. NO. 98-857, pt.2, at 10 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2694. Since that time, the number of patent cases filed in district courts has greatly increased. In 1993 for example, only 1553 suits were commenced nationwide, while this number increased steadily to 2520 in 2001. See *Table C-2A, Judicial Business of the United States Courts 1997*, at http://www.uscourts.gov/judicial_business/contents/html (last visited Nov. 20, 2002); *Table C-2A, Judicial Business of the United States Courts 2001*, at <http://www.uscourts.gov/judbus2001/contents.html> (last visited Nov. 20, 2002).

This effect is demonstrated by the recent case, *Andrx Pharmaceuticals Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002). In *Andrx*, the (first) thirty-month stay on Andrx's ANDA approval was set to expire on February 25, 2001 or upon the date of judicial resolution. See *id.* at 1372. Andrx received a favorable decision on the merits by the Federal Circuit on February 13, 2001, only twelve days prior to the expiration of the stay. See *id.*

82. In *Andrx*, a second patent for an extended release formulation of the drug approved by the NDA was listed in the Orange Book on January 8, 2001. See *id.* at 1372. Andrx received notice from the FDA on February 2, 2001 that its ANDA would not be approved, and Andrx subsequently filed a declaratory judgment suit for non-infringement. *Id.* at 1373. A second thirty-month stay was triggered, set to expire this time on August 8, 2003. *Id.* at 1375. The Federal Circuit reversed the District Court's decision to shorten the stay, as the District Court's decision was based upon its opinion that the pioneer company's (Biovail's) "actions with regard to obtaining the [second patent] after tentative approval of Andrx's generic drug and changing the formulation of its own approved drug . . . to come within the newly obtained patent [was] done to impede or delay the expeditious resolutions of the patent [action]" between the two competitors. *Id.* at 1376 (quoting *Andrx Pharmaceuticals v. Biovail Corp.*, 175 F. Supp. 2d 1362, 1374 (S.D. Fla. 2001)). In so striking, the Federal Circuit held that allegedly improper conduct before the FDA was not proper basis for a district court to shorten a thirty-month stay, that the statute does not purport to only impose one thirty-month stay only for the original listed patent, and that the review of decisions may be obtainable under the Administrative Procedure Act. *Id.* at 1376-79.

In the end, Mylan's ANDA controversy took fifteen months to resolve judicially.⁸³ Although Mylan was apparently incorrect in bringing a direct action for de-listing the '365 patent, there is no indication that a declaratory judgment action for non-infringement under § 271(e)(2)(A) would have taken any less time to resolve than did BMS's infringement suit, as *In re Buspirone Patent Litigation* was filed within 45 days of BMS's receiving notice of Mylan's ANDA.⁸⁴ Though recognition of the de-listing cause of action could partially sidestep an in-depth judicial review of the claims of the patent in question, this proposition is speculative at best.⁸⁵

Thus even in the clearest and most obvious case of improper listing in the Orange Book, the pioneer company has nothing to lose and everything to gain by simply filing suit after receiving Paragraph IV notice and waiting. As the mechanics of the system thus greatly favor the pioneer companies, an alternative is desperately needed.

VI.

A BRIEF ECONOMIC PICTURE

The potential for abuse of the current system can only be appreciated when considering the extremity of the changes that the pharmaceutical market faces between now and 2005. Keeping in mind that generic drug sales typically account for around 50% of the total sales for a drug within the first six months of the generic's

83. The '365 patent was listed on November 21, 2000, and a decision of non-infringement was finally reached by the district court for the Southern District of New York on February 14, 2002. *Buspirone I*, 185 F. Supp. 2d 343, 363 (S.D.N.Y. 2002). As discussed above, it is somewhat unclear as to the total number of months that generic buspirone was unavailable to the public, though it is clear that the generic version was delayed market entry for four months. See *supra* note 62 and accompanying text.

84. 21 U.S.C. § 355(j)(5)(B)(iii) requires that a suit for infringement be brought within forty-five days of the notice of the ANDA. See *supra* notes 68 and 70.

85. If Mylan's case had been successfully brought as a de-listing action, application of the existing law established in *Hoechst-Roussel* to a basic scientific understanding of the '365 patent, i.e., that the patent claimed a buspirone metabolite, may have resulted in a faster decision than one of non-infringement. However, the district court for the Southern District of New York did not cite to *Hoechst-Roussel*, instead conducting an in-depth analysis of the scope of the '365 patent's claims and concluding that the claims did not cover any uses of buspirone. See *Buspirone I*, 185 F. Supp. 2d at 355–59. This demonstrates that a result of non-infringement could have been reached via several routes in this case, and that a direct de-listing cause of action, inherently invoking any of these available routes, may not result in a quicker verdict than would a non-infringement action.

availability,⁸⁶ the following list of pioneer drugs coming off patent and their annual earnings amply demonstrates the incentive and upcoming opportunities for Hatch-Waxman abuse.⁸⁷

Drug Brand Name	Pioneer Co.	Patent Expiration	Global Sales, 2001 (in Millions)
AXID	Eli Lilly	Apr. 2002	\$ 285
CLARITIN	Schering-Plough	Dec. 2002	3,159
INTRON A	Schering-Plough	Dec. 2002	1,447
RELAFEN	GlaxoSmithKline	Dec. 2002	Not Available
SINGULAIR	Merck & Co.	Feb. 2003	1,375
FLONASE	GlaxoSmithKline	Nov. 2003	726
FLOVENT	GlaxoSmithKline	Nov. 2003	1,317
ENGERIX-B	GlaxoSmithKline	Dec. 2003	641
DIFLUCAN	Pfizer	Jan. 2004	1,066
PARAPLATIN	Bristol-Meyers Squibb	Apr. 2004	702
XENICAL	Roche Laboratories	Jun. 2004	570
LAMISIL	Novartis Pharmaceuticals	Jul. 2004	832
LIPRON	Tap Pharmaceutical	Oct. 2004	833
LOVENOX	Aventis Pharmaceuticals	Dec. 2004	1,301
BIAXIN	Abbott Laboratories	May 2005	1,159
ZOFRAN	GlaxoSmithKline	Jun. 2005	865
PREVACID	Tap Pharmaceutical	Jul. 2005	2,951
AREDIA	Novartis Pharmaceuticals	Aug. 2005	752
ZOLADEX	AstraZeneca	Sep. 2005	728
PRAVACHOL	Bristol-Myers Squibb	Dec. 2005	2,173
ZOCOR	Merck & Co.	Dec. 2005	6,670
ZOLOFT	Pfizer	Dec. 2005	2,366
Total			\$31,918 million ⁸⁸

86. See Ron Winslow & Barbara Martinez, *Efforts to Switch Patients to Generic Prozac Advance*, WALL ST. J., Aug. 20, 2001, at A3.

In 2001, the sale of generics in the South American market rose 614.3%. See *Sale of Generics Rose 600% in 2001*, S. AM. BUS. INFO.: JORNAL DO COMMERIO, Apr. 12, 2002, 2002 WL 6784085. Exponential growth in particular markets, such as this one, may cause an increase in generics' early market performance in the next few years.

87. Table information from Scussa, *supra* note 1, at 54.

88. Adding into this figure the 2001 sales of popular antibiotics such as Augmentin (\$2,046 million—GlaxoSmithKline), Cipro (\$1,758 million—Bayer), and Zithromax (\$1,506 million—Pfizer) coming off patent by 2005, the total is \$37.228 billion dollars. *Id.* As discussed *supra*, the FDA does not permit Orange Book patent listings for antibiotics. See *supra* notes 37–38 and accompanying text. Thus, though these antibiotics' values greatly affect the overall market impact of

Compounding the pressures on pioneer companies facing these patent expirations is a dramatic increase in the cost of research and development (“R&D”) of new drugs. According to the Pharmaceutical Research and Manufacturers of America, \$26 billion was spent by its member companies on R&D in 2000, an increase of 10% from 1999.⁸⁹ This figure constitutes over 20% of the total revenues of these companies.⁹⁰ This breaks down to “an average [R&D cost] of \$500 million per drug.”⁹¹ The continuance of this trend increases the existing pressure on pioneer companies to recoup as much profit on their blockbuster drugs as possible,⁹² at the expense of companies’ incentive to proffer the investment into new and innovative medicines.

The overall market for generic drugs is expanding rapidly, and is expected to reach \$43 billion in 2003.⁹³ To make matters worse for pioneers, some insurance companies such as Blue Cross & Blue Shield are launching aggressive efforts to switch consumers from brand-name to generic drugs.⁹⁴ Insurance providers would be able to retain a much greater amount of their premiums as profit by expending less on costly brand-name prescriptions.⁹⁵

Pioneer companies do have an impressive arsenal of competitive tactics, including “new patents and new indications filings, adding time-release formulas to immediate-release medicines, manufacturing generics themselves, grassroots publicity campaigns against generics and lobbying for legislation state-by-state to inhibit

patent expiration, which will be felt by blockbuster patent applications, the author does not consider these drugs as contributing to the potential for Hatch-Waxman abuse.

89. See Al Heller, *Chains Anticipate New Growth in Generic Drugs’ Market Share*, DRUG STORE NEWS, Mar. 5, 2001, at 46, 2001 WL 13147129.

90. See *id.*

91. *Id.*

92. Though “[d]rug company profits as a percentage of revenue were slightly over 18 percent in 1999,” in comparison to the 5 percent profit percentage of other Fortune 500 companies that year, see *id.*, no profit is actually realized until drug companies compensate for R&D costs. See *id.*

93. This is a dramatic increase from the \$27 billion market value from 1998, and takes into account a whopping 9.8% projected annual growth rate for 2003. See Taren Grom, *Generics: Best Years to Come*, MED AD NEWS 1, Oct., 1999, at 2.

94. See David Barkholz, *Blues Plan’s Ad Campaign Touts Generic Drugs*, BUS. INS., Aug. 27, 2001, at 14.

95. For example, Blue Cross of Michigan “spends more than \$2 billion a year on prescription drugs, 75% of which goes for brand-name medications.” See Winslow & Martinez, *supra* note 86. According to Blue Cross, switching only an additional 3% of its customers’ prescriptions to generics in Michigan, for example, would reduce the Blue Cross’ expenditures by \$100 million. See *id.* Whether any of these savings would be passed on to consumers is a separate question.

competition from bioequivalent generic pharmaceuticals.”⁹⁶ The availability of these other competitive alternatives increases the already considerable benefit to closing the loophole created by the mechanism of thirty-month stay activation and reducing the potential for unfair and perhaps unethical competition. Though representatives from the Pharmaceutical Research and Manufacturers of America assert that only a small fraction of ANDAs have been contested by pioneer companies since 1984,⁹⁷ today’s changing market forces are likely to increase the potential for foul play.

VII.

THE CURRENTLY ENVISIONED SOLUTIONS: PENDING LEGISLATION, INEQUITABLE CONDUCT, MISUSE, ANTITRUST, AND UNFAIR COMPETITION

Currently, there is legislation pending which would reform the Hatch-Waxman Act in part, but this legislation does not propose any change or remedy to the imbalance in equities created by the thirty-month stay. Further, though the Federal Circuit hinted in *Mylan II* that the de-listing action issue “may be akin to an estoppel defense or an unenforceability defense for a patentee’s inequitable conduct in prosecuting a patent in the Patent and Trademark Office,”⁹⁸ the assertion of either of these defenses in a declaratory judgment action for non-infringement does not necessarily benefit the ANDA applicant in getting a patent de-listed from the Orange Book.

As an initial matter, there are substantive obstacles to be overcome before the defenses of inequitable conduct and misuse may be raised to successfully rebut a claim of infringement following a Paragraph IV certification. More importantly, however, inequitable conduct and misuse in their traditional senses are “shields” to patent infringement, not independent causes of action. Therefore, an ANDA applicant must proceed through the following stages prior to obtaining a decision on the merits: filing the Paragraph IV certification, filing a Declaratory Judgment Action for non-infringement in district court, waiting for the pioneer company to assert its coun-

96. Heller, *supra* note 89.

97. Jeff Trewitt, spokesman for the organization comprised of pioneer companies, asserts that 94% of the generic approvals since 1984 have been undisputed. See Scussa, *supra* note 1, at 55. Assuming that the number is correct, it remains unclear how many of these disputes have occurred in the last several years and whether they are becoming more frequent.

98. *Mylan II*, 268 F.3d 1323, 1331 (Fed. Cir. 2001); see also *supra* note 64 and accompanying text.

terclaim for patent infringement, asserting an affirmative defense to the infringement counterclaim, and then waiting for judicial resolution. In addition to the substantive difficulties in asserting these affirmative defenses, these alternatives do not address the problem of having to file suit and wait out resolution under the umbrella of the thirty-month stay.

Alternatively, there has been recent judicial recognition of antitrust liability for pioneer companies who improperly invoke the thirty-month stay. However, the better solution is one that not only deters improper listing at the outset, but one that better deals with the postural imbalance at the onset of the generic approval process.

A. *The Greater Access to Affordable Pharmaceuticals Act of 2001*⁹⁹

The Greater Access to Affordable Pharmaceuticals Act of 2001 (“GAAPA”) was introduced in the Senate in May of 2001,¹⁰⁰ with the hope of alleviating some of the barriers to generic drug access.¹⁰¹ The Federal Circuit in *Mylan II* stated that GAAPA proposes amending the forty-five day rule to allow a declaratory judgment action to be brought sooner.¹⁰²

However, the new bill does not explicitly mention allowing for a declaratory judgment, but allows for a similar action “to determine the legal status” of an Orange Book patent after one year has passed from the listing of the patent.¹⁰³ Although in some cases

99. S. 812, 107th Cong. (2001); H.R. 1862, 107th Cong. (2001).

100. GAAPA was introduced in light of the findings that enhanced competition between generic and brand-name manufacturers will be beneficial to the American public, and that Congress should take measures to effectuate the Hatch-Waxman amendments. See S. 812, § 2; see also Lawrence M. Sung, ‘Mylan’ Presents Setback for Generic Drug Makers, NAT’L L.J., Jan. 21, 2002, at C8.

101. GAAPA includes, among other things, a provision whereby the first generic company obtaining ANDA approval may in several ways forfeit its 180-day period of exclusivity, thus allowing for accelerated generic drug competition. See S. 812, § 3. Furthermore, the 180-day exclusivity period would only be awarded if the first ANDA contained a Paragraph IV certification and a patent infringement suit was filed. See *id.*

102. See *Mylan II*, 268 F.3d at 1333.

103. Section 6 of GAAPA proposes the following amendment to 21 U.S.C. § 355(j)(5):

(H) CIVIL ACTION TO DETERMINE LEGAL STATUS.—Notwithstanding any other provision of law, if information on a patent for a listed drug has been published under subsection (c)(2) for at least one year after the date on which an [ANDA] was filed under this subsection in relation to a listed drug, the person that filed the abbreviated application or the holder of the approved application for the listed drug may immediately bring a civil action to determine the legal status of the patent for the listed drug.

S. 812 §6(2)(H) (emphasis added).

this one-year delay may be inconsequential, under the statute eleventh-hour patents such as those in *Mylan* will remain effective at delaying ANDA approval, even if this provision is construed to have the same effect as a declaratory judgment action.¹⁰⁴

GAAPA does not propose a de-listing cause of action. Thus, even if GAAPA does become law, generic companies such as Mylan will still be limited to bringing declaratory judgment actions to determine the legal status of the pioneer patents just as they always have been, according to the traditional defenses to patent infringement.¹⁰⁵ As no additional relief from the thirty-month stay on ANDA approval is proposed, another approach is needed.

B. The Affirmative Defense Bases—Inequitable Conduct and Misuse

The Federal Circuit suggests an analogy between inequitable conduct in patent prosecution and inequitable conduct in listing patents in the Orange Book.¹⁰⁶ Inequitable conduct is an affirmative defense to patent infringement based upon the patent applicant's conduct during the patent application process. Such conduct may encompass a broad array of actions including "misrepresentation, a misleading statement, or even an omission."¹⁰⁷ Inequitable conduct is present where a material "nondisclosure or misrepresentation" occurred and "the patent applicant acted with the intent to deceive the PTO."¹⁰⁸ Aside from the common difficul-

104. See generally Sung, *supra* note 100. Though the bill aspires "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," eleventh-hour patenting seems to live on within the realm of the law. See S. 812 § 2(b)(2).

105. The provision entitled "Civil Action for Declaratory Judgment," S. 812 § 6(2)(G), and (2)(H) seem to merely codify the existing right to bring suit. See also *supra* note 103.

106. See *supra* note 64 and accompanying text; see also *Mylan II*, 268 F.3d at 1331.

107. See CHISUM, *supra* note 11, at § 19.03[2].

108. *Li Second Family Ltd. P'ship v. Toshiba Corp.*, 231 F.3d 1373, 1378 (Fed. Cir. 2000). A patent applicant is charged with a duty to disclose material information to the PTO based on the duties of "candor, good faith, and honesty." See *id.* A breach of this duty may be affected by "affirmative misrepresentations of material facts, failure to disclose material information, or submission of false information." *Id.* Intent does not need to be proven by direct evidence, as "direct proof of wrongful intent is rarely available but may be inferred from clear and convincing evidence of the surrounding circumstances." *Id.* at 1381 (citing *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1330 (Fed. Cir. 1998)). "Once the threshold levels of materiality and intent have been established, the trial court must weigh materiality and intent to determine whether the equities warrant a conclusion that inequitable conduct occurred." *Id.* at 1378.

ties in proving fraudulent intent, there is another problem with applying the inequitable conduct doctrine to the FDA listing process. That is, whereas the procurement of a patent necessitates an affirmative showing of novelty, utility, and non-obviousness,¹⁰⁹ the listing of a patent in the Orange Book requires nothing but a certification by the patent holder that the patent complies with 35 U.S.C. § 355(b)(1).¹¹⁰ The evidentiary burden that must be borne by the procurer is substantially different in these scenarios. Furthermore, it may be argued that there is a notable difference between the limited monopoly right granted by a patent and the duration of this right which is altered by an Orange Book listing.¹¹¹

For this analogy to work, “materiality” of the information withheld or procured in obtaining patent property rights would have to be analogous to “materiality” of the information submitted to the FDA for Orange Book listing. Despite the Federal Circuit’s suggestion, it may be somewhat hazardous to attempt to predict the success of the assertion of such a link due to these differences.¹¹²

Additionally, because inequitable conduct before the PTO presumably alters results in the awarding of patent rights where they otherwise would not be due, the traditional consequences of a finding of inequitable conduct can affect the patent rights themselves and do not simply punish the patent holder. Such consequences include the invalidity of the patent, unenforceability of the patent, and a suit for cancellation by the government.¹¹³ Even in a case

109. See 35 U.S.C. §§ 101–03 (2000).

110. See *supra* note 20 and accompanying text.

111. A patent holder is able to exclude all others “from making, using . . . [and] selling” his invention within the jurisdiction of the patent, and actually is given a monopoly over his invention for a limited time (twenty years from the date of filing). See 35 U.S.C. §§ 154(a)(1) & (2) (2000). Contrarily, a pioneer company listing a patent in the Orange Book is only enabled to assert a claim of infringement against a party; the listing itself does not create the rights to be asserted. See *supra* note 20 and accompanying text. At best, it may be argued that listing a patent in the Orange Book effectively extends the monopoly of the patent. However, it cannot be argued that the Orange Book listing itself establishes any monopoly rights in the first place.

112. As discussed *infra*, the United States District Court for the Southern District of New York has recently held that improper listing may constitute a higher degree of fraud than is necessary in establishing inequitable conduct. Though the decision is a positive one for generic companies, the author suggests that this line of reasoning may not ultimately prevail based on the aforementioned doctrinal differences.

113. Other possible consequences include “an award of attorney’s fees to a prevailing defendant in an infringement suit,” “liability for damages under the antitrust laws,” “recovery of prior royalties paid to the patentee,” “loss of attorney-client and work product privileges,” and “disciplinary action against an attorney or

where a pioneer company knowingly and intentionally lists a patent in the Orange Book that does not cover the listed drug, it does not follow that the patent rights themselves were procured by fraud. Although any of these judicial actions would discipline the pioneer company in the end, the fact that these remedies would be applied to rescind legal pre-conduct activity may further deter the finding that inequitable conduct may be successfully asserted in improper listing actions.

The affirmative defense of patent misuse, which relates primarily to actions that extend the economic effects of a patent beyond the patent's scope,¹¹⁴ may seem more applicable. Like an improper Orange Book listing, misuse relates to the wrongful use of patent rights to obtain an unfair commercial advantage, such as prohibiting production or sale of competing goods.¹¹⁵ However, as an affirmative defense, the misuse doctrine offers little valuable remedy.

As in the case of successful assertion of the inequitable conduct defense, the ANDA-counter-defendant could possibly successfully assert misuse and effectuate a finding that the Orange Book patent

agent registered to practice before the Patent and Trademark Office." See CHISUM, *supra* note 11, at § 19.03[6]. However, only in a case where the "misconduct . . . rises to the level of common law fraud and [would] support an antitrust claim" will such requests be considered reasonable. See *Argus Chem. Corp. v. Fibre Glass-Evercoat Co.*, 812 F.2d 1381, 1387 (Fed. Cir. 1987) (Nies, J., concurring). Antitrust claims are discussed *infra* Part VII.C.

114. The successful assertion of misuse requires that an alleged infringer show that the patent holder has "impermissibly broadened the 'physical or temporal scope' of the patent grant with anticompetitive effect." *Virginia Panel Corp. v. Mac Panel Co.*, 133 F.3d 860, 868 (Fed. Cir. 1997) (citing *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001 (Fed. Cir. 1986)). If a practice is deemed to so extend the patentee's rights, "the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Virginia Panel*, 133 F.3d at 869 (citing *State Oil Co. v. Khan*, 118 S. Ct. 275, 279 (1997)). This is called a "rule of reason" analysis. See *id.*

115. The three classic acts of misuse are: "(1) requiring the purchase of unpatented goods for use with patented apparatus or processes, (2) prohibiting production or sale of competing goods, and (3) conditioning the granting of a license under one patent upon the acceptance of another and different license." See CHISUM, *supra* note 11, at §19.04[3]. These elements are common to misuse as an affirmative defense (the "shield") and as an independent action under the antitrust laws (the "sword"). Misuse itself is not an independent cause of action. See *infra* note 117. However, an antitrust action may lie based on these same elements in certain circumstances. See *infra* Part VII.C.

was unenforceable against it.¹¹⁶ However, there is no remedy for damages as the result of patent misuse.¹¹⁷ In addition, the assertion of the defense only addresses the nature of the use of the patent and not its substance. Thus, the merits of the pioneer company's assertion that the production, use, and sale of a generic drug infringes its Orange Book patents, contrary to an ANDA's Paragraph IV certification, are never addressed. For these reasons, the misuse defense offers little relief to generic companies pinned down under the thirty-month stay.

C. *The Antitrust Cause of Action*

There is great breadth to the doctrine of misuse and only the highest offenses within the spectrum of misuse will amount to an antitrust violation.¹¹⁸ Because there is no independent tort of misuse,¹¹⁹ the boundary between misuse and antitrust behavior is significant in assessing the options of a generic manufacturer in pursuing relief from the thirty-month stay.

When Mylan filed its ANDA with the FDA, it presumably already knew or suspected that BMS's '365 patent was improperly listed. Thus it follows that companies such as Mylan would assert that the pioneer company is using its patent to unfairly extend its monopoly rights, and unfairly enforce those rights by contesting the Paragraph IV certification and eventually bringing suit for infringement. However, differentiations between legitimate patent

116. However, contrary to a finding of inequitable conduct, the unenforceability derived from misuse only lasts until the misuse is purged, "[s]uch purging occurs upon abandonment of the abusive practice and dissipation of any harmful consequences." CHISUM, *supra* note 11, at § 19.04.

117. See *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1427 (Fed. Cir. 1997) (stating that the misuse defense renders a patent unenforceable until the misuse is purged, but it does not result in a damages award). It has been established that patent misuse is not an actionable tort, as misuse

developed as an equitable doctrine to provide an equitable defense . . . [and] [t]hat the doctrine does not create an independent cause of action for the alleged infringer is implicit in the black letter statement of the effect of finding patent misuse: Misuse of a patent merely suspends the owner's right to recover for infringement of a patent.

CHISUM, *supra* note 11, at §19.04[4] (internal quotations omitted).

118. See DONALD S. CHISUM ET AL., *PRINCIPLES OF PATENT LAW* 1096 (2d ed. 2001). There are in fact two different types of patent misuse corresponding to two different levels of anticompetitive behavior: "(1) an antitrust violation that is significantly related to the patent; and (2) an act whereby the patentee sought to extend the patent beyond the original scope of its grant, not necessarily amounting to an antitrust violation." See Katherine E. White, *A Rule for Determining When Patent Misuse Should be Applied*, 11 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 671, 677 (2001).

119. See *supra* note 117.

enforcement, wrongful use, and anticompetitive behavior giving rise to an antitrust cause of action complicate the inquiry as to how this action may be classified.¹²⁰

Section 3 of the Patent Misuse Reform Act, 35 U.S.C. § 271(d)(3), provides that “[n]o patent owner otherwise entitled to relief from infringement or contributory infringement of a patent shall be . . . deemed guilty of misuse . . . by reason of his having . . . sought to enforce his patent rights against infringement or contributory infringement.”¹²¹ Because the listing of a patent in the Orange Book, contesting a Paragraph IV certification, and triggering the thirty-month stay are forms of protection against infringement by the pioneer company, it would seem that no cause of action would be available.¹²²

In accord with the statute, the filing of suit in good faith has traditionally been found not to constitute a violation of the antitrust laws, or even patent misuse.¹²³ However, there are two important exceptions to this rule. First, an antitrust plaintiff may prove that the asserted patent was obtained through willful and knowing fraud within the meaning of *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*¹²⁴ *Walker Process* fraud, in contrast to common law fraud, requires independent and clear evidence of deceptive intent as well as a clear showing of reliance.¹²⁵ As a reflection of this high threshold, treble damages may be recovered for

120. For a basic discussion of the traditional interaction between antitrust principles and the monopoly-creating patent system, see Robert P. Taylor & Bradford E. Biegon, *Antitrust Issues in the Enforcement of Patents and Copyrights*, in INTELL. PROP. ANTITRUST 1999, at 731–37 (PLI Pat., Copyright, Trademarks, & Lit. Prop. Course, Handbook Series No. G0-005M, 1999).

121. 35 U.S.C. § 271(d)(3) (2000).

122. The statute reflects the public policy that a patentee should be able to freely enforce his patent right against potential infringers. See, e.g., *Duplan Corp. v. Deering Milliken, Inc.*, 444 F. Supp. 648, 701 (D.S.C. 1977), *aff'd in part and rev'd in part* by *Duplan Corp. v. Deering Milliken, Inc.*, 594 F.2d 979 (4th Cir. 1979) (stating that “[p]atents would be of little value if infringers of them could not be notified of the consequences of infringement or proceeded against in the courts”).

123. See CHISUM, *supra* note 11, §17.05[3]. Contrarily, bad faith patent infringement suits may constitute an antitrust violation. See *infra* note 127 and accompanying text.

124. 382 U.S. 172, 177 (1965); see also *Glass Equip. Dev. Inc. v. Besten, Inc.*, 174 F.3d 1337, 1343 (Fed. Cir. 1999). As with all fraud claims, particularity is required in plaintiff’s fraud pleadings in accordance with FED. R. CIV. P. 9(b).

125. See *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070–71 (Fed. Cir. 1998) (noting that “[a] finding of *Walker Process* fraud requires higher threshold showings of both intent and materiality than does a finding of inequitable conduct,” such as a showing that “the patent would not have issued but for the misrepresentation or omission”). This “rigorous standard of deceit” re-

the successful assertion of *Walker Process* fraud and a corresponding violation of Section 2 of the Sherman Act.¹²⁶

Alternatively, an antitrust plaintiff may demonstrate that the patent infringement suit was “a mere sham to cover what is actually no more than an attempt to interfere directly with the business relationships of a competitor.”¹²⁷ Though traditionally bad faith was the determinative inquiry,¹²⁸ the Federal Circuit has recently reiterated its position that “an antitrust defendant’s subjective motivation is immaterial” if the patent infringement lawsuit is not “objectively baseless.”¹²⁹ A suit is objectively baseless if “no reasonable litigant could realistically expect success on the merits,” that is, if no objective party could find that the suit is “reasonably calculated to elicit a favorable outcome.”¹³⁰ Thus, even in a clearer case of patent inapplicability such as *Mylan*, an assertion that a pioneer company listed a patent in the Orange Book in order to wrongfully assert its patent rights for anticompetitive purposes must pass an extremely high hurdle before an antitrust action can lie.

After either exception to § 217(d)(3) is proven, the antitrust plaintiff must also prove a violation of section 2 of the Sherman Act in order to establish its claim.¹³¹ *Walker Process* and sham litigation claims are “extremely difficult to plead and prove,” and for that

quires “clear, convincing proof of intentional fraud involving affirmative dishonesty.” *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1364–65 (Fed. Cir. 1998).

126. Treble damages may be awarded under Section 4 of the Clayton Act. *See Walker Process*, 382 U.S. at 174, 177.

127. *Glass Equip. Dev.*, 174 F.3d at 1343. These types of decisions are commonly referred to as “Handgards” decisions, following the Ninth Circuit’s decision in *Handgards, Inc. v. Ethicon, Inc.*, which explained that “the requirement of bad faith litigation easily affords the equivalent of the sham exception.” 743 F.2d 1282, 1294 (9th Cir. 1984).

128. *See Handgards*, 743 F.2d at 1294.

129. *Nobelpharma AB*, 141 F.3d at 1072; *see also* *Baltimore Scrap Corp. v. David J. Joseph Co.*, 237 F.3d 394, 399 (4th Cir. 2001).

130. *Prof’l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993).

131. Section 2 of the Sherman Act states that “[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony” 15 U.S.C. § 2 (2000). To determine whether a patentee has met the elements of § 2, it is “necessary to appraise the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved.” *Walker Process*, 382 U.S. at 177. *See also* *Abbott Labs. v. Brennan*, 952 F.2d 1346, 1354–55 (Fed. Cir. 1991) (stating that the determination “is governed by the rules of application of the antitrust laws to market participants, with due consideration to the exclusivity that inheres in the patent grant”).

reason have been “extremely unsuccessful before the courts.”¹³² Despite these obstacles, there is evidence that an antitrust action based on wrongful initiation of the thirty-month stay may not be without merit.

In the recent decision *Andrx Pharmaceuticals Incorporated v. Biovail Corporation International*,¹³³ the United States Court of Appeals for the District of Columbia held that an agreement to withhold generic competition may not enjoy antitrust immunity.¹³⁴ In this case, Andrx signed an agreement with Hoechst Marion Roussel, Inc. (“Hoechst”), the manufacturer and patent holder of the brand name drug Cardizem CD.¹³⁵ Andrx had previously submitted an ANDA for a generic version of the drug, and Hoechst initiated an infringement suit in response to Andrx’s Paragraph IV certification.¹³⁶ In their contract, Andrx agreed not to sell their generic drug until the conclusion of Hoechst’s infringement suit against it, even after the thirty-month stay had expired.¹³⁷ Because Andrx never began selling its generic drug, it never forfeited its 180-day period of exclusivity and other generic manufacturers were unable to sell generic Cardizem CD as well.¹³⁸ The court held that the District Court’s dismissal of Biovail’s action with prejudice was erro-

132. David R. Steinman & Danielle S. Fitzpatrick, *Antitrust Counterclaims in Patent Infringement Cases: A Guide to Walker Process and Sham-Litigation Claims*, 10 TEX. INTELL. PROP. L. J. 95, 99, 108 (2001). From 1985 to 1993, “only two out of twenty-five cases in which *Walker-Process* claims were finally adjudicated were successful.” *Id.* at 99 n.22. From 1993 to 2001, “only one case . . . found liability for a *Walker Process* claim.” *Id.* (referencing *Nobelpharma*, 141 F.3d 1059 (Fed. Cir. 1998)).

133. 256 F.3d 799 (D.C. Cir. 2001).

134. *See id.* at 809–10.

135. Cardizem CD “consists of a once-daily dosage of the chemical compound diltiazem hydrochloride [and] is widely prescribed for treatment of chronic chest pains (angina) and hypertension and for the prevention of heart attacks and strokes.” *Id.* at 803.

136. *See id.*

137. *See id.*

138. In 1997, Biovail filed an ANDA for generic Cardizem CD, following Andrx in 1996. *See id.* The agreement lasted one year, and Andrx was given \$40 million (\$10 million per quarter) to refrain from generic production. *See id.* These types of agreements are not rare in the industry. Recently, the FTC itself has challenged several agreements between pioneer and generic drug companies that have allegedly delayed or attempted to delay generic competition, charged companies with monopolization or attempted monopolization, and launched an investigation into the business relationships between pioneer and generic drug companies in an attempt to curtail the growing problem. *See generally Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements Before the Committee on the Judiciary United States Senate* (May 24, 2001), attached as Exhibit D to Lorman, *supra* note 35, at 449–50 (discussing the agreements challenged by the FTC and ongoing litigation thereon).

neous,¹³⁹ because the “agreement not to trigger the running of [Andrx’s] 180-day exclusivity period” does not enjoy antitrust immunity.¹⁴⁰

Though this case involved a potential abuse of the 180-day exclusivity period by the generic manufacturer and not an abuse of the thirty-month stay by the pioneer company, the *Andrx* decision demonstrates that antitrust actions may lie within what seems to be a *prima facie* legal use of the FDA’s drug approval mechanism.

In yet another recent development in the BuSpar litigation, the United States District Court for the Southern District of New York has taken this concept even further, by denying BMS’s motions to dismiss antitrust claims brought by Mylan for improper Orange Book listing.¹⁴¹ Though the court recognized that Mylan and Watson could have but did not plead that the ‘365 patent was *procured* by *Walker Process* fraud, it recognized that the plaintiffs pled sufficient facts to allege that BMS engaged in “fraud on the FDA by submitting information on the ‘365 patent and claiming that the Patent covered the approved uses of buspirone, when [BMS] knew that these statements were false.”¹⁴² Though BMS argued that its conduct was not *objectively baseless*,¹⁴³ this argument was not given weight.¹⁴⁴

In recognizing that “the FDA’s [listing] actions are non-discretionary” and that the FDA “has no expertise . . . much less any statutory franchise . . . to determine matters of substantive patent law,”

139. *Andrx*, 256 F.3d at 808.

140. *Id.* at 810, 819.

141. *See Decision of Interest*, N.Y.L.J., Mar. 7, 2002, at 25 (documenting *In re* Buspirone Patent Litigation, MDL-1410 opinion and order denying BMS’s motions to dismiss).

142. *See id.* at Part II.B.

143. *See supra* notes 129-30 and accompanying text.

144. The court stated that the appropriate inquiry is whether the improper listing conduct may be deemed “petitioning activity” for determining whether antitrust immunity exists in this context. *See Decision of Interest*, *supra* note 141, at pt. II. Petitioning activity is a request for governmental action, or conduct aimed at convincing the government of a position. *Id.* The court iterated that “[i]t is critical to distinguish between activities in which the government acts or renders a decision only after an independent review of the merits of a petition and activities in which the government acts in a merely ministerial or non-discretionary capacity in direct reliance on the representations made by private parties.” *Id.* A reason for extending immunity to antitrust defendants’ petitioning activity exists because the anticompetitive effects in question were only obtained after the government was convinced of the merits of the action. *Id.* The court stated that BMS’s listing conduct was not petitioning activity, but that their decision was independent of this finding. *Id.*

the court rationalized that "listing is much more like the filing of a tariff than the kind of conduct through which private parties seek to influence governmental decision making and that has traditionally been immunized" from antitrust liability.¹⁴⁵ Because of these risks of abuse involved in the listing process, the court established that the *Walker Process* goals of keeping patent monopoly rights within their legitimate scope are preserved in holding that improper-listing defendants must not enjoy immunity to antitrust liability.¹⁴⁶

Should the law progress in this direction of equating fraud on the FDA with fraud on the PTO,¹⁴⁷ the *Walker Process* cause of action (and the treble damages award it brings) will be a successful deterrent for pioneer companies to improperly list patents.¹⁴⁸ However, and regardless of its continued future success,¹⁴⁹ this route is only one of two efficient deterrents. The antitrust route may effectuate punishment for *abuse* of the FDA approval regime. Due to the great imbalance in power between the pioneer and generic companies from the outset, created by the authority to impose the thirty-

145. *See id.* at pt. II.A.

146. *See id.* at pt. II.B. ("Hence, even if listing were petitioning [activity], the Walker Process exception would apply to [BMS]'s alleged conduct in this case."). The Federal Trade Commission is in accord with this decision. *See FTC: Antitrust Rules Should Apply to Orange Book Filings*, GENERIC LINE, Jan. 25, 2002, 2002 WL 9869356; *FTC Sides Against Bristol-Myers Squibb in BuSpar Antitrust Case*, DRUG MARKETING, January 23, 2002, 2002 WL 9864372; Gardiner Harris, *FTC is Opposing Bristol-Myers Stance in Generics Suit*, WALL ST. J., Jan. 10, 2002, at B6.

147. For reasons discussed *supra* notes 106-13, this equation may not necessarily be affirmed.

148. *See supra* note 126 and accompanying text. Mylan's lawyers believe that the \$160 million that BMS gained in the delay of generic BuSpar will not be enough to cover BMS's costs if it is found guilty of antitrust violations. *See BuSpar Ruling Casts Pall Over Brand Efforts to Protect Markets*, *supra* note 80. It is speculated that BMS's potential antitrust liability could reach hundreds of millions of dollars. *See Paula L. Stepankowsky, Anxiety Drug is Expected to Get Cheaper in Wake of Ruling on Bristol-Myers Patent*, WALL ST. J., Feb. 21, 2002, at B13.

149. In a critical Federal Circuit decision, *In re Independent. Service Organizations Antitrust Litigation*, CSU, L.L.C. v. Xerox Corp. ("Xerox"), the court held that absent any "illegal tying [(utilizing a patent monopoly to further another monopoly on non-patented goods)], fraud in the [PTO], or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling" his invention. 203 F.3d 1322, 1327 (Fed. Cir. 2000). The Supreme Court denied certiorari. CSU, L.L.C. v. Xerox Corp., 531 U.S. 1143 (2001). In light of the narrowness of the antitrust "exception" to these patent rights as iterated in *Xerox*, and despite the favorable position of the FTC, the author suggests that though alternate routes may be applied by the lower courts, these new causes of action may not ultimately stand.

month stay, a mechanism for better balancing these equities must be in place at the beginning: the *use* of the listing process.

D. Anticompetitive Conduct—Unfair Competition

While the antitrust cause of action is designed to protect overall competition in the marketplace amongst many competitors, the commercial tort of unfair competition is designed to keep in check the continued prosperity of one specific competitor.¹⁵⁰ Section 45 of the Federal Trade Commission Act (“FTC Act”) declares “unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce . . . unlawful.”¹⁵¹

“Unfair competition” is extremely difficult to define, and its meaning is fluid and often refined on a case-by-case basis by lawyers and judges.¹⁵² Generally speaking, the elements of an action of unfair competition are: the existence of “a representation, omission, or practice that . . . is likely to mislead consumers acting reasonably under the circumstances . . . [and] the representation, omission, or practice is material.”¹⁵³ Some courts have added that unfair competition requires consumer injury, which may be established by the FTC by a showing that “consumers were injured by a practice for which they did not bargain.”¹⁵⁴

150. See 15 U.S.C. § 45(a)(2) (2000) (“The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations . . . from using unfair methods of competition . . . [as described]”).

The FTC Act does not provide for a private right of action. See, e.g., *Holloway v. Bristol-Myers Corp.*, 485 F.2d 986, 988–89 (D.C. Cir. 1973). States have enacted their own unfair competition statutes, which do contain private rights of action. See, e.g., 73 PA. STAT. ANN. tit. 73, § 201–1 (West 2002). This author doubts that an unfair competition action, based on improper listing of a patent with the FDA, a federal branch of government, would stand under state unfair competition laws.

151. 15 U.S.C. § 45(a)(1) (2000).

152. See, e.g., 1 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 1:8 (4th ed.) (1996) (including a lengthy discussion of the abstract concept of unfair competition claims and difficulty in forming a precise test at law).

153. *FTC v. Gill*, 265 F.3d 944, 950 (9th Cir. 2001) (internal citations omitted); *FTC v. Five-Star Auto Club, Inc.*, 97 F. Supp. 2d 502, 526 (S.D.N.Y. 2000); *FTC v. P.M.C.S., Inc.*, 21 F. Supp. 2d 187, 190 (E.D.N.Y. 1998).

154. *FTC v. J.K. Publ’ns, Inc.*, 99 F. Supp. 2d 1176, 1201 (C.D. Cal. 2000). The court in *JK Publications, Inc.* also stated that “[i]njury may be sufficiently substantial if it causes a small harm to a large class of people,” such as the injury unavailability of a generic drug alternative may produce in the ANDA context, and that an unfair practice “produces clear adverse consequences for consumers that are not accompanied by an increase in services or by benefits to competition,” which is clearly the case with any Orange Book listing. *Id.*

The FTC has long taken the position that “conduct may constitute ‘unfair competition’ under FTC Act § 5 even if it does not violate other antitrust laws.”¹⁵⁵ It would appear then that the tort of unfair competition would encompass improper Orange Book listing for the purpose of unlawfully extending patent profits.¹⁵⁶ As the FTC Act gives the FTC the authority to obtain injunctive relief against an offender,¹⁵⁷ such a remedy could encompass ordering that the patentee request removal of the patent from the Orange Book so that the FDA may proceed in approving pending ANDAs.¹⁵⁸

Perhaps not suprisingly, the FTC has in fact very recently involved itself in the improper Orange Book listing context. In a complaint dated April 23, 2002, the FTC alleged that Biovail Corporation (“Biovail”) illegally acquired an exclusive patent license and then wrongfully listed that patent in the Orange Book.¹⁵⁹

The Biovail fact pattern imitated somewhat the *Mylan* situation in the “eleventh hour patenting” respect. Andrx, a generic manufacturer, was in 1998 the first ANDA applicant for Tiazac, a chest

155. See David S. Copeland, *An Overview of Antitrust Enforcement and an Introduction to the Antitrust Laws Regarding Relationships Among Competitors*, in BASIC ANTITRUST LAW, at 19 (PLI. Corp. Law. & Practice Course, Handbook Series No. B4-7083, 1994). This position was derived from *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 239–44 (1972), and its progeny. See *id.* See also MCCARTHY, *supra* note 152, at § 1:24.

156. In the past, FTC allegations of anticompetitive conduct in the pharmaceutical industry were mainly complaints of illegal payments made to generic companies to delay generic drug availability. In the past, pioneer companies have been accused of paying off the first ANDA applicant for a generic version of their drug, as generic availability by all manufacturers can be delayed if the first ANDA applicant never starts running its 180-day exclusivity period by actually marketing their generic drug. See, e.g., Press Release, FTC, Administrative Law Judge Dismisses FTC Allegations of Anticompetitive Conduct by Schering-Plough and Upsher-Smith (July 2, 2002), available at www.ftc.gov/opa/2002/07/schering.htm.

157. See 15 U.S.C. §45(a)(2) (2000) (“The Commission is hereby empowered and directed to prevent persons . . . from using methods of unfair competition . . .”) (emphasis added); see also 15 U.S.C. § 53(a) (2000) (authorizing the FTC to seek injunctive relief to restrict the dissemination of false advertising).

158. This remedy is exactly the kind of relief that the court ordered in *Abbott Labs. v. Novopharm Ltd.*, 104 F.3d 1305 (Fed. Cir. 1997), after finding that the patent in that case was improperly listed because it had expired. The validity of this option, and thus an analogy between a district court order and an order by the FTC following a favorable decision by an administrative law judge, is thus bolstered by the *Abbott* decision.

159. See Press Release, FTC, Wrongful “Orange Book” Listing Raises Red Flag with FTC; Leads to Consent Order with Biovail Corp. Concerning its Drug Tiazac (Apr. 23, 2002), available at www.ftc.gov/opa/2002/04/biovailtiazac.htm (announcing the filing of the complaint).

pain and high blood pressure medication patented by Biovail. After Andrx submitted its Paragraph IV certification, Biovail commenced an infringement suit, triggering the thirty-month stay. Andrx obtained a favorable district court ruling in September 2000 and its ANDA was tentatively approved. However, prior to its market entry, Biovail acquired an exclusive license for an additional patent (U.S. Patent 6,162,463, the “‘463 patent”) covering Tiazac from a New Jersey manufacturer, and listed the new patent in the FDA’s Orange Book for Tiazac.¹⁶⁰ Andrx was unable to procure a license itself, as Biovail obtained exclusive license rights. Andrx in the meanwhile led a second Paragraph IV certification, and was again sued by Biovail, triggering a second thirty-month stay in January 2001.

The FTC alleged that Biovail’s conduct in obtaining the exclusive rights to the ‘463 patent, and then listing it in the Orange Book in order to receive the benefits of an additional thirty-month stay, was unfair marketplace competition.¹⁶¹ Its proposed consent order required that Biovail divest some of its exclusive rights to the ‘463 patent back to the New Jersey manufacturer, and that Biovail would thereafter be “prohibited from taking any action that would trigger any statutory stays on final FDA approval of a generic form of Tiazac, and [be] prohibited from wrongfully listing any patents in the Orange Book for a product for which the company already has an FDA-approved NDA.”¹⁶²

Despite best efforts and perhaps legitimacy in this route of action, it is doubtful whether the FTC will be successful in its unfair competition claims.¹⁶³ The unfair competition claim is most often

160. Biovail later submitted a declaration to the FDA stating that the new patent was eligible for listing in connection with Tiazac. The FTC contends that this was misleading because Biovail did not clarify whether the patent was used for FDA-approved Tiazac or a version of Tiazac that did not yet have approval; likewise the patent actually covered the newer and unapproved version and was not applicable to the approved Tiazac’s Orange Book entry.

161. Specifically, the complaint alleged that Biovail’s exclusive license constituted an unlawful asset acquisition in violation of Section 7 of the Clayton Act and Section 5 of the FTC Act, and that Biovail violated the FTC Act by engaging in activity to willfully maintain its monopoly on Tiazac.

162. Additionally, the proposed order contains “certain reporting and other standard FTC monitoring provisions to help the Commission ensure that Biovail fully complies with its terms.”

163. In a report dated July 29, 2002, the FTC has also urged Congress to amend Hatch-Waxman to redact the thirty-month stay provision altogether, and supported a proposal by Senator Patrick Leahy (Dem. Vt.) to prevent pioneers from paying the first ANDA applicant to refrain from starting the clock on its 180-day exclusivity period. See Press Release, FTC, FTC Recommends Legislative

premised on the finding that the representation, omission, or practice is “deceptive” and “material.”¹⁶⁴ As patents have a presumption of validity, and as that validity may be asserted against potential infringers in order to protect those rights,¹⁶⁵ it may be difficult to draw a distinction between bona fide listing and “deceptive” or unfair listing of a patent in the Orange Book.

In hindsight, it may be apparent that a patent’s claims do not cover the drug for which it is listed; such was the case in *Mylan*. However, to make the jump to “deceptiveness” in such a listing may present a challenge.

Because there is no “intent” requirement in unfair competition, the claim depends on the resolution of the truth of the matter asserted, i.e. actual deceptiveness. Where a business owner makes false statements about its business, for example, the deception aspect of the unfair competition claim is easily disposed with; it is easy in that case to tell whether the statement is true or untrue in fact. However, with Orange Book patent listing, there is no way to tell if the claims do or do not cover the drug (i.e., are deceptive) *as a matter of fact*, because the scope of the claims must be determined *as a matter of law* by the district court after presentation of evidence. Inherently, an unfair competition claim can only lie after a judgment of non-infringement in the district court, and thus, the possibility of utilizing the thirty-month stay for “improper” purposes at the beginning of the generic drug approval process is unthwarted.

Though there may be redress in the mechanism of an unfair competition claim, any mechanism for re-balancing the equities between the pioneer and generic manufacturer *after* the end of the thirty-month stay and judicial resolution of the merits is not a preferred solution, as it does not close the improper listing loophole. Any such judicial solution occurs after a great expense to the generic manufacturer—an expense that may be significant enough to serve as a motivation for pioneer companies to improperly list patents regardless of any later liability in suit. For this reason, a system whereby the equities are kept in check from the beginning of the generic drug approval process is preferable. By eliminating “after-

Changes to Hatch-Waxman Act (July 30, 2002), *available at* <http://www.ftc.gov/opa/2002/07/genericdrugstudy.htm>. Although this author contends that eliminating the stay is too harsh an alternative to pass muster, the FTC’s battle-ready stance will surely catalyze legislative change on perhaps a more intermediate level—perhaps in ways akin to this author’s proposed remedy of the thirty-month stay bond requirement. See *infra* Part VIII.

164. See *supra* note 153 and accompanying text.

165. See *supra* note 5 and accompanying text.

the-fact” re-balancing of the parties’ respective positions, the possibility of encountering irreversible damage to the generic manufacturer is avoided.

VIII. PROPOSED REMEDY: THE THIRTY-MONTH STAY BOND REQUIREMENT

A. *The Preliminary Injunction Model*

A preliminary injunction is an order that prevents an alleged patent infringer from continuing its infringing activities until the resolution of an infringement suit filed by the patent holder. The purpose of a preliminary injunction is to protect a patent owner’s rights during the course of a patent infringement suit.¹⁶⁶ In order for a district court to order a preliminary injunction, the patent holder must demonstrate that the following four equitable factors are present, namely: “(1) likely success on the merits . . . ; (2) irreparable harm [to the movant-patentee] absent an injunction; (3) that the balance of hardships favors granting the injunction; and (4) that public policy favors granting the injunction.”¹⁶⁷ None of these factors, “taken individually, are . . . dispositive; rather, the district court must weigh and measure each factor against the other factors.”¹⁶⁸ There are two procedural requirements for obtaining a preliminary injunction: first, that the non-moving party, or alleged infringer, receive notice, and second, that a bond is posted to indemnify the alleged infringer against potential loss if the movant is not in fact entitled to injunctive relief.¹⁶⁹

Under 35 U.S.C. § 283, a preliminary injunction may be granted by a court “in accordance with the principles of equity to prevent the violation of any right secured by [a] patent, on such terms as the court deems reasonable.”¹⁷⁰ The “grant or denial of a

166. See CHISUM, *supra* note 11, at § 20.04[1]. In contrast, a permanent injunction is issued after a patent owner prevails on the merits of a patent infringement claim and unless the public interest otherwise dictates. *Id.* at § 20.04[2]. The permanent injunction enjoins against future infringement of the patent.

167. Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1362 (Fed. Cir. 2002).

168. Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001).

169. See FED. R. CIV. P. 65(a), (c) (2000).

170. 35 U.S.C. § 283 (2000).

preliminary injunction . . . is within the discretion of the district court.”¹⁷¹

In an infringement action brought in district court, the *patentee* bears the burden of establishing the four preliminary injunction factors. Upon meeting this burden, the district court, within its discretion, may award a preliminary injunction whereby the accused infringer is enjoined from its presumably infringing activity until the resolution of the suit. The purpose of the preliminary injunction is thus “to preserve the status quo until the [c]ourt has an opportunity to fully review the merits of a case at trial.”¹⁷²

The status quo is maintained under the Federal Rules by the requirement that a security is posted by the movant prior to obtaining the injunction. The movant-patentee thus bears the initial burden of proof on the merits, as well as the burden to post a security. The bond represents the value of the injunction, and should equate to the amount of money which will be lost by the non-movant during the injunctive period. In return, the movant obtains the injunction against the alleged infringer and may begin presumably to reestablish its market position and goodwill. Should the patentee lose on the merits in court, the accused infringer may presumably collect upon the posted security to compensate for its losses during the injunctive period. Thus, a specific equitable balance is constantly maintained, while the public interest in protecting patents is also maintained.¹⁷³

In the pharmaceutical context, a generic manufacturer may be enjoined from allegedly patent-infringing activity, that is, the filing of the Paragraph IV certification and the approval of its ANDA, and subsequently the sale of its generic drug product. This estoppel is

171. *Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1367 (Fed. Cir. 1996). It follows that a district court’s decision to deny or grant a preliminary injunction will only be overturned by the Federal Circuit (or other appellate court in non-patent contexts) upon a showing that the court’s decision was “an abuse of discretion, based upon an error of law, or a serious misjudgment of the evidence.” *Hoop v. Hoop*, 279 F.3d 1004, 1006 (Fed. Cir. 2002).

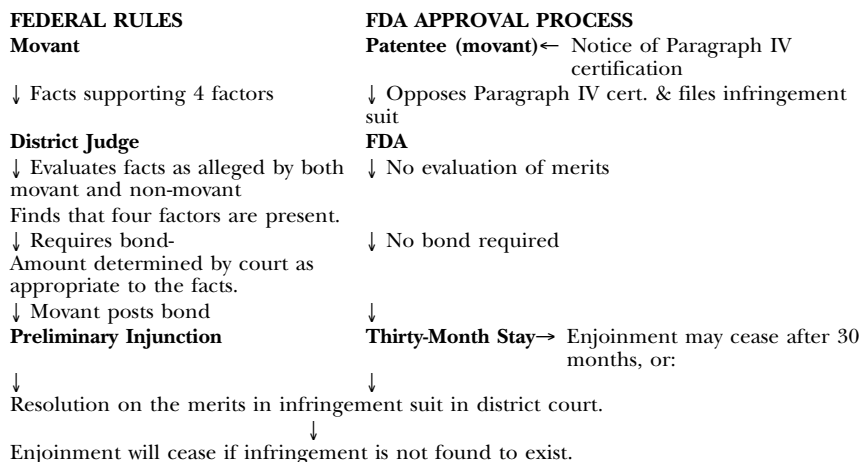
172. *Dynamic Mfg. Inc. v. Craze*, 46 U.S.P.Q.2d 1548, 1550 (E.D. Va. 1998); *see also CMM Cable Rep., Inc. v. Ocean Coast Props., Inc.*, 48 F.3d 618, 620 (1st Cir. 1995).

173. “Where a likelihood of infringement has been shown, the public interest is almost always served by vindicating the patentee’s rights.” *Lawman Armor Corp. v. Winner Int’l, Inc.*, 2002 WL 123342, at *20 (E.D. Pa. 2002). “In patent cases, the focus of the district court’s public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief.” *Id.* (internal citation omitted). “Courts have only in rare instances exercised their discretion to deny injunctive relief in order to protect the public interest, generally [only] in instances where the public health was at stake.” *Id.*

achieved by the activation of the thirty-month stay, where the generic manufacturer is functionally enjoined from such activities until the stay's expiration or the resolution of the infringement issue by the court.

The purpose of the thirty-month stay, like that of the preliminary injunction, is to protect the patentee's rights and preserve the status quo during the pendency of the infringement suit. However, unlike in the injunction context, the patentee (pioneer company) bears *no* burden before activating the thirty-month stay against an ANDA applicant. The patent holder in this situation must only oppose the ANDA and file an infringement action in district court before the generic manufacturer is enjoined from gaining FDA approval for its generic drug and beginning sales.¹⁷⁴ There is no requirement that the pioneer company show that its opposition is meritorious, that it is likely to succeed in its infringement claim, that it would be irreparably harmed, that its injury outweighs any injury to the generic manufacturer, or that the injunction would be in accord with the public interest.¹⁷⁵ This system does not achieve an equitable balance between the parties, but allows the pioneer company to obtain the equivalent to injunctive relief against infringement for thirty months all on merely their word that infringement exists, and the district court filing fee for their infringement suit. Figure 1 illustrates the equitable imbalance between the injunctive schemes under the Federal Rules and under the FDA drug approval regime:

FIGURE 1



174. See *supra* notes 32–36 and accompanying text.

175. Cf. *supra* note 168 and accompanying text.

B. The Better Remedy is the Bond, Not the Burden

The FDA's deferment of generic approval under the current regime does anything but preserve the status quo of the companies involved, as the pioneer company is able to gain incredible profits at the generic manufacturer's expense during this period regardless of the merits of its infringement claim. It is therefore apparent that in order to achieve an equitable balance in the drug approval system, the pioneer company must be subjected to some additional restrictions. This author proposes that the solution is not to impose a substantive burden on the pioneer company analogous to the four-part preliminary injunction test, but to instead charge the FDA with the authority and the responsibility to require the posting of a reasonable security prior to the activation of the thirty-month stay, akin to the bond requirement under the federal rules. It is thus imperative that Congress amend the FDCA to incorporate the bond requirement into the FDA's statutory mandate of authority and responsibility.¹⁷⁶ This proposition is best understood against a backdrop of the pioneer company's investments as well as the FDA's current position in patent disputes.

Any proposed solution to the imbalance in equities must not ignore the effects of newly created burdens on the pioneer company. The pioneer company, after all, has invested millions of dollars in research, development, testing, patent prosecution, drug approval, and marketing in its pioneer drug, and in doing so has facilitated market entry of generics who do not have to proffer this great investment. Any reform requiring additional investment by the pioneer company has the potential to deter or slow future research and development of new drugs. Though the profits on pioneer drugs greatly exceed R&D costs, the pioneer company provides all of the initial investment and may be less willing to do so if protecting its rights down the road would cut too deeply into its payoff. The goal in reform must be to impose the least burdensome requirement upon the pioneer companies while nonetheless closing the Hatch-Waxman loophole.

The United States Court of Appeals for the District of Columbia's recent opinion in *American Bioscience v. Thompson*¹⁷⁷ best articulates the FDA's position on its role as a patent adjudicator. The court noted, "The FDA has a longstanding policy not to get involved in patent disputes. It administers the Hatch-Waxman Amendments in a ministerial fashion simply following the intent of

176. See *supra* note 13.

177. 269 F.3d 1077 (D.C. Cir. 2001).

the parties that list patents.”¹⁷⁸ Should Congress delegate the responsibility for making a preliminary evaluation of patent infringement claims on the merits prior to halting ANDA approval, the FDA may not maintain its current policy of non-involvement. In contrast, should Congress delegate the responsibility for requiring bond-posting, the FDA’s administrative and “ministerial” role in settling patent disputes will not be altered.¹⁷⁹ Rather, because the bond requirement would help to ensure the lack of prejudicial effect on either party, the FDA remains a neutral, administrative third party in the patent dispute.

The substantive evaluation of the merits of a claim by a district court is a preliminary ruling by the body in whose forum the eventual infringement case will be borne out in full. There is little advantage to a preliminary substantive ruling by the FDA when the FDA may not displace the role of the judge or jury as the final infringement adjudicator. Substantive evaluation of the merits of the infringement claim therefore is clearly inconsistent with the FDA’s position of non-involvement, as well as its role as an executive (and not judicial) governing body.

An argument may be made that the FFDCA (and Hatch-Waxman) should be amended to require the patentee pioneer company to make a substantive showing of infringement on the merits prior to relief.¹⁸⁰ Though the requirement of *any* additional burden is cumbersome to the pioneer companies, the imposition of a substantive burden of proof is especially burdensome and is sure to be met with a ferocious lobby.

Imposing a substantive burden would require the pioneer to make a showing to the FDA and not to a judicial body, but nonetheless through costly attorney representation, that its infringement claim is meritorious as a matter of law. This author does not suggest that the imposition of a bond requirement will not be met with an equal share of resistance. However the imposition of a procedural burden, especially one that is monetary in nature and whose

178. *Id.* at 1084; *see also* Andrx Pharm., Inc.v. Biovail Corp., 276 F.3d 1367, 1373 (Fed. Cir. 2003) (noting that the FDA continued to “list the [patent] in the Orange Book without further inquiry or investigation, even though Biovail conceded in its statement of disputed material facts to the district court that the ‘FDA filings in this case preliminarily stated that the [patent] does not claim the approved drug product in the . . . NDA.’”).

179. *See Am. Bioscience*, 269 F.3d at 1084; *supra* note 55.

180. Such a requirement would be analogous to the first preliminary injunction factor, which requires the patent holder to make a showing of validity and infringement from the outset. *See* text accompanying *supra* note 168.

effects are reversible if the pioneer company is in the right,¹⁸¹ is surely the preferred recourse.

C. *Mechanics of the Bond Proposal*

1. The Terms

A district court has complete discretion in setting the amount of bond to be posted by the movant seeking a preliminary injunction, although it must set the security at a reasonable fee in light of the particular facts of each case.¹⁸² In the ANDA context, the terms of the bond ought also be flexible and responsive to the facts of each specific case, as a flat-fee system would not create the necessary balance sought by this proposed system.

It is at times possible to predict the sales of a pioneer drug in a certain period of time based on its past sales history. Indeed it is also often possible to predict the success of a generic, considering that typically generics grab 50% of the market share for a drug within the first six months of its availability.¹⁸³ The duration of the preliminary injunction is not discretionary,¹⁸⁴ as the maximum duration of the injunction is limited to the date of trial.¹⁸⁵ It would

181. *See infra* Part VIII.C.3.

182. *See supra* note 170 and accompanying text.

183. *See supra* note 86 and accompanying text.

184. The author recognizes that different jurisdictions adjudicate at different paces. For example, the Eastern District of Virginia is known as a “rocket docket” for its quick turnaround. *See* William P. DiSalvatore, *Filing Considerations in Patent Litigation*, in PAT. LITIG. 2001, at 92–93 (PLI Pat., Copyrights, Trademarks, & Lit. Prop. Course, Handbook Series No. G0-00P7 (2001)) (“The Eastern District has been utilized as the forum of choice to litigate patent cases . . . by plaintiffs who have little or no connection to the forum beyond a desire for a speedy court in which to litigate.”). This argument does not address the effects of variations between different districts in judicial calendars except to notice that these differences may make litigation more or less advantageous there depending on what side of the thirty-month stay the drug company is on. The author simply suggests that once the court has created its case schedule and a trial date is set, there is little unpredictability regarding the maximum duration of an injunction if one were to issue.

185. Specifically, the date of verdict will be dispositive, as ruling will predicate the lifting of the preliminary injunction and the issuance of a permanent injunction against future infringement. This author recognizes that if the district court does not automatically lift the preliminary injunction after a finding of non-infringement, and the court is requested to do so via a pro forma motion requested by counsel, there could exist a time period between a verdict of non-infringement and the lifting of a preliminary injunction in a case. However, this author suggests that this variation is not significant enough to greatly alter the calculations of potential loss, and further, that calculations of loss should not be attempted that are so extraordinarily sensitive and calculate to the exact day.

therefore seem possible to create a formula that may be applied universally in all ANDA cases, taking into account both the market dynamics at the time as well as the number of generic companies filing ANDAs for a specific drug.¹⁸⁶ Such a formula also seems desirable because it would alleviate the FDA's active involvement in the process.

However, the benefits to this scheme are mostly illusory. Just like in the Federal Rules, there can be no "formula" that will sufficiently incorporate and balance the interests of all parties universally in the ANDA infringement context. The application of a boilerplate bond scheme does not take into account any special circumstances, such as costs of halting production, which may be relevant to the inquiry of potential cumulative loss.¹⁸⁷ Additionally, such a scheme would be unjust to any small drug manufacturer who procures a blockbuster patent, but who is not yet in the position to absorb a blockbuster expense in maintaining its rights. There is no limit to the type and quantity of special and unpredictable circumstances which may arise in the pharmaceutical industry just as in all others, and which must be considered in any analysis in equity.

2. The FDA's Role

Therefore, the proposed bond-posting scheme requires that the FDA determine the amount of bond to be posted in each case. Though this is not overall a "passive" role for the FDA in accord with its stated position, it makes sense that the FDA oversees the bond determination. As an initial matter, all of the mechanics of the ANDA process are under the FDA's control from the start, and matters would only transfer to the court (as they do now) for judg-

186. One might attempt to create a precise formula for a precise set of circumstances—an exercise that notably no district court has ever deemed necessary to complete.

For example, where there is one ANDA applicant, one could imagine a calculation of potential loss that equals: Generic (% total sales) x (180 days exclusivity/revenue per day, calculated from the current yearly revenue) x (30 months – 180 days + 45 days to file suit). Where there is more than one ANDA applicant, one could formulate the loss using this model as: Generic (% total sales) x (2.5 years – 180 days of other company's exclusivity + 45 days to file suit).

Both of these equations are based on the assumption that the pioneer company will delay filing its infringement suit until the 45th day. Most importantly, these equations also take into account the presumption that calculations of loss can be made to the specific day, and more fundamentally that such rigid specificity is desired.

187. See, e.g., *Am. Standard, Inc. v. Lyons Indus., Inc.*, 1998 U.S. Dist. LEXIS 22882, at *39–40 (D.N.J. 1998) (recognizing the importance of considering the costs involved in halting production).

ment on the merits of the infringement claim. It would be inefficient and cumbersome for the district courts to work with the FDA in overseeing the posting of the thirty-month stay bond, when no questions of law are present and the only issue is the amount of security that is reasonable. Additionally, as the governmental overseer of the pharmaceutical marketplace, the FDA is in a better position than the court would be in making determinations regarding pharmaceutical market forces.¹⁸⁸

Despite inevitable resistance by the FDA to this charge of authority, this position best ensures that the FDA remains completely impartial in the resolution of patent disputes. Because the thirty-month stay bond would be mandatory under this proposed scheme, the FDA does not exercise any discretion in determining *whether* a security is required. Furthermore, any security calculated by the FDA is not completely irrevocable, as its ultimate fate rests on the trier of fact in the patent infringement case. Should an inaccurate or unreasonable security be demanded by the FDA, the pioneer company would be able to recover the amount if it wins on its infringement claim under the proposed scheme.

3. Bond Recovery

Before a court may execute a bond under Rule 65(c), it “must find that the enjoined or restrained party was wrongfully enjoined or restrained.”¹⁸⁹ If the alleged infringer is found not to have infringed, “[t]here is a rebuttable presumption that [the] wrongfully enjoined party is entitled to have the bond executed and recover provable damages up to the amount of the bond.”¹⁹⁰

188. This proposition is in accord with the rule of administrative law established by the Supreme Court in *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*—that the governmental agency is presumed to be in the best position to decide matters which are within its realm of expertise. 467 U.S. 837, 844, 865–66 (1984). Because of this, courts accord considerable legal deference to administrative decisions. *See id.* Though the amount of deference may vary based on the circumstances of the agency’s decision, the underlying principle of deference indicates the Court’s willingness to delegate decisions of legal implication based on a specialized knowledge and area of expertise. *See generally* Scott H. Angstreich, *Shoring up Chevron: A Defense of Seminole Rock Deference to Agency Regulatory Interpretations*, 34 U.C. DAVIS L. REV. 49 (2000) (discussing the Supreme Court’s iterations that agency decisions made under formal agency regulations are given great deference, while those made under informal interpretations such as enforcement guidelines, opinion letters, policy manuals and the like are afforded less deference, and the implications of this distinction).

189. *Jacobson v. Cox Paving Co.*, 26 F.3d 138 (Table), 1994 WL 131741, at *6 (Fed. Cir. 1994) (internal quotation omitted).

190. *Id.*

Because the awarding of a bond is not within the Federal Circuit's exclusive jurisdiction, the court applies the procedural law of the regional circuit to the awarding of the bond.¹⁹¹ In some circuits the recovery of a bond is not automatic. For example, a bond may not always be recovered in the Fifth Circuit by the alleged infringer if the plaintiff acted in good faith.¹⁹² Even more severely, an alleged infringer may not recover in the Fourth Circuit "unless it can be shown that the plaintiff prosecuted the suit maliciously and without probable cause."¹⁹³

Under the proposed bond scheme, however, it is imperative that recovery of the thirty-month stay bond is automatic. Because of the nature of the pharmaceutical marketplace, any district court finding of infringement necessarily follows an incredible loss of profit by the accused infringer. The patentee's ability to collect its thirty-month stay bond without further delay thus bears no additional burden on the infringer, as its loss followed from the injunction and not the bond itself.

Importantly, however, a finding of *non-infringement* also necessarily follows a great financial loss by the ANDA applicant. Thus, in

191. *Hupp v. Siroflex of Am., Inc.*, 122 F.3d 1456, 1467 (Fed. Cir. 1997). The Federal Circuit has exclusive jurisdiction over appeals of district court actions arising, at least in part, "under any act of Congress relating to patents." 28 U.S.C. § 1338(a) (West 2002). Once an appeal is properly before the Federal Circuit, the court has jurisdiction over any other matters relating to the appeal, such as review of an injunction, even though such matters are not related to patent law. *CHISUM*, *supra* note 11, at § 11.03 (citing *Panduit Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564, 1572 n.9 (Fed. Cir. 1984)); *see also* *Atari, Inc. v. JS & A Group, Inc.*, 747 F.2d 1422, 1440 (Fed. Cir. 1984) (holding that the Federal Circuit court had jurisdiction over an appeal from a preliminary injunction against copyright infringement when the action below also contained a claim for patent infringement). The Federal Circuit applies the law of the regional circuit to such procedural issues, and "in all but the substantive law fields assigned exclusively to this court." *Id.* at 1439. Thus, without setting specific parameters within the proposed scheme, the district courts (and Federal Circuit on appeal) would be forced to adopt these stringent circuit views in adjudicated disputes over bond recovery. *See infra* notes 192–93 and accompanying text.

192. *See Hupp*, 122 F.3d at 1467–68 (also noting that this approach has not been universally applied in the Fifth Circuit and has been criticized by the Seventh Circuit, but has not been overruled).

193. *CVI/BETA Ventures, Inc. v. Custom Optical Frames, Inc.*, 893 F. Supp. 508, 525 (D. Md. 1995); *Pargas, Inc. v. Empire Gas Corp.*, 423 F. Supp. 199, 244 (D. Md. 1976). The *CVI/BETA* Court further noted the requirement that "damages claimed under an injunction bond must arise from the operation of the injunction itself, not from damages occasioned by the suit independently of the injunction." *CVI/BETA*, 893 F. Supp. at 525. This author questions whether there would be any such distinguishability between damages incurred by the thirty-month stay and the infringement suit itself within the relevant time period.

order to re-balance the parties after a finding on the facts, the alleged infringer must also be able to recover on the bond without any further burden of proof or delay.¹⁹⁴ Though a mechanism may be proposed in accordance with this scheme to challenge the amount of bond to be recovered where the actual loss by the ANDA applicant was much less than the bond posted, this burden should rest with the patentee in accord with a “rebuttable presumption” of recovery.¹⁹⁵

IX. CONCLUSION

As one-third of the nation’s prescription medications come off patent by 2005,¹⁹⁶ including blockbusters such as Prilosec, Prozac, Glucophage, and Claritin in 2002,¹⁹⁷ additional patents may be listed in the Orange Book to extend periods of exclusivity and attempt to cushion this fall in profits. In such a critical time for the FDA’s generic drug approval system and for the American health care system at large, a bond-posting requirement will help ensure that only meritorious infringement claims serve to deter generic drug availability to the American public.

Requiring the posting of a bond upon the triggering of the thirty-month stay by the pioneer drug company is an equitable solution to the problem of the imbalances favoring the pioneer company inherent in the generic drug approval process. Although other methods of relief for Orange Book abuse may be available, the requirement of bond posting prior to the pioneer company’s

194. This author does not suggest that the FDA’s prediction of loss, like the estimation by district courts, could ever be completely accurate to the actual loss in a case. Where the FDA has required a thirty-month stay bond that is lower than the actual loss, there should be no further burden on the ANDA applicant in collecting this amount. It is illogical to impose a burden on the alleged infringer where the patentee cannot be harmed by the awarding of the inadequate bond and in fact benefits overall. Though this situation is unfortunate for the generic company, it reflects an inherent risk in any bond-posting scheme, just like that currently in place with the Federal Rules, and must, like in non-patent litigation, be absorbed. Such loss is unfortunate, but protected against as much as is possible under the current scheme by enabling the FDA, arguably the best entity to judge pharmaceutical marketplace trends, to determine potential loss out of the starting gate. Where the estimated loss is higher than the actual loss, however, the patentee pioneer company has a reason to challenge the automatic awarding of the bond and must be presented with such an opportunity.

195. See *supra* note 188 and accompanying text.

196. See *supra* note 1 & *supra* Part VI.

197. See Lewis Krauskopf, *N.J. Drug Makers Swallow Hard, Expect More Rough Times*, THE RECORD (Bergen County, N.J.), Jan. 20, 2002, at B1.

use of the thirty-month stay creates balance between the pioneer and generic manufacturer throughout the dispute resolution in a way that *ex post* punishment cannot. Additionally, the bond requirement functions to deter pioneer companies from “listing and litigating” solely for the purpose of securing a longer exclusivity period at the expense of their generic competitors.

Regardless of the good or bad faith of the pioneer company in listing an 11th-hour patent or adding another new patent to their Orange Book listing, this requirement will better ensure that an adequate internal review of the applicability of the patent to the drug was conducted before the patent is submitted to the FDA for Orange Book listing. It is possible that pioneer companies would still opt to post a security and pay attorney’s fees in bringing an infringement suit for a patent which it knows may be wrongly listed in the Orange Book—in light of the amount of money to be made at a generic’s expense, there may be nothing that will completely deter unnecessary legal action in such a case. However, the posting of a bond at the onset would at least help to ensure that the controversy is real and prosecuted in good faith.

The generic manufacturer would benefit by having the security of knowing that its potential losses may be compensated for, and, by knowing that money is in escrow, it may be more motivated to defend its non-infringement position. Importantly, the generic manufacturer gains this security at the time it needs it most—at the point of the initial stay of its ANDA application. This is important in an era where complaints of generic-pioneer settlements that disrupt the availability of generics to the American public, perhaps unnecessarily, are causing heightened levels of public and governmental concern.

The bond-posting requirement, though aiding the position of the generic companies in patent disputes, does not alter the positions of the FDA and the pioneer companies. Because the FDA would not exercise a great deal of discretion in enforcing such a rule, and because bonds by their nature are revocable, the FDA remains a neutral party consistent with its policy. Additionally, placing some of the burden upon the FDA in balancing the competing forces in the pharmaceutical industry is consistent with both the principle of judicial efficiency and the belief that a specialized governmental agency is in a better position to decide matters within its realm of expertise.

It may be argued that pioneer companies should not have to bear the burden of paying to defend their patent rights granted by the PTO. However, the thirty-month stay is not part of the patent

210 NYU ANNUAL SURVEY OF AMERICAN LAW [Vol. 59:163

grant; it is akin to an injunction under Rule 65(c). It is not unreasonable that an additional price is paid to secure this additional right. Although the thirty-month stay was originally balanced with benefits to the generic companies through the creation of the Hatch-Waxman Act, the maintenance of this balance currently requires an additional sacrifice.