VIRGINIA JOURNAL OF LAW & TECHNOLOGY

WINTER 2004 UNIVERSITY OF VIRGINIA VOL. 9, NO. 1

Consumer Protection, Patents and Procedure: *Generic Drug Market Entry and the Need To Reform the Hatch-Waxman Act*

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ABSTRACT

As the importance of prescription drugs in our health care system and national economy has increased, there has been a concomitant increase in attention to the issue of access to these pharmaceuticals. Congress has sought to facilitate the entry of generic drugs into the market, beginning with the passage of the Hatch-Waxman Act of 1984, which provided a mechanism for faster generic drug entry. But abuse of the procedures established by Hatch-Waxman has led to effects that are contrary to the act's intent. The automatic stays granted to patent holders that postpone market entry by generics, along with the strategic use of statutory windows of exclusivity, have allowed patent holders to extend illicitly their hold on monopoly prices.

These effects have been well documented by the FTC and have spurred procedural change at the FDA. Consumer suits show that consumers are also real parties in interest in controversies regarding generic drug entry. FTC recommendations and the recent Gregg-Schumer Amendments would repair major gaps in the original statutory framework but not completely eliminate opportunities for misuse. Together with the FTC's suggestions, changes we propose — the duty to litigate, not settle, infringement suits; changes in Orange Book listing practice; and a real market-based disgorgement of excess profits accrued during an automatic stay — would ensure that brand-name pharmaceutical companies receive their due patent protection, but nothing more.

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For assistance with this paper, the authors acknowledge Laurie Allen, Havi Glaser, James Laur, and Professor Joseph Singer. An abbreviated, unpublished version of this article won first place in the Boston Patent Law Association's 2003 Writing Competition

TABLE OF CONTENTS

¶ 1 As the importance of prescription drugs in our health care system and national economy has increased, there has been a concomitant increase in attention to the issue of access to these pharmaceuticals.[1] There have been two major governmental approaches to ensuring widespread access to prescription drugs: increasing government subsidies for

1. This issue took on particular visibility during the 2000 presidential election. *See, e.g.*, Jill Wechsler, *Medicare, Prices, and Research*, BIOPHARM, Nov. 1, 1999, at 22.

consumers, and promoting competition within the pharmaceutical industry. A number of recent legislative proposals have been introduced in Congress to provide an increased prescription drug benefit as part of Medicare,[2] and States have tried to adopt aggressive cost-saving measures as part of their drug subsidy benefits.[3]

¶ 2 Although these proposals for increased subsidies clearly anticipate various methods of price savings, the legislative reforms have avoided attempting direct price controls as a solution to the problem of access.[4] Rather, Congress has looked to competition in the drug market as a solution to price concerns. Facilitating the entry of generic drugs, without infringing valid patents, can produce competitive prices and minimize the risk of price manipulation. Congress' first attempt to increase generic competition was the Hatch-Waxman Act of 1984, which provided a mechanism for faster generic drug entry. The Senate recently passed the Gregg-Schumer Amendments to the Medicare bill, which contain some important reforms of this Act, the first in its 19-year lifetime.[5] The Hatch-Waxman Act certainly increased the availability of generic drugs, but in recent years it also has been misused to keep generic drugs off the market, costing consumers billions of dollars every year. The recently adopted Gregg-Schumer Amendments would repair some major gaps in the original statutory framework, but opportunities for misuse would not be completely eliminated.

¶ 3 Questions of validity and infringement of pharmaceutical patents are generally decided in suits only between members of the pharmaceutical industry, and practical questions of market entry are often controlled by the FDA, but the outcomes of these suits and administrative actions are of great significance to purchasers of pharmaceuticals. The availability of a generic alternative can mean a price savings for

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2. *See, e.g.*, Medicare Modernization and Prescription Drug Act of 2002, H.R. 4984, 107th Cong. (2002).

3. *See, e.g.*, Pharm. Research and Mfrs. of Am. v. Concannon, 249 F.3d 66 (1st Cir. 2001), *aff'd sub nom.* Pharm. Research and Mfrs. of Am. v. Walsh, 538 U.S. 644 (2003) (holding that Maine's prescription drug access plan, which allowed all state residents to enroll in a discount plan, was not preempted by the federal Medicare statute).

4. The possibility of some sort of pricing premium has not escaped some members of Congress. *See, e.g.*, Bernie Sanders, *New Figures Prove Pharmaceutical Industry Continues To Fleece Americans, at* http://bernie.house.gov/prescriptions/profits.asp (last visited Dec. 1, 2003) (noting that top seven drug companies took in $20.3 billion in profits in 2001, compared with $15.4 billion taken in by the top seven auto companies in 2001). Some have suggested that pharmaceutical profit margins garner little scrutiny in Congress due to industry donations to members of Congress. *See, e.g.*, Robert Pear & Richard A. Oppel Jr., *Results of Elections Give Pharmaceutical Industry New Influence in Congress*, N.Y. TIMES, Nov. 21, 2002, at A34 (discussing a meeting of pharmaceutical industry leaders seeking ways to use effectively the political capital they gained by donations to the campaigns of elected congressmen). The Federal Trade Commission ("FTC") and plaintiffs' attorneys, on the other hand, have seen price inflation as a primary problem. In addition to suits whose substance revolves around patent construction and procedure, explored *infra* Parts II.B and II.C, plaintiffs have filed suits that target inflated prices allegedly due to misleading advertising and manipulation of prices which are supposed to be set by Average Wholesale Price ("AWP") lists.

5. S.1225, 108th Cong. (2003). The Amendment is titled the "Greater Access to Affordable Pharmaceuticals Act," and is also known as the Gregg-Schumer Amendments after its sponsors. *See* discussion *infra* Part III.A.

consumers equal to one quarter of the price of the brand-name drug.[6] Once the generic enters the market, the brand-name manufacturer can no longer engage in monopoly pricing, but in recent cases favorable arrangements between the brand-name and generic manufacturers have maintained the monopoly premium, and abuses of FDA procedure by brand-name companies have frustrated legitimate efforts of generic entrants.

¶ 4 Ironically, these arrangements and abuses take advantage of statutory provisions of the Hatch-Waxman Act, which was enacted to facilitate and encourage the development of generic drugs.[7] A series of enforcement actions by the FTC has barred certain types of collusive settlements between particular brand-name and generic companies. A study by the FTC found that the current structure of the federal agencies that regulate the pharmaceutical industry has contributed to the continued imposition of a brand-name monopoly where generics would otherwise enter the market. With the recent judicial and administrative scrutiny of these practices, consumer groups have realized that they are also real parties in interest in these suits over patent validity. Suits brought by these consumer groups have sought to vindicate their interests.[8]

¶ 5 Part I of this paper examines the existing statutory and regulatory framework for encouraging the development and market introduction of generic drugs. Part II illustrates the shortcomings of this framework as shown through the recent FTC investigation, FTC enforcement actions, and consumer class action suits. In Part III, we examine existing proposals to reform the Hatch-Waxman framework. Finally, in Part IV, we propose solutions to these problems through a duty to litigate fully patent suits, changes to the FDA's practices, and amendments to some provisions of the Hatch-Waxman Act.

I. STATUTORY AND REGULATORY FRAMEWORK

A. The Hatch-Waxman Act, ANDAs, and the Orange Book

¶ 6 In 1984, Congress enacted the Drug Price Competition and Patent Restoration Act of 1984,[9] commonly known as the Hatch-Waxman Act after its sponsors.[10] The Act

6. Congressional Budget Office, *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998, *available at* http://www.cbo.gov/showdoc.cfm?index=655&sequence=0.

7. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2000)); *see* David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L. J. 321 (2000).

8. *See infra* Parts II.B and II.C. There are also a number of consumer suits against the pharmaceutical industry for antitrust violations not related to generic drug entry. For example, there is a suit alleging improper promotion of the anti-allergy drug Claritin, New Jersey Citizen Action v. Schering Plough Corp., Civil Action No. MID-L-007838-01 (N.J. Super. Ct. Law Div. filed Oct. 31, 2001), and one alleging manipulation of the "Average Wholesale Price" on which reimbursements are based, *In re* Pharm. Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172 (D. Mass. 2003) (No. 01-12257 PBS).

9. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2000)).

10. The bill's sponsors were Sen. Orrin Hatch (R-Utah) and Rep. Henry A. Waxman (D-Cal.). Kristin E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?*, 57 FOOD DRUG L.J. 247, 250 (2002).

served two somewhat conflicting goals: (1) to provide developers of new drugs with increased lengths of market exclusivity to compensate them for the patent time lost while their drugs were undergoing regulatory approval, and (2) to simplify and expedite the market entry of generic versions of pharmaceuticals.[11] Toward the former end, the Act provided an extension to the patent term equal to one half of the time spent in human clinical trials and the drug application period, for a maximum extension of 5 years.[12] Toward the latter end, the Act created a regime by which manufacturers who wished to bring a generic version of a previously approved ("listed"[13]) drug to market could take advantage of safety and efficacy studies of the listed drug.[14] Ordinarily, the manufacturer of a new drug must file a New Drug Application ("NDA"), which requires extensive scientific and clinical proof of the safety and efficacy of that drug prior to approval ("listing").[15] A manufacturer seeking to make a generic version of a listed drug can file an Abbreviated New Drug Application ("ANDA"), which differs from the New Drug Application in that an ANDA relies on the safety and efficacy studies performed for the previously listed drug.[16] Rather than require a repetition of these studies, an ANDA only requires the filer to demonstrate that the route of administration, dosage form, and strength of the applicant drug is the same as that of the listed drug, that the applicant drug is bioequivalent to the listed drug, and that the labeling for the applicant drug is the same as that of the listed drug.[17]

¶ 7 The effect of this ability to rely on the scientific studies submitted for the original listed drug is that it is vastly less expensive to bring a generic drug to market under Hatch-Waxman than it is to get a non-previously listed drug approved.[18] To ensure that

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11. Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 188-90 (1999).

12. *Id*. at 190.

13. Approved drugs are listed by the Food and Drug Administration (FDA) in its "Approved Drug Products with Therapeutic Equivalence" publication, commonly known as the "Orange Book." 21 U.S.C. § 355(j)(7)(A).

14. 21 U.S.C. § 355 (j).

15. 21 U.S.C. § 355 (b). Once the studies are completed, the actual NDA is submitted. The FDA's average NDA approval time for the decade of 1991-2000 has been 16.8 months. *See FDA's Drug Review and Approval Times*, *at* http://www.fda.gov/cder/reports/reviewtimes/default.htm#Approval%20Time (last viewed Apr. 13, 2003).

16. 21 U.S.C. § 355 (j)(2).

17. 21 U.S.C. § 355 (j)(2)(iii)-(v).

18. The pharmaceutical industry association claims that the average cost for the development of a new drug is $802 million, which is the figure developed by the Tufts Center for the Study of Drug Development. *See* Tufts Center for the Study of Drug Development, *Backgrounder: A Methodology for Counting Costs for Pharmaceutical R&D*, *available at* http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=5 (last modified Sept. 3, 2003), *cited in* Pharmaceutical Research and Manufacturers of America, *Delivering on the Promise of Pharmaceutical Innovation: The Need to Maintain Strong and Predictable Intellectual Property Rights*, submitted to Federal Trade Commission and the Department of Justice Antitrust Division (Apr. 22, 2002) at 7, *available at* http://www.ftc.gov/os/comments/intelpropertycomments/phrma020422.pdf. However, the Tufts study has been criticized due to its reliance on confidential, unaudited data, and the disparity between the $802 million figure and figures submitted to the IRS for a certain class of tax credits for "Orphan Drug" development. *See* Consumer Project on Technology, *IRS Data Shows Drug Industry Cost Estimates Exaggerated*, *available at* http://lists.essential.org/pipermail/ip-health/2001-November/002489.html (last visited Dec. 15, 2003). Even if

generic manufacturers do not market drugs which are still protected by patents, an ANDA filer must include one of four certifications (paragraph I-IV certifications): "(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."[19] If an applicant makes a paragraph I or II certification, the certification causes no delay in approval.[20] If an applicant makes a paragraph III certification, the application can be approved effective on the date of patent expiration.[21] In applications with the first three types of certifications, the application is unaffected by significant provisions governing paragraph IV certifications.

¶8 If an applicant makes a paragraph IV certification, two special features of the Act apply: the 30-month stay and the 180-day marketing exclusivity period. Under the 30-month stay provision, the ANDA filer is required to provide notice to the patent holder and the NDA holder, including a detailed factual and legal analysis of why the patent is not infringed or is invalid.[22] If the patent holder or NDA filer does not bring suit within 45 days of being provided with such notice, the ANDA can be approved immediately upon such occurrence.[23] If, however, suit is brought, then approval is stayed for 30 months, unless the patent expiration date or finding of noninfringement occurs before the end of the 30 months, in which case the ANDA may be approved immediately.[24] Under the 180-day marketing exclusivity provision, the first manufacturer who files an ANDA with a paragraph IV certification is granted a 180-day head start on other generic manufacturers, effectuated by the FDA's delaying approval of any subsequent filer's ANDA until 180 days after the first ANDA filer's drug is marketed or there is a judgment

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$802 million is a "highball" figure, drug development is a multi-million dollar cost that generic manufacturers do not incur.

19. 21 U.S.C. § 355 (b)(2)(A), *also at* 21 U.S.C. § 355 (j)(2)(A)(vii).

20. 21 U.S.C. § 355 (j)(5)(B)(i).

21. 21 U.S.C. § 355 (j)(5)(B)(ii).

22. 21 U.S.C. § 355 (j)(5)(B)(iii). The originally contemplated stay duration was 18 months; it was changed to 30 months through the efforts of the pharmaceutical industry. Mossinghoff, *supra* note 11, at 190. It could be argued that any statutory stay is unnecessary and counterproductive, because the threat of liability for infringement should act as a deterrent, and parties should be able to gamble on the strengths of their litigation positions. However, we argue that a stay of some length is appropriate in this context, where the generic company's revenues are generally less than the lost revenues of the brand-name manufacturer. Therefore, if the manufacture and sale of the generic is in fact infringement, the generic may be unable to pay the brand-name restitution. This is because the monopoly profit is larger than the competitive profit, so because the consumers will retain the difference, the generic will not have all of the money that the brand-name is owed. Whether 30 months is the appropriate length for the stay is another matter. An FTC study suggests that 30 months may approximate the length of time that it takes the FDA to approve a non-paragraph IV ANDA or the time required for a resolution of infringement litigation. *See infra* Part II.A.1. We fail to see how either of these are meaningful stay length benchmarks. There is no rational basis for the length of the stay approximating the approval time, and if the idea is to stay the application pending the resolution of the litigation, the stay period could be exactly that long. An optimal predetermined statutory stay period would strive to achieve a balance between allowing informed risk-taking and guarding against the possibility of irreparable harm. *See infra* Part IV.C.

23. 21 U.S.C. § 355(j)(5)(B)(iii).

24. *Id.*

finding the brand-name's patent invalid or not infringed.[25] The 180-day period provides a huge incentive[26] for the first generic company to challenge a drug's patent where subsequent generic manufacturers will be able to follow at reduced cost.[27]

B. Judicial Interpretation of the Hatch-Waxman Act in Lawsuits Between Generic and Brand-Name Manufacturers

¶ 9 Courts have had to clarify some of the ambiguities in the Hatch-Waxman Act concerning the 30-month stay and 180-day exclusivity provisions. Many of these decisions arose out of litigation between generic and brand-name manufacturers, and courts have so far declined to use their equitable powers to correct questionable conduct relating to provisions of the Hatch-Waxman Act. These cases provide useful guidance for identifying statutory provisions that are particularly subject to abuse.

1. Mova Pharmaceutical Corp. v. Shalala

¶ 10 In *Mova Pharmaceutical Corp. v. Shalala*[28] the D.C. Circuit held that the 180-day exclusivity period was not contingent on the existence of litigation with the NDA holder. In December 1994, Mova Pharmaceutical Corp. ("Mova") filed an ANDA with a paragraph IV certification for micronized glyburide, which is used to treat type II diabetes.[29] The patent holder and NDA filer, Pharmacia & Upjohn Co. ("Pharmacia"), sued within the 45-day window, launching the 30-month stay.[30] In November 1995, Mylan Pharmaceuticals, Inc. ("Mylan") filed an ANDA for the same product.[31] Pharmacia did not sue Mylan until after the 45-day period, and therefore Mylan's application was not stayed. Under the FDA regulations interpreting the Hatch-Waxman Act then in force, the FDA required that to activate the 180-day exclusivity period, the applicant must successfully defend a patent action.[32] Because Mova had not yet defended the infringement action, FDA approved Mylan's ANDA without delay.[33]

¶ 11 Mova sued, seeking a temporary restraining order and preliminary injunction requiring the FDA to approve Mylan's ANDA no earlier than 180 days after Mova either commenced commercial marketing or prevailed in its infringement action, and the court

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25. 21 U.S.C. § 355(j)(5)(B)(iv).

26. For example, when Barr Laboratories marketed a generic form of Prozac, it earned $366 million in revenue during the 180-day exclusivity period. In the following 180 days, when other competitors entered, it earned only $4 million in revenues. Gardiner Harris & Joanna Slater, *Bitter Pills: Drug Makers See "Branded Generics" Eating Into Profits*, WALL ST. J., Apr. 17, 2003, at A1.

27. Subsequent entry will require fewer legal fees, both for litigation and for the initial evaluation of which patents are likely to be found invalid.

28. 140 F.3d 1060 (D.C. Cir. 1998).

29. Glynase label, *available at* http://www.pfizer.com/download/uspi_glynase.pdf (last visited Dec. 15, 2003).

30. *See Mova Pharm. Corp.*, 140 F.3d at 1062.

31. *Id.* at 1065. Mylan had originally filed a paragraph III certification, but changed it to a paragraph IV certification. *Id*.

32. 21 C.F.R. § 314.107(c)(1)

33. *Mova Pharm. Corp.*, 140 F.3d at 1065.

granted a preliminary injunction to that effect.[34] While the appeal was pending, Mova prevailed in the infringement litigation, triggering the 180-day stay.[35]

¶ 12 The FDA conceded that there was no literal textual basis for its regulation, but argued that "bizarre results" would occur from a "literal reading of the statute in (1) cases in which the first applicant is never sued, and (2) cases in which the first applicant loses its suit."[36] This is because the exclusivity period granted to the first paragraph IV ANDA filer would be exhausted only after one of those two occurrences, and if they never occurred, then the exclusivity period would never expire. In case (1), if the applicant decides to not put its drug on the market, then neither the marketing trigger nor the favorable court decision trigger can be activated. In case (2), the applicant does not have the option of going on the market, and the loss of the suit means that the favorable court decision trigger is unavailable. Whether through the generic manufacturer's choice in case (1) or a litigation loss in case (2), under a literal reading of the statute, no subsequent manufacturer's ANDA could ever be approved.

¶ 13 The court found that the FDA's regulations were impermissible under the *Chevron* standard of administrative review.[37] The court pointed to an approach that would be narrower and more consistent with the statutory language. Instead of a "win first" requirement, the FDA could have adopted a "wait-and-see" policy, under which later applicants "would need to wait to see whether the first applicant won or lost its patent infringement suit. If the first applicant lost, the exclusivity period would not apply; if he won, it would."[38] The court also criticized the FDA's rule on the grounds that it "write[s] the commercial-marketing trigger out of the statute," in that "if the first applicant begins marketing its product before it wins its infringement suit, the 180 days of exclusivity do not begin to run; other applicants remain eligible for FDA approval to begin marketing their products, at least up to the date that the first applicant wins the infringement action."[39] As a result, the court affirmed the district court's striking of the FDA's successful-defense requirement.[40]

¶ 14 We agree with the *Mova* court's analysis. Both the literal reading of the statute and the FDA's interpretation created problems that seem to have been unintended by the statute: it aims to create an incentive for the first paragraph IV filer, not an impermeable barrier to subsequent filers, and the commercial-marketing trigger demonstrates that the exclusivity period was not intended to be dependent on the existence of litigation. The court's sensible suggestion is in accord with the Solutions section of this paper.

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34. *Id*. at 1065-66.
35. *Id*. at 1066.
36. *Id*. at 1067.
37. *Id*. In a *Chevron* analysis, the court asks whether "Congress has directly spoken to the precise question at issue"; if so, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).
38. *Mova Pharm. Corp.*, 140 F.3d at 1068.
39. *Id*. at 1069-70.
40. *Id*. at 1076.

2. Mylan Pharmaceuticals, Inc. v. Thompson

¶ 15 In *Mylan Pharmaceuticals, Inc. v. Thompson*,[41] the Federal Circuit held that in ANDA infringement litigation, the generic company could not obtain an order requiring the delisting of a patent that had been improperly listed in the Orange Book. In the litigation, Mylan brought a declaratory judgment suit against the FDA and Bristol-Myers Squibb Company ("BMS"), claiming that BMS had improperly listed a patent in the Orange Book[42] and thereby caused undue delays in the approval of Mylan's ANDA. Mylan had filed an ANDA with a paragraph III certification to market a generic version of BMS's BuSpar, an anti-anxiety drug.[43] Eleven hours before the expiration of BMS's patent covering BuSpar, BMS delivered to the FDA a copy of a patent issued that same day that claimed a method of using the active metabolite of BuSpar to treat anxiety, and sought to have this new patent listed in the Orange Book as covering BuSpar.[44] As a result of the BMS listing, the FDA suspended approval of Mylan's ANDA and those of other generic manufacturers seeking to market a generic version of BuSpar.[45] Mylan wrote to the FDA to challenge the listing of the new patent, and the FDA responded by seeking clarification from BMS.[46] BMS recertified to the FDA that the listing was proper, and the FDA accepted BMS's statement.[47] Mylan then brought its suit seeking declaratory judgment and an injunction requiring BMS to take steps to delist the patent and the FDA to approve Mylan's ANDA.[48]

¶ 16 The United States District Court for the District of Columbia held that under the Declaratory Judgment Act, a delisting order was a defense to the infringement suit that BMS could have brought, and that the order would not be private enforcement of the Federal Food Drug and Cosmetic Act ("FFDCA").[49] The court reviewed the substance of the patent claims in the suit, held that Mylan was likely to succeed on the merits, and granted Mylan's injunction.[50]

¶ 17 The Federal Circuit reversed in an opinion by Chief Judge Mayer, holding that the delisting order was not a defense to patent infringement, but rather was an impermissible private enforcement of the FFDCA.[51] Under the well-pleaded complaint rule, the court looked to the "action that the declaratory defendant would have brought" to determine the

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41. 268 F.3d 1323 (Fed. Cir. 2001). The factual occurrences at issue in this litigation are also those at issue in *In re Buspirone Patent & Antitrust Litigation*. *See infra* Part II.B.3.

42. For a description of the Orange Book, see *supra* note 13.

43. *Mylan Pharms., Inc.*, 268 F.3d at 1327. BuSpar is BMS's trade name for buspirone hydrochloride. BuSpar information sheet, *available at* www.buspar.com/prodinfo.htm (last visited Dec. 15, 2003).

44. *Mylan Pharms., Inc.*, 268 F.3d at 1327-28.

45. *Id*. at 1328.

46. *Id*.

47. *Id*.

48. *Id*.

49. *Id*. The FFDCA is codified at 21 U.S.C. §§ 301–97.

50. *Mylan Pharms., Inc.*, 268 F.3d at 1328. .

51. *See id*. at 1330-33. The court also noted that the district court granted the injunction even though it acknowledged that Mylan had made no showing of irreparable harm. *Id*. at 1328.

applicable law, and determined that BMS's action would have been for infringement.[52] The court held that because delisting of a patent from the Orange Book does not serve as a defense to an infringement action (because FDA listing schemes have no bearing on patent validity), it is not available in a declaratory judgment action anticipating an infringement action.[53] Further, the court examined the Hatch-Waxman Act to determine whether it created a private cause of action for delisting, and found that it did not.[54]

¶ 18 While the court's decision makes it clear that there is no private cause of action for delisting a patent from the Orange Book, the court left open two possible avenues for a delisting order in a suit between two private parties. First, the court noted 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."[55] The court's mere mention of this possibility gives little indication of what it would have done if Mylan had in fact asserted such a link, but the decisions in this case and in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*[56] do not indicate any enthusiasm on the court's part to craft an equitable doctrine around the Hatch-Waxman Act. Second, the court reiterated a previous holding stating that "as part of its inherent enforcement power to give effect to a judgment, a court may order the delisting of a patent in the context of a properly filed patent infringement suit."[57]

¶ 19 It is not clear why delisting could be necessary to give effect to the judgment in an infringement suit, but not necessary to give effect to the judgment in a declaratory judgment action in anticipation of an infringement suit, and in fact, the court's careful effort to align the declaratory judgment suit with the infringement suit that it anticipates suggests that the opposite should be the case. The court did not consider any cause of action that Mylan might have asserted against the FDA. Because the FDA argued that the portion of the district court's order requiring it to approve Mylan's ANDA was harmless error, it is not clear if the Federal Circuit would have allowed relief to have been available under that avenue.[58]

¶ 20 We think that if delisting is a remedy in an infringement suit, then it should be available in a declaratory judgment action anticipating such a suit. Other than the fact that the argument was not raised by the parties, the court failed to provide a principled distinction explaining why this is the case, and its general care in aligning the declaratory judgment action and the action it references suggest that delisting should have been available here.

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52. *Id*. at 1330.
53. *Id*. at 1331.
54. *See id*. at 1331-32.
55. *Id*. at 1331.
56. *See infra* Part I.B.3.
57. *Mylan Pharms., Inc.*, 268 F.3d at 1333, *citing* Abbott Laboratories v. Novopharm Ltd., 104 F.3d 1305, 1309 (Fed. Cir. 1997).
58. *Mylan Pharms., Inc.*, 268 F.3d at 1329.

3. Andrx Pharmaceuticals, Inc. v. Biovail Corp.

¶ 21 *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*[59] illustrates a problem with the FDA's Orange Book listing process that allows a brand name manufacturer to claim extended protection to which it is clearly not entitled. The litigation arose out of Andrx Pharmaceuticals' ("Andrx") attempt to market a generic version of Biovail Corporation's ("Biovail") Tiazac, which is prescribed for hypertension and angina.[60] Andrx filed an ANDA with a paragraph IV certification in 1998.[61] Biovail sued for infringement, triggering a 30-month stay, but lost the infringement action in a ruling affirmed by the Federal Circuit in 2001.[62] However, while the infringement suit was pending, Biovail obtained rights to a patent for an extended release form of the active ingredient of Tiazac, and listed this patent in the Orange Book as covering diltiazem hydrochloride.[63] As a result, the FDA indicated that it would not be approving Andrx's ANDA upon the expiration of the 30-month stay.[64]

¶ 22 Andrx sought a declaratory judgment that it had not infringed the newly filed patent and that the newly filed patent was invalid, and sought delisting of the patent from the Orange Book and shortening of the 30-month period.[65] The district court ruled, prior to but consistently with the Federal Circuit's decision in *Mylan*, that there was no private right of action to delist a patent from the Orange Book.[66] However, the district court held that Biovail's actions with regard to the new patent were "done to impede or delay the expeditious resolution of the patent actions between Biovail and Andrx over approval of Andrx's generic equivalent to Tiazac" and ordered that the 30-month stay be shortened, but stayed the order so that Biovail could seek review.[67]

¶ 23 In an opinion written by Judge Dyk, the Federal Circuit vacated the district court's order, holding that the district court did not have the power to shorten the statutory 30-month stay in an infringement action.[68] The court's interpretation was a correct technical interpretation of the law, but points to a major problem with the current regime, which was that Biovail succeeded in unlawfully delaying the entry of Andrx's generic product by listing a patent that *could not* have covered Tiazac, because the

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59. 276 F.3d 1368 (Fed. Cir. 2002).

60. Tiazac is the brand-name of diltiazem hydrochloride. Tiazac package insert, *available at* http://www.biovail.com/include/asp/filedownload.asp?color=white&disposition=inline&getFile={86E4D1D6-1035-4A08-B323-7209BB16CC32} (last visited Dec. 18, 2003).

61. *Andrx Pharms., Inc.*, 276 F.3d at 1372.

62. *Id.*

63. *Id.*

64. *Id.*

65. *Id.* at 1373.

66. *Id.* at 1373–74.

67. *Id.* at 1374–75.

68. The court held that while Andrx could have possibly obtained a shortening of the stay by suing the FDA directly under the Administrative Procedure Act, 5 U.S.C. §§ 702–06, it did not do so, and was therefore not entitled to relief that would be possible under such a claim, and that shortening of the stay was available only in response to a delay in resolving the infringement action, not merely a delay in the broader patent dispute. *Id.* at 1376.

technology that the patent claims was developed after the marketing of Tiazac.[69] The court was "somewhat confus[ed]" by Biovail's attempt to change the formulation of Tiazac so that it fell within the claims of the newly acquired patent,[70] and this would indeed be a confusing situation if it were not the case that by doing so Biovail was able to obtain another 30-month delay in Andrx's generic market entry. Biovail's behavior also confused the FDA, causing it to list a drug that should not have been listed.

¶ 24 The court, however, ought not have been confused about the potential for the use of confusion in achieving favorable and unwarranted outcomes at the FDA. The court noted that "Biovail's changing of its manufacturing process could not have been designed to justify the listing of the [new] patent in the Orange Book,"[71] which is indeed a correct statement of the law, but overlooks the fact that through misapplication of complex regulatory schemes, the FDA process is subject to abuse by parties claiming protections to which they are not legally entitled, and which are, technically, legally impossible.[72] The fact that Andrx's product could be subject to a 30-month stay in such a situation is an example of the abusive potential of the 30-month stay provision, and the Federal Circuit's technical dismissal of Andrx's claims in the face of clear abuse is not an encouraging portent of the judiciary's ability to promote socially useful operation of the Hatch-Waxman apparatus in the face of manipulation by listing companies.

¶ 25 Andrx argued that the district court could be affirmed on the alternative ground that Andrx had a claim against the FDA for delisting under the Administrative Procedures Act ("APA") because the FDA's decision was contrary to law or arbitrary and capricious.[73] The court agreed that "claims might properly be brought under the APA in this case to challenge the FDA's failure to issue the ANDA," but although Andrx's complaint had alleged jurisdiction under the APA, the complaint did not allege any violations of the APA, the suit against the federal defendants had been dismissed at the district court, and the dismissal was not appealed.[74] The court did not close the door on this avenue of relief, saying "[w]e, of course, express no opinion here as to whether the FDA's action in refusing to inquire into the correctness of a listing, which then caused the FDA to stay the approval of an ANDA, might represent action that is arbitrary, capricious or not in accordance with law."[75]

69. *See* 35 U.S.C. § 102(b) (a patent must disclaim as prior art any product that has been marketed).
70. *Andrx Pharms., Inc.*, 276 F.3d at 1373.
71. *Id*. at 1376.
72. *See infra* Part III.B.
73. *Andrx Pharms., Inc.*, 276 F.3d at 1376-77.
74. *Id.* at 1379-80. The court noted that "[a]n APA claim can hardly lie when the government is no longer a party to the action." *Id*. at 1380.
75. *Id*. at 1380 n.8.

II. FAILURES IN THE STATUTORY FRAMEWORK

A. FTC Investigations

1. Report - Generic Drug Entry Prior To Patent Expiration: An FTC Study

¶ 26 The FTC developed a sense of problems in the implementation of the Hatch-Waxman Act through its antitrust enforcement actions against companies whose agreements in the context of paragraph IV certifications and ensuing litigation the FTC believed to be anticompetitive.[76] In order to determine whether the abuse of the 30-month stays and 180-day exclusivity periods that they had encountered in enforcement actions were systemic problems, the FTC subpoenaed documents relating to Hatch-Waxman practice from pharmaceutical companies.[77] In July 2002, the FTC published a study that analyzed the data it had obtained in its investigation.[78]

¶ 27 The FTC study examined the outcomes in cases in which the brand-name manufacturer initiated infringement litigation against a paragraph IV ANDA filer. In the court decisions analyzed by the study, generics prevailed in 73% of the cases.[79] The study also examined settlements entered into after the brand-name manufacturer began infringement litigation against a paragraph IV ANDA filer. Of the 20 settlements studied, 9 involved a payment to the generic, 7 involved licensing the patent to the generic, and 2 allowed the generic to distribute the brand-name's drug under its NDA, rather than the generic's ANDA.[80] The FTC found that 14 of the 20 settlements had the potential to "park" the generic's 180-day exclusivity period, preventing the approval of any subsequently filed ANDAs.[81]

¶ 28 The FTC also identified two phenomena that were not noticeable prior to 1998 but have taken on increased prominence since then. First, for drugs with high sales figures, brand-name companies are suing generics over an increased number of patents.[82] The effect of this greater number of litigated patents in a suit is that it takes longer to

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76. *See infra* Part II.A.2.

77. "The FTC's special orders required the brand-name companies to produce agreements with generic applicants that relate to the ANDA filing, results of ANDA patent infringement litigation with generic applicants, listing of patents in the FDA's Orange Book, sales information, and the use of citizen petitions. Generic applicants were required to produce agreements relating to the innovator's drug products for which they had filed an ANDA containing a paragraph IV certification, and to respond to questions about the results of patent infringement litigation with the brand-name company, sharing of litigation expenses with other generic applicants, allegations of improper Orange Book listings, and sales information." FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 11 (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

78. *Id*.

79. *Id*. at 13.

80. *Id*. at 25.

81. *Id*. at 34.

82. *Id*. at 39.

obtain a court decision in all of the related actions. Second, brand-name companies are listing later issued patents in the Orange Book after ANDAs are filed, thus generating additional 30-month stays.[83] The FTC found that most of these listings "raise questions about whether the FDA's patent listing requirements have been met. For example, many of the later-issued patents do not appear to claim the approved drug product or an approved use of the drug."[84] Nonetheless, because the FDA does not review the validity of patents or the propriety of listing them in the Orange Book, submitting such a patent for listing in the Orange Book will provide the opportunity for an additional 30-month stay.

2. FTC Enforcement Actions

¶ 29 Over the last five years, the FTC has undertaken several enforcement actions addressing settlements between generics and brand-name manufacturers. The settlements typically include some payment in exchange for the first generic's staying out of the market, and thereby preventing other generics from entering. The enforcement actions illustrate the extent of abuse of the Hatch-Waxman provisions, and the limited ability of courts to handle this abuse. While not providing an exhaustive examination of all existing Hatch-Waxman abuses, the four FTC enforcement actions described in the following section provide a detailed look at problematic practices.

a. Abbott and Geneva

¶ 30 A settlement agreement between Abbott Laboratories and Geneva Pharmaceuticals provides an example of abuse of the Hatch-Waxman 180-day exclusivity provision. Hytrin is the trade name of terazosin hydrochloride, a drug used to treat high blood pressure and enlarged prostate in elderly patients.[85] Abbott's annual domestic sales of Hytrin in 1998 (the time of the agreement) amounted to over $540 million, or 20 percent of Abbott's total domestic pharmaceutical sales.[86] Geneva Pharmaceuticals filed ANDAs for a capsule and tablet form of terazosin HCl in 1993 and 1995, respectively.[87] In 1996, while Geneva's ANDAs were pending, Abbott listed a patent in the FDA's Orange Book as covering Hytrin.[88] In response, Geneva filed a paragraph IV certification that its ANDAs did not infringe Abbott's listed patent for either the capsule or tablet form.[89] Abbott filed suit for patent infringement against Geneva for only the tablet form of Hytrin, triggering the 30-month stay of FDA approval of that ANDA.[90] Meanwhile, the ANDA for the capsule form of terazosin hydrochloride proceeded to be approved by

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83. *Id.* at 40.
84. *Id.*
85. Complaint, In the Matter of Abbott Laboratories and Geneva Pharms., Inc., 2000 FTC Lexis 65 (F.T.C. May 22, 2000) (No. C-3945), at ¶ 10, *available at* http://www.ftc.gov/os/2000/05/c3945complaint.htm [hereinafter Abbott Complaint]; Abbott Laboratories, *Patient Information About Hytrin* (Oct. 1999), *available at* http://www.rxabbott.com/pdf/Hypat.pdf (last visited Dec. 15, 2003).
86. Abbott Complaint, *supra* note 85, at ¶¶ 1, 10.
87. *Id.* at ¶ 16.
88. *Id.* at ¶ 17.
89. *Id.*
90. *Id.* at ¶ 18.

the FDA on March 30, 1998.[91] Because Geneva was the first generic to receive approval and it was a paragraph IV certification, Geneva was granted a 180-day exclusive marketing period.[92]

¶ 31 Abbott and Geneva then entered into an agreement that effectively kept all generics out of the market for terazosin hydrochloride while their litigation over the tablet formulation proceeded. On the day that Geneva received FDA approval of the capsule formula, Geneva contacted Abbott and negotiated an agreement not to enter the market with its newly-approved drug, nor to transfer or assign its 180-day exclusivity period.[93] In return, Abbott paid Geneva $4.5 million per month until the resolution of its patent litigation over the other formulation of the drug.[94] Because Geneva did not begin to market the generic capsule form of terazosin hydrochloride, no other generics could enter the market during this time. Abbott thus purchased 16 months of monopoly protection for Hytrin, with annual sales of $540 million, for the price of $72 million.

¶ 32 The consent decree that settled FTC's complaint against Abbott and Geneva prevents similar agreements, but does little to provide restitution for the actions of the two companies. The consent decree and order requires Abbott and Geneva to refrain from entering into future agreements in which the ANDA first filer is prohibited from transferring the 180-day exclusivity, or agreements in which the ANDA first filer must refrain from researching or marketing any drug other than the one that is subject to an infringement suit.[95] The two companies are also barred from entering into an agreement where (1) the parties do not settle a suit, (2) the NDA holder provides anything of value to the alleged infringer, and (3) the alleged infringer agrees to refrain from selling that drug or chemically identical drugs.[96] The settlement also requires Geneva to relinquish its 180-day exclusivity rights to terazosin hydrochloride in capsule form.[97] Other than this relinquishment and a few monitoring requirements, the consent decree does not include any punitive measures. The consent decree lacks any refund of the excess prices paid by consumers and health care providers for drugs during operation of the challenged and abandoned arrangement.

b. Hoechst Marion Roussel and Andrx

¶ 33 An agreement between Hoechst Marion Roussel, Inc. ("Hoechst MRI") and Andrx Corporation attracted the FTC's attention, even without alleging an actual delay of

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91. *Id.* at ¶ 22.
92. *Id.* at ¶ 23.
93. *Id.* at ¶¶ 24-26.
94. *Id.* at ¶ 27.
95. Decision and Order, In the Matter of Abbott Laboratories, 2000 FTC Lexis 65 (F.T.C. May 22, 2000) (No. C-3945), at § II, *available at* http://www.ftc.gov/os/2000/03/abbott.do.htm (last visited Dec. 12, 2003) [hereinafter Abbott Decision and Order]; Decision and Order, In the Matter of Geneva Laboratories 2000 FTC Lexis 65 (May 22, 2000) (No. 981 0395), at § II, *available at* http://www.ftc.gov/os/2000/03/genevad&o.htm (last visited Dec. 12, 2003) [hereinafter Geneva Decision and Order].
96. Abbott Decision and Order, *supra* note 95, at § III; Geneva Decision and Order, *supra* note 95, at § III.
97. Geneva Decision and Order, *supra* note 95, at § VI.

generic drug market entry. Hoechst MRI and Andrx entered into an agreement that had the effect of excluding other generics from the market for once-a-day diltiazem.[98] Diltiazem is used for the treatment of chest pain and hypertension.[99] Hoechst MRI sells its formulation of diltiazem under the trade name Cardizem CD, which accounted for 70% of the $1 billion once-a-day diltiazem market in 2000.[100] In September 1995, Andrx filed an ANDA for a generic version of Cardizem CD, and in December 1995, filed a paragraph IV certification that the drug did not infringe any valid patents of Hoechst MRI.[101] Hoechst MRI filed an infringement suit in January 1996, triggering the 30-month stay of FDA approval.[102] In September 1997, the two companies entered into an agreement that guaranteed Andrx would not enter the market for generic Cardizem CD until (1) litigation was finally resolved, (2) Andrx exercised an option on a license from Hoechst MRI, or (3) Hoechst MRI allowed another generic to enter the market.[103] The agreement also provided that Andrx would not give up the 180-day exclusivity right it had received by being the first to file an ANDA with a paragraph IV certification.[104] Finally, Hoechst MRI agreed to pay Andrx $10 million per quarter if Andrx received FDA approval for its ANDA (after the 30-month stay expired), plus $60 million per year if Hoechst MRI lost the litigation, so long as Andrx stayed out of the market for Cardizem CD.[105] Plainly, this agreement would create a strong incentive for Andrx not to enter the market, and through its 180-day exclusivity right, preclude other generics from entering the market.

¶ 34 Ultimately, the agreement did not result in a delay of bringing generic Cardizem CD to market because Andrx was still having technical problems in the manufacture of the drug at the conclusion of the stay. In July 1998, with the infringement lawsuit still pending but the 30-month stay concluded, Andrx received FDA approval for its original ANDA.[106] Pursuant to the parties' agreement, $10 million quarterly payments began.[107] In September 1998, Andrx submitted a supplement to its ANDA with a reformulation of its generic Cardizem CD that it was capable of producing.[108] In June 1999, the FDA approved this reformulation and Andrx began to market the reformulated generic, triggering its 180-day exclusivity right.[109] Around the same time that the FDA approved

98. Complaint, In the Matter of Hoechst Marion Roussel, Inc., 2000 FTC Lexis 142 (F.T.C. Mar. 16, 2000) (No. 9293) at ¶ 29, *available at* http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm (last visited Dec. 12, 2003) [hereinafter Hoechst MRI Complaint].

99. Aventis Pharmaceuticals, Prescribing Information: Cardizem CD (July 2000), *available at* http://www.cardizem.com/graphics/CardizemCD.pdf (last visited Dec. 12, 2003).

100. Hoechst MRI Complaint, *supra* note 98, at ¶ 12.

101. *Id.* at ¶ 17.

102. *Id.* at ¶ 18.

103. *Id.* at ¶ 23.

104. *Id.*

105. *Id.* at ¶ 24.

106. *Id.* at ¶ 27.

107. *Id.*

108. *Id.* at ¶ 28. This reformulation had a different dissolution profile from the original formulation, which was the subject of the patent dispute. Federal Trade Commission, Analysis to Aid Public Comment, *In re* Hoechst MRI at 3, *available at* http://www.ftc.gov/os/2001/04/hoechstanalysis.pdf (last visited Dec. 12, 2003).

109. Hoechst MRI Complaint, *supra* note 98, at ¶ 28.

the reformulated generic, Andrx met with Hoechst MRI.[110] Andrx agreed not to sell the original formulation, so both parties agreed to dismiss the lawsuit over the original formulation and terminate the agreement of September 1997, which related only to the original formulation.[111]

¶ 35 The FTC had been investigating the agreement. While it concluded that there was no actual delay in reaching market (because of Andrx's difficulties in manufacturing the original formulation), the FTC concluded that the challenged agreement was not justified by any countervailing efficiencies.[112]

¶ 36 The consent decree and order contains similar provisions to the provisions in *In the Matter of Abbott Laboratories*. The order, applying to both Hoechst MRI and Andrx, prospectively bars the companies from entering into agreements between ANDA first filers and brand-name manufacturers in which the ANDA first filer could not relinquish its 180-day exclusivity or in which the ANDA first filer agrees not to enter the market for the drug.[113] The order also bars the companies from entering into agreements, in the context of a patent infringement suit, in which the parties do not dismiss litigation, but the NDA holder pays the alleged infringer, and the infringer agrees to refrain from selling the drug or chemical equivalent.[114] This clause also has an exception for stipulated preliminary injunctions at the outset of patent infringement litigation, so long as the court is made aware of this consent decree and the FTC is notified and allowed to intervene.[115] These provisions parallel the requirements of the *In the Matter of Abbott Laboratories* consent decree, but without requiring the generic to give up the 180-day exclusivity, presumably because the FTC did not find an actual delay in this case.

c. Schering-Plough, Upsher-Smith, and American Home Products

¶ 37 The only FTC complaint to reach an administrative law judge ("ALJ") achieved mixed results for the FTC. While the FTC settled favorably with one of the parties, American Home Products ("AHP") during the hearings,[116] the ALJ ultimately dismissed

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110. *Id.*
111. *Id.*
112. Analysis to Aid Public Comment, *In re* Hoechst MRI, *supra* note 108, at 4.
113. Decision and Order, In the Matter of Hoechst Marion Roussel, Inc., 2001 FTC Lexis 56 (F.T.C. May 8, 2001) (No. 9293), at § II, *available at* http://www.ftc.gov/os/2001/04/hoechstdo.pdf (last visited Dec. 12, 2003) [hereinafter Hoechst MRI Decision and Order]. This clause has an exception for agreements that lead to a sale of drugs within 20 days when the 180-day exclusivity period has been triggered or the ANDA first filer gives up its 180-day exclusivity.
114. *Id.* at § III. The consent decree and order also contains provisions for notification and compliance, and a 10-year time limit. *Id.* at §§ IV to IX.
115. *Id.*
116. Decision and Order, In the Matter of Schering-Plough Corp. (F.T.C. Feb. 19, 2002) (No. 9297), *available at* http://www.ftc.gov/os/2002/02/ahpdo.pdf (last visited Dec. 12, 2003) [hereinafter Schering-Plough Decision and Order]. The hearings began on January 23, 2002. The AHP settlement was announced on February 19, 2002. The hearings continued with the other two parties until March 28, 2002. The ALJ's decision was released on June 27, 2002.

the complaint with respect to the other two parties.[117] The FTC is presently appealing the decision to the full commission.[118]

¶ 38 The FTC's complaint arose from two settlements of patent infringement cases relating to Schering-Plough's ("Schering") K-Dur 20, the first of which was with Upsher-Smith ("Upsher").[119] K-Dur 20 is the brand-name for a formulation of potassium chloride in a 20 milliequivalents controlled release dose, used to treat low blood potassium levels.[120] In August 1995, Upsher filed an ANDA with a paragraph IV certification to manufacture a generic version of K-Dur 20.[121] Schering sued for infringement, triggering the 30-month stay of FDA approval.[122] In June 1997, the two parties reached a settlement on the eve of trial for their patent dispute.[123] Under the terms of the settlement, Schering paid Upsher $60 million, both parties agreed to dismiss the lawsuit without prejudice, Upsher would not enter the market for K-Dur 20 with the generic it planned or any equivalent, and Schering received licenses for five Upsher products.[124] According to the complaint, the five licenses granted to Schering were not worth anywhere near $60 million.[125] Dismissing the suit without prejudice had the effect of keeping generics out of the market because an adverse judgment for Schering would trigger the tolling of the 180-day exclusivity period, and an adverse judgment for Upsher would allow another generic to seek the 180-day exclusivity period.[126] Upsher eventually received FDA approval for its ANDA in November 1998, after the 30-month stay had expired, but Upsher did not bring its generic to market, pursuant to the settlement agreement.[127] No other generics received final approval of their ANDAs because the 180-day exclusivity period had not begun to run.[128]

¶ 39 The other settlement receiving FTC scrutiny involved a subsidiary of AHP named ESI Lederle, Inc. ("ESI"). ESI submitted an ANDA with a paragraph IV certification in December 1995, planning to launch a generic after Upsher's 180-day exclusivity period expired.[129] Schering sued ESI for infringement shortly after it submitted its ANDA.[130] In

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117. Initial Decision, *In re* Schering-Plough Corp. et al., 2002 FTC Lexis 40 (F.T.C. June 27, 2002) (No. 9297), *available at* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf *and* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf (last visited Dec. 12, 2003).

118. Appeal Brief, *In re* Schering-Plough Corp. et al. (No. 9297) (Aug. 9, 2002), *available at* http://www.ftc.gov/os/2002/08/scheringtrialbrieftext.pdf (last visited Dec. 12, 2003).

119. These factual occurrences are also the subject of antitrust litigation. *See infra* Part II.C.2.

120. Complaint, In the Matter of Schering-Plough Corp., 2001 FTC Lexis 39 (F.T.C. Apr. 2, 2001) (No. 9297), at ¶¶ 31, 34, *available at* http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf (last visited Dec. 12, 2003) [hereinafter Schering Complaint]; K-Dur Product Information Sheet, *available at* http://www.spfiles.com/pikdur.pdf (last visited Dec. 6, 2003).

121. Schering Complaint, *supra* note 120, at ¶ 38.

122. *Id.* at ¶ 39.

123. *Id.* at ¶ 44.

124. *Id.*

125. *Id.* at ¶¶ 45, 46.

126. *Id.* at ¶ 47.

127. *Id.* at ¶¶ 48, 49.

128. *Id.* at ¶ 50.

129. *Id.* at ¶¶ 51, 52.

130. *Id.* at ¶ 53.

January 1998, an agreement in principle was reached, which was finally executed in June 1998.[131] Under the terms of the agreement, Schering would pay ESI up to $30 million, AHP and ESI would not market a generic version of K-Dur 20 until January 2004, and then they would market only one version of the generic from January 2004 until the expiration of Schering's patent in September 2006.[132] In exchange, Schering would receive a license for two generic drugs that ESI had patented, and the lawsuit would be dismissed with prejudice.[133] According to the complaint, Schering has made no sales of the licensed drugs.[134]

¶ 40 AHP settled the complaint with the FTC soon after the hearings began, on terms similar to those in the other consent decrees described earlier. AHP agreed to refrain from entering into agreements in the context of a patent infringement suit (regardless of whether or not the parties agree to dismiss the lawsuit) in which the NDA holder pays the alleged infringer and the ANDA holder agrees to stay out of the market for the relevant drug.[135] AHP also agreed not to enter into future agreements in which an ANDA first filer agrees not to market the generic drug and not to relinquish its 180-day exclusivity.[136]

¶ 41 The FTC complaint against Schering and Upsher was ultimately dismissed by the ALJ. The ALJ found that the "side deal" between Schering and Upsher, which granted licenses on five drug products, was a bona fide commercial transaction at fair market value.[137] The ALJ also found that the relevant market for assessing the charges of monopolization was the market for potassium supplements, not just potassium chloride at 20 mEq, and therefore the agreements did not restrain trade.[138] This analysis directly conflicts with findings that similar agreements were *per se* restraints of trade in the Cardizem CD antitrust litigation and the terazosin antitrust litigation.[139]

¶ 42 We think that the ALJ placed undue weight on the side deal. A bona fide purchase seems implausible, especially when it is a brand-name company electing to license generic drugs where they never sought to market those drugs, and in light of the potential of splitting the monopoly profits using the 180-day exclusivity provision.[140] The evidence relied upon by the ALJ to make his finding is also the sort that may be manipulated by

131. *Id.* at ¶¶ 54, 58.
132. *Id.* at ¶ 55.
133. *Id.*
134. *Id.* at ¶ 56.
135. Schering-Plough Decision and Order, *supra* note 116, at §§ II, IV.
136. *Id.* at § III.
137. Initial Decision, *In re* Schering-Plough Corp. et al., 2002 FTC Lexis 40, *248-50, 2002 WL 1488085, *166-67, *239-40 (F.T.C. June 27, 2002) (No. 9297), *also available at* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf at 108 (last visited Dec. 12, 2003).
138. *Id.* at 2002 FTC Lexis 40, *194-95, *also available at* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf at 87 (last visited Dec. 12, 2003).
139. *See infra* Parts II.B.1 and II.B.2.
140. *Cf.* Initial Decision, *In re* Schering-Plough Corp. et al., 2002 FTC Lexis 40, *260 (F.T.C. June 27, 2002) (No. 9297), *also available at* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf at 112 (last visited Dec. 12, 2003) (dismissing without argument the anticompetitive potential of the agreement).

the two companies,[141] so less than honorable agreements may be easily disguised as bona fide.

d. Biovail and Andrx

¶ 43 The Biovail (Tiazac) case illustrates the potential for abuse of the 30-month stay provision through listing inappropriate patents in the Orange Book. Tiazac is a diltiazem-based drug with an extended release formula that is used to treat high blood pressure and angina.[142] Biovail's sales of Tiazac were $200 million in 2000, which was approximately 38% of Biovail's total gross sales.[143] In June 1998, Andrx filed an ANDA with a paragraph IV certification for a generic version of Tiazac, and in October 1998, Biovail initiated a patent infringement suit.[144] In March 2000, the district court found that Andrx's drug did not infringe Biovail's patent, which was affirmed by the Federal Circuit on February 13, 2001.[145] While the appeal was underway, the FDA tentatively approved the ANDA for Andrx's generic drug, pending the conclusion of the 30-month stay.[146] Final approval was not granted after the appeal, however, due to a patent that Biovail acquired while the appeal was pending.

¶ 44 Biovail received another 30-month stay of FDA approval by acquiring a license for a patent on a different diltiazem-based drug formulation. On December 19, 2000, a patent issued (the "'463 patent") to an inventor with a company called DOV Pharmaceuticals, Inc. ("DOV") for a formulation of diltiazem that involved an initial release combined with an extended release.[147] Biovail quickly acquired a license for this patent and caused it to be listed in the Orange Book under Tiazac on January 8, 2001.[148] While Andrx unsuccessfully challenged the listing of the patent in the Orange Book,[149] Andrx also filed a paragraph IV certification of non-infringement on February 16,

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141. *See, e.g.*, Initial Decision, *In re* Schering-Plough Corp. et al., 2002 FTC Lexis 40, *168-69 (F.T.C. June 27, 2002) (No. 9297), *also available at* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf at 76 (citing testimony of two executives that the 180-day exclusivity provision was never discussed as part of the settlement). *See also* Initial Decision, *In re* Schering-Plough Corp. et al., 2002 FTC Lexis 40, *63-64 (F.T.C. June 27, 2002) (No. 9297), *also available at* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf at 30 (citing testimony of several board members that any deal for the patent licenses would have to stand on its own; that is, claiming that they paid fair market value for the licenses).

142. Complaint, In the Matter of Biovail Corp., 2002 FTC Lexis 56 (F.T.C. Oct. 2, 2002) (No. C-4060), at ¶ 18, *available at* http://www.ftc.gov/os/2002/10/biovailcmp.pdf (last visited Dec. 12, 2003) [hereinafter Biovail Complaint].

143. *Id*. at ¶ 24.

144. *Id*. at ¶¶ 25, 26.

145. *Id*. at ¶ 27; Biovail Corp. v. Andrx Pharms., Inc., 239 F.3d 1297 (Fed. Cir. 2001).

146. Biovail Complaint, *supra* note 142, at ¶ 28.

147. *Id*. at ¶¶ 29, 30.

148. *Id*. at ¶¶ 33, 34. According to the FTC complaint, Biovail finalized the agreement for the license on January 12, 2001, after it had caused the patent to be listed on January 8, 2001. *Id*. Biovail had only until January 19, 2001, to cause the patent to be listed, because a patent must be listed within 30 days of issuance. *Id.* at ¶ 32; 21 U.S.C. § 355(c)(2).

149. Andrx Pharms., Inc. v. Biovail Corp., 175 F. Supp. 2d 1362 (S.D. Fla. 2001) (no private cause of action to have a patent de-listed under Hatch-Waxman); *see supra* Part I.B.3.

2001.[150] This certification was followed by an infringement suit on April 5, 2001 and the FDA granted another 30-month stay as a result of the new suit.[151]

¶ 45 After Andrx's unsuccessful attempt to de-list the '463 patent, the FTC issued a complaint against Biovail, followed shortly by a consent decree. In the consent decree, Biovail agreed to dismiss with prejudice all claims for enforcement of the '463 patent within five days of the consent decree, followed by divestment of all exclusive licenses to the '463 patent within 30 days.[152] Biovail also was barred from seeking any more 30-month stays of Andrx's ANDA approval.[153] The FTC also required notice prior to the acquisition of any patent or license for the purposes of listing that patent in the Orange Book.[154] It is noteworthy that the FTC sought divestment of these licenses; perhaps this reflects the FTC's view that the patents did not cover Tiazac or feared additional anticompetitive uses of the licenses.

¶ 46 All of the enforcement actions discussed in this section were resolved in cease and desist orders, which may be effective on a case-by-case basis, but are insufficient for systemic, industry-wide change and do not provide for continued monitoring.[155] The common features from the settlements must be incorporated into the Hatch-Waxman mechanisms, so that judicial and administrative supervision is automatic and comprehensive, rather than sporadic and piecemeal.[156]

B. Existing Consumer Suits

¶ 47 In addition to the FTC, private parties have noticed anticompetitive problems in the implementation of the Hatch-Waxman Act that they believe caused them antitrust injury. The following section examines suits brought by these parties, evaluates their development, and demonstrates that private lawsuits can be effective, albeit expensive, remedies for Hatch-Waxman abuses.

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150. Biovail Complaint, *supra* note 142, at ¶ 45.

151. *Id.* at ¶ 46.

152. Decision and Order, In the Matter of Biovail Corp., 2002 FTC Lexis 56 (F.T.C. Oct. 2, 2002) (No. C-4060), at §§ III, IV, *available at* http://www.ftc.gov/os/2002/10/biovaildo.pdf (last visited Dec. 12, 2003) [hereinafter Biovail Decision and Order].

153. *Id.* at § VI.

154. *Id.* at § VIII. The FTC also required Biovail to obey the applicable law with respect to the Orange Book. *Id.* at § VII. We would expect Biovail to obey the law in any case, but this provision does provide an alternative enforcement mechanism by the FDA seeking an injunction. *See* 15 U.S.C. § 45 (granting FTC the power to seek injunction and/or monetary fines for violating a consent decree).

155. While the existence of enforcement actions does have a deterrent effect, the lack of punitive remedies available to the FTC means that optimal deterrence cannot be achieved absent perfect enforcement capability. Even if punitive sanctions were available, we argue in Part IV, *infra*, that statutory changes are available that solve the problem more cheaply and completely.

156. *See infra* Part IV.A (describing how this solution is incorporated into the duty to litigate challenges to paragraph IV certifications).

1. Cardizem CD

¶ 48 Concurrent with the FTC investigation of Hoechst MRI and Andrx,[157] a consumer class action suit was filed against the two companies. On June 6, 2000, the district court hearing the consolidated class action granted partial summary judgment to the plaintiffs, finding the agreement between Hoechst MRI and Andrx was a *per se* antitrust violation.[158] The district court's analysis in the Cardizem CD antitrust litigation could be applied to a host of other settlements between generic and brand-name manufacturers.

¶ 49 The court found the agreement between Hoechst MRI and Andrx to be a *per se* illegal restraint of trade. This agreement was entered into in September 1997, shortly after Andrx received tentative FDA approval of its generic version of Cardizem CD.[159] The agreement prevented Andrx from entering the market for any Cardizem CD bioequivalent until a final, unappealable judgment in the patent case; prevented Andrx from relinquishing its right to the 180-day exclusivity; and provided for $10 million quarterly payments from Hoechst MRI from the time that final FDA approval was reached until Andrx entered the market.[160] The illegal restraints of trade were: (1) preventing Andrx from marketing its generic version when final FDA approval was granted in July 1998, (2) preventing Andrx from marketing any bioequivalent of Cardizem CD, including non-infringing bioequivalents, and (3) preventing other companies from entering the Cardizem CD bioequivalent market by restraining Andrx from relinquishing its 180-day exclusivity period.[161] The court made its determination by simply examining the provisions of the agreement for whether horizontal competitors attempted to allocate the relevant market.[162] No further analysis was required at this stage of summary judgment because the act of conspiring was enough to constitute a *per se* violation of the Sherman Act.[163]

¶ 50 The court rejected each of the defendant's arguments against summary judgment. Defendants argued that the two companies could not be horizontal competitors because Hoechst MRI had a valid patent and Andrx's drug would infringe that patent. However, at the time the agreement was made, during the infringement suit, there was a very real potential that they would be rivals.[164] Furthermore, the agreement eliminated all avenues of rivalry in the relevant market by restraining Andrx from marketing all bioequivalents of Cardizem CD, including potentially non-infringing drugs.[165]

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157. *See supra* Part II.A.2.b.

158. *In re* Cardizem CD Antitrust Litig., 105 F. Supp. 2d 682 (E.D. Mich. 2000) [hereinafter "*In re* Cardizem"]. The court, in a separate opinion, also denied the defendants' motions to dismiss. *See In re* Cardizem CD Antitrust Litig., 105 F. Supp. 2d 618 (E.D. Mich. 2000).

159. The facts in the court's opinion were the same as those recited in the FTC complaint. Hoechst MRI Complaint, *supra* note 98, at ¶ 17-20; *see supra* Part II.A.2.b.

160. *In re Cardizem*, 105 F. Supp. 2d at 699.

161. *Id.*

162. *Id.*

163. *Id.* at 701, *relying on* United States v. Socony-Vacuum Oil Co., 310 U.S. 150 (1940).

164. *In re Cardizem*, 105 F. Supp. 2d at 700, *citing* Palmer v. BRG of Ga., Inc., 498 U.S. 46 (1990).

165. *In re Cardizem*, 105 F. Supp. 2d at 700, *citing* 11 H. HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION, ¶ 1901b at 185 (1998 ed.).

¶ 51 The pro-competitive justifications for the agreement were also rejected. The agreement did more than settle the claim for injunctive relief, because the restraints exceeded the usual scope of a court-ordered preliminary injunction.[166] The agreement also did not facilitate the expeditious resolution of the infringement suit. In fact, by providing $10 million quarterly payments, it created a large incentive for Andrx to postpone the date of final and unappealable order or judgment.[167] These payments were also not intended to be used as capital to design new, non-infringing drugs, because the agreement also barred marketing bioequivalents.[168] Finally, any possible pro-competitive effects of the option to license did not cure the overall anticompetitiveness of the agreement.[169] In its treatment of the licensing agreement, the court in the consumer action sharply departed from the decision on similar facts by the ALJ in the Schering FTC action, in that the court was willing to effectively treat alleged consideration as a sham.

¶ 52 The court appeared to dismiss offhand one of the potentially most difficult issues in the antitrust suits: the definition of the relevant market. This issue was virtually dispositive in the ALJ's dismissal of the FTC complaint in the case involving Schering-Plough and Upsher.[170] The court addressed the issue of the relevant market in the Cardizem CD case in one sentence: "Defendants do not dispute that they perform at the same level of the market structure or that they are currently competitors in the U.S. market for Cardizem CD or its bioequivalents."[171] The question remains whether the market for Cardizem CD is the relevant market for antitrust purposes. Cardizem CD is a calcium channel blocker used for treatment of hypertension and chest pain.[172] At least 20 other calcium channel blockers are currently available by prescription, with seven different active ingredients.[173] Cardizem CD offers superior treatment for certain forms of hypertension, perhaps even being uniquely well-suited for some conditions.[174] Of course,

166. *In re Cardizem*, 105 F. Supp. 2d at 704 (identifying, in particular, the terms that (1) barred entry of Andrx to the market beyond the resolution of the suit at the district court, (2) provided for large payments paid to Andrx in contrast to the usual Rule 65(c) bond, (3) barred Andrx from transferring the 180-day exclusivity, and (4) barred Andrx from marketing bioequivalents to Cardizem CD, which were not at issue in the patent infringement case).

167. *Id.* at 705. One of the more interesting provisions of the agreement, on which the court did not focus, was one requiring repayment of the $10 million in quarterly payments if Andrx stipulated in writing or in open court and on the record that the patent controlled by Hoechst MRI was valid and the Andrx product infringed that patent. *Id.* at 697. Through this provision, Hoechst MRI created a strong disincentive against its opponent's ever conceding. The effect, of course, was to keep the 180-day exclusivity in the control of Andrx. It should be noted that the duty to litigate we propose in Part IV.A, *infra*, will not have this effect because it will not allow the payments from the brand-name to the generic. Hoechst MRI's deal is akin to a fighter propping up his opponent because he knows that the match has to go 12 rounds.

168. *Id.* at 705.

169. *Id.* ("[T]he clear and unambiguous terms of the Agreement indicate that its main thrust was to have Andrx refrain from going to market with its generic version of Cardizem CD… .").

170. *See supra* Part II.A.2.c.

171. *In re Cardizem*, 105 F. Supp. 2d at 700.

172. *See* Prescribing Information: Cardizem CD, *supra* note 99.

173. *See* WebMD Health, *Heart Disease Medicine: Calcium Channel Blockers* (July 2003), *available at* http://my.webmd.com/content/pages/9/1675_57814.htm?lastselectedguid={5 (last visited Dec. 12, 2003).

174. Hoechst MRI Complaint *supra* note 98, at ¶ 12.

superiority of a product does not render that product a market in and of itself.[175] Nonetheless, the pharmaceutical industry is based on the prescription system, which removes choice from the cost-bearing consumer and effectively creates a single market for the drug prescribed. Thus, treating each prescription drug and its generic versions as the "relevant market" for antitrust purposes is sound policy.[176]

2. Terazosin

¶ 53 Shortly after the *Cardizem* decision, another court found a settlement between a generic and a brand-name a *per se* antitrust violation. The suit was brought by various consumers, pharmacies, and direct purchasers of terazosin hydrochloride ("terazosin"), used to treat high blood pressure and enlarged prostate, against Abbott, Geneva, and Zenith Goldline Pharmaceuticals, Inc. ("Zenith").[177] The suit focused on agreements between Abbott, manufacturer of the brand-name version of terazosin, and two potential generic manufacturers: Geneva and Zenith.[178] As in the *Cardizem* decision, the court granted summary judgment for the plaintiffs and rejected pro-competitive justifications submitted by the defendants.

¶ 54 The two agreements provided for payments to the generic manufacturer to stay out of the market. The agreement between Abbott and Geneva was subject to an FTC complaint and consent decree, and the facts in the summary judgment opinion are the same as those alleged in the FTC complaint.[179] Zenith, another generic manufacturer, submitted an ANDA shortly after Geneva.[180] For several years, Zenith and Geneva were engaged in a heated race to become the first to prevail in their respective infringement

175. This argument was not fully considered in the ALJ's opinion in the case involving Schering-Plough and Upsher, because the ALJ found K-Dur 20 to be interchangeable with other potassium supplement products. *See* Initial Decision, *In re* Schering-Plough Corp. et al., 2002 FTC Lexis 40, *195-200, 206-15 (F.T.C. June 27, 2002) (No. 9297), *also available at* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf at 87-89, 91-95 (last visited Dec. 12, 2003).

176. The ALJ found the relevant market to be the market considered by the doctor, but price does not influence the doctor's "demand curve," so to speak, and thus the market-clearing price would not be expected among competing pharmaceutical products. *See* Initial Decision, *In re* Schering-Plough Corp. et al., 2002 FTC Lexis 40, *196-98 (F.T.C. June 27, 2002) (No. 9297), *also available at* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf at 88 (last visited Dec. 12, 2003). The doctor's choice is influenced primarily by product quality, the availability of information on that product, and the particular patient's condition. A full development of this argument is beyond the scope of this note. *Cf.* W.E. "Ted" Afield, Note, *The New Drug Buyer: The Changing Definition of the Consumer for Antitrust Enforcement in the Pharmaceutical Industry*, 2001 COLUM. BUS. L. REV. 203 (arguing that the shift in drug selection decision-making from physicians to consumers and managed care organizations as a result of increased direct to consumer advertising and managed care structures necessitates a reevaluation of prescription drug market analysis).

177. *In re* Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1341 (S.D. Fla. 2000).

178. *Id.* at 1343. The FTC investigation, for unknown reasons, focused only on the agreement between Abbott and Geneva. *See supra* Part II.A.2.a.

179. *See supra* Part II.A.2.a. The court made clear that the FTC consent decree did not govern the court's decision. *See In re Terazosin*, 164 F. Supp. 2d at 1343 n.2.

180. *Id.* at 1344.

suits against Abbott.[181] In March 1998, however, Geneva received final FDA approval for a generic capsule form of terazosin.[182] Zenith asked the Federal Circuit to hold Zenith's appeal in abeyance. Then, one day after Abbott discovered that Geneva had received approval, Zenith reached an agreement with Abbott.[183] The Zenith settlement included $3 million to dismiss the action plus $6 million per quarter not to sell or market any terazosin product.[184] The settlement also required Zenith to refrain from aiding or assisting any person or entity to gain FDA approval for a generic terazosin.[185]

¶ 55 Both agreements were found to be *per se* restraints of trade. The court examined the agreements both on their face and in the context of the larger factual scenario.[186] The court found that:

> Abbott dissuaded Geneva and Zenith from marketing the first generic terazosin hydrochloride drugs in the United States for an indefinite period, eliminated the risk that either drug maker would sell or purchase the right to introduce such drugs in the interim, and enlisted their potential cooperation in opposing or refusing to support other drug makers' ANDAs.[187]

¶ 56 As in *Cardizem*, the court deferred judgment on causation and damages, but left no uncertainties with regard to the legality of the agreements between the generics and the brand-name.

¶ 57 The court also dismissed the pro-competitive justifications offered by the defendants. The agreement did not facilitate the resolution of a wasteful patent dispute because, in Geneva's case, it actually prolonged the suit. The agreement prevented Geneva from entering the market until final, unappealable judgment, thus prolonging the dispute beyond the district court.[188] Geneva also agreed to join Abbott in any motion extending the 30-month stay of FDA approval.[189] The Zenith agreement similarly lacked any pro-competitive justification. The agreement dismissed a potentially meritorious suit and delayed Zenith's entry to the market until another generic entered, in return for

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181. *Id.* at 1344-45. At the time, the FDA awarded 180-day exclusivity to the first ANDA paragraph IV filer to defend successfully its infringement suit. This regulation was challenged, struck down, abandoned by the FDA, reinstated by another federal judge, and finally eliminated by the Federal Circuit in *Mova Pharm. Corp. v. Shalala*,140 F.3d 1060 (D.C. Cir. 1998); *see supra* Part I.B.1.

182. *In re Terazosin*, 164 F. Supp. 2d at 1345-46.

183. *Id.* at 1346.

184. *Id.* It is unclear from the opinion what were the terms of the dismissal. If it was with prejudice with respect to Zenith's claims of non-infringement, then the FDA would not be able to approve the generic. Therefore the dismissal was either without prejudice or was with prejudice with respect to Abbott's claims of infringement.

185. *Id.* at 1346.

186. *Id.* at 1348-49; *cf. In re Cardizem*, 105 F. Supp. 2d at 695-99 (examining only the text of the agreement for restraints of trade).

187. *In re Terazosin*, 164 F. Supp. 2d at 1349.

188. *Id.* at 1350-51.

189. *Id.* at 1351, n.11.

millions of dollars.[190] The court also found the lack of final FDA approval irrelevant because the act of conspiring was enough to trigger antitrust liability.[191]

3. Buspirone

¶ 58 Bristol-Myers Squibb Company ("BMS") obtained a patent in 1980 for the use of buspirone as an anti-anxiety agent, and has been marketing it under the name "BuSpar" since it received FDA approval in 1986.[192] A variety of plaintiffs, including purchasers of buspirone products, third-party payers, generic manufacturers, consumer protection organizations, and thirty states, brought suit against BMS alleging numerous claims arising out of two separate circumstances: an alleged "sham" settlement with a generic manufacturer that hid the invalidity of the buspirone patent, and alleged abuse of the FDA Orange Book procedure that resulted in a delay of the onset of generic competition.[193] Plaintiffs raised federal and state causes of action for antitrust, unfair competition, deceptive trade practices, and unjust enrichment.[194] All of the cases, including those for patent infringement by BMS against the generic manufacturers, were consolidated in the Southern District of New York.[195]

¶ 59 In the alleged conspiracy to restrain trade, Danbury Pharmacal, Inc. ("Danbury") and its affiliate Schein Pharmaceuticals, Inc. ("Schein"), settled an infringement suit brought by BMS by agreeing not to market generic buspirone before the expiration of BMS's patent.[196] Plaintiffs also alleged that in exchange for the settlement of $72.5 million, Danbury and Schein agreed to support the perception that BMS's buspirone patent was valid, despite the knowledge of all parties that it in fact was not.[197]

¶ 60 Plaintiffs claimed that BMS abused the FDA process and wrongfully delayed the entry of generic buspirone. According to the plaintiffs, this delay was accomplished by listing a newly obtained patent which could not have covered buspirone in the Orange Book less than a day before the expiration of the BuSpar patent, representing to the FDA that a reasonable claim of infringement could be asserted against a generic manufacturer of buspirone based on the newly listed patent, and filing infringement suits against generic manufacturers waiting to enter the market, thereby triggering the automatic 30-month stay.[198] BMS responded by arguing in its motion to dismiss that the listing activities were immune from suit under the *Noerr-Pennington* doctrine.[199]

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190. *Id.* at 1351.

191. *Id.* at 1352, *citing* United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 224 n.59 (1940). Geneva's final approval was pending the "validation" stage of FDA approval. Zenith's final approval would have to wait until 180 days after Geneva entered the market.

192. *In re* Buspirone Patent & Antitrust Litigation, 185 F. Supp. 2d 363, 365 (S.D.N.Y. 2002).

193. *Id.* at 365-66.

194. *Id.* at 366-67.

195. *Id*. at 363.

196. *Id*. at 366.

197. *Id*.

198. *Id*.

199. *Id*. at 369. The *Noerr-Pennington* doctrine holds that combining efforts to petition the government does not violate the Sherman Act. *See* Eastern R.R. Presidents Conference v. Noerr Motor

¶ 61 The court issued two rulings on February 14, 2002.[200] In the first ruling, the court granted summary judgment to the generic manufacturers on BMS's claim of patent infringement for the later-listed patent. [201] This ruling cleared the way for FDA approval of the generic ANDAs. In the second, the court denied BMS's motion to dismiss, finding that listing a patent in the Orange Book is not entitled to *Noerr-Pennington* immunity, because such immunity is "not applicable to conduct through which private parties seek to achieve anticompetitive aims by making representations to the government in circumstances where the government does not perform any independent review of the validity of the statements, does not make or issue any intervening judgment and instead acts in direct reliance on the private party's representations."[202] The court analogized the listing of a patent in the Orange Book, over which the FDA has no discretion if the applicant provides the required certification, to the filing of a tariff which took effect without FCC review of its legal validity that the Second Circuit found not to constitute petitioning activity in *Litton Systems, Inc. v. AT&T Co*.[203] Furthermore, the court ruled that even if *Noerr-Pennington* immunity did apply, so would the *Walker Process* and objectively baseless exceptions.[204] In so ruling, Judge Koeltl had harsh words for BMS:

> This is . . . not a case in which there are occasional places in which Bristol-Myers has mischaracterized or mistaken the relevant issues or legal standards. It is a case where Bristol-Myers has repeatedly argued for a position that requires establishing a number of claims, each one of which has no basis, and each one of which depends upon reframing or mischaracterizing some critical issue or legal standard for its apparent cogency. This is also not a case in which Bristol-Myers has been arguing for reasonable extensions or developments of the law. Bristol-Myers has taken the straightforward position that it can, in effect, extend a monopoly and reclaim an invention after the expiration of its patent on the invention, when "[i]t is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property." The public has already paid for its right to these uses by the grant of a limited patent monopoly to Bristol-Myers, which

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Freight, Inc., 365 U.S. 127 (1961), and United Mine Workers v. Pennington, 381 U.S. 657 (1965). *Noerr-Pennington* immunity can be lost in two ways: if the patent was obtained through fraud as defined in *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965), or if the patent infringement suit was objectively baseless and subjectively motivated by a desire to impose collateral, anticompetitive injury rather than to obtain a justifiable legal remedy. *See* Nobelpharma A.B. v. Implant Innovations, Inc., 141 F.3d 1059, 1071 (Fed. Cir. 1998).

200. Opinions No. 18 and 19 in MDL Docket No. 1410, reported at *In re* Buspirone Patent & Antitrust Litig.185 F. Supp. 2d 340 and *In re* Buspirone Patent & Antitrust Litig., 185 F. Supp. 2d 363.

201. *See In re* Buspirone Patent & Antitrust Litig., 185 F. Supp. 2d 340.

202. *In re* Buspirone Patent & Antitrust Litig., 185 F. Supp. 2d 363, 370.

203. Litton Systems, Inc. v. Am. Tel. & Tel. Co., 700 F.2d 785 (2d Cir. 1983).

204. *See In re Buspirone Patent & Antitrust Litig.*, 185 F. Supp. 2d at 373-76.

> has expired. Bristol-Myers's argument ignores the law and tries to justify taking property that belongs to the public.[205]

¶ 62 Judge Koeltl said more in that statement than was necessary to dispose of a motion to dismiss and clearly conveyed to the parties his view of the substantive issues in the case. Moreover, the judge viewed the issues as legal, rather than factual. Because BMS' new patent could not possibly be construed to cover generic buspirone,[206] the plaintiffs were likely to prevail, so the question is whether the parties will settle or if not, what the remedy will be. In this scenario, the presence of consumer protection organizations seeking injunctions against future anticompetitive behavior is significant, because they may be unwilling to accept a strictly monetary settlement that would otherwise be acceptable to the business plaintiffs.

C. Developing Suits

¶ 63 Several other suits relating to abuses of the Hatch-Waxman Act have been brought by an alliance of consumer groups and plaintiff's class action firms. These suits, which allege antitrust violations due to agreements between companies and abuse of the Hatch-Waxman regulatory apparatus, are presently in various stages of litigation, and those that have not yet had a ruling on the substantive issues in the case are briefly described below.

1. Ciprofloxacin

¶ 64 At least eight different plaintiffs have brought antitrust class action suits on behalf of consumers who purchased Bayer's antibiotic ciprofloxacin in response to settlement of ANDA litigation by the companies. Ciprofloxacin, sold under the brand-name of "Cipro," was the best selling antibiotic in the world from 1993 to2001, with gross sales of more than $1 billion in the United States alone.[207] Bayer holds a patent on the active ingredient in Cipro.[208] Bayer's subsidiary and licensee Miles, Inc. received FDA approval for Cipro in October 1987.[209] Barr Laboratories ("Barr") filed an ANDA on October 27, 1991, alleging in its paragraph IV certification that the Cipro patent was invalid and unenforceable.[210] Bayer sued Barr, triggering the 30-month stay of FDA approval.[211] On November 30, 1992, Bayer and Barr entered into a stipulation that the stay would extend

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205. *Id.* at 376, *quoting* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 152 (1989) (quoting with approval Singer Mfg. Co. v. June Mfg. Co., 163 U.S. 169, 185 (1896) (internal quotation marks omitted)) (citations omitted).

206. *See* Buspirone Patent & Antitrust Litig., 185 F. Supp. 2d 340, 352–63; *see also In re* Buspirone Patent & Antitrust Litig., 185 F. Supp. 2d 363, 376.

207. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 166 F. Supp. 2d 740, 743 (E.D.N.Y. 2001). Cipro is used in fighting anthrax and gained widespread attention in the anthrax scares of 2001. *See* Charles P. Wallace, *Bayer's Silver Bullet*, TIME, Oct. 29, 2001, at 74.

208. *In re Ciprofloxacin*, 166 F. Supp. 2d at 743. The 4,670,444 ("444") patent was filed May 29, 1984, and issued June 2, 1987. *Id.*

209. *Id*.

210. *Id.* at 743-4.

211. *Id*. at 744.

until final judgment in the infringement action and that Barr would not manufacture, use, or sell ciprofloxacin until a final judgment was entered.[212] It is unclear whether Barr received anything in return for this stipulation.[213]

¶ 65 The agreement that led to the antitrust suit occurred four years after the infringement suit began. On January 8, 1997, Bayer entered into an agreement with Barr, Rugby Group ("Rugby"), and Hoechst MRI settling the infringement suit.[214] Barr agreed to recognize the validity of the Cipro patent and refrain from manufacturing or using ciprofloxacin until the expiration of Bayer's patent in December 2003.[215] In exchange, Barr and Rugby received $24.55 million up front with Bayer retaining an option either to pay $25 million per year or to supply Barr and Hoechst MRI with ciprofloxacin to sell as a generic.[216] Unsurprisingly, Bayer elected to make payments rather than allow Barr and Hoechst MRI to enter the market.[217] Pursuant to the agreement, Barr and Bayer entered into a consent judgment, dated January 16, 1997, extinguishing all claims raised in the patent litigation.[218]

¶ 66 The plaintiffs' claims were removed and consolidated by the Judicial Panel on Multidistrict Litigation, but ultimately remanded to state court. While no ruling on the merits of the antitrust claim has been given so far, the district court stated that antitrust liability could attach without proving the invalidity of the patent.[219] Such a finding suggests that a *per se* violation of the Sherman Act is likely to be found, consistent with decisions of the district courts in the Cardizem CD and terazosin antitrust cases.[220]

2. In re K-Dur Antitrust Litigation

¶ 67 In *In re K-Dur Antitrust Litigation*, suits were filed throughout the country by individuals, consumer organizations, and health care and benefit plans against Schering-Plough, American Home Products and Upsher-Smith Laboratories.[221] The suits alleged conspiracy to prevent generic competition in the K-Dur market through collusive settlements between Schering-Plough, the brand-name manufacturer, and generic

212. *Id.*

213. Indeed, it is unclear that the parties had the power to extend the stay of FDA approval. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (providing that extension of the 30-month stay can only occur if a party failed to reasonably cooperate or if a court actually finds infringement). Even if the court issues a preliminary injunction against the manufacture or use, the 30-month stay can only be shortened, not lengthened. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(III).

214. *In re Ciprofloxacin*, 166 F. Supp. 2d at 745. While the role of Rugby and Hoechst MRI in the case is unclear, Hoechst MRI had agreed to assist in financing Barr's litigation against Bayer on March 29, 1996. *Id.* at 745 n.6.

215. *Id*. at 745.

216. *Id.*

217. *Id.*

218. *Id.*

219. *Id*. at 750.

220. *See supra* Parts II.B.1 and II.B.2, respectively.

221. *See In re* K-Dur Antitrust Litig., 162 F. Supp. 2d 688 (J.P.M.L. 2001). *See also supra* Part II.A.2.c (discussing the FTC enforcement action relating to this drug).

manufacturers.[222] The Judicial Panel transferred sixteen actions for consolidated or coordinated procedure in the District of New Jersey, and noted that sixteen other subsequently-filed actions would be treated as potential tag-along actions.[223]

3. In re Tamoxifen Citrate Antitrust Litigation

¶ 68 *In re Tamoxifen Citrate Antitrust Litigation*, which challenges a settlement between a generic and a brand name pharmaceutical company, was consolidated in the Eastern District of New York by the Judicial Panel on Multidistrict Litigation in August 2001.[224] Tamoxifen citrate is marketed under the trade name "Nolvadex," and is used to treat breast cancer in pre-menopausal women.[225] Barr Laboratories filed an ANDA to market a generic version of Nolvadex, and prevailed against Imperial Chemical Industries, PLC ("ICI") at the district court level. The two parties then entered into a settlement in which ICI would pay Barr $21 million and supply it with generic Nolvadex to market, in exchange for a joint request to the Federal Circuit that it vacate the district court's finding.[226] The Federal Circuit granted that request.[227] Plaintiffs alleged that instead of the usual price difference of 30–80% between the generic and the brand name, generic Nolvadex sold at a price only 5% lower than that of the brand-name.[228]

¶ 69 The plaintiffs also alleged further harms based on the actions described in *Mylan Pharmaceuticals, Inc. v. Henney*.[229] In that case, two subsequent ANDA filers for Nolvadex, Mylan and Pharmachemie, were sued by the brand-name manufacturer, triggering 30-month stays.[230] When there were one and two months left on the stays, Barr petitioned the FDA, seeking to stay the new ANDAs on the basis that it was still entitled to its 180-day exclusivity period because it had never marketed under its ANDA.[231] Barr's argument was based on the view that the parties' requested vacation of the district

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222. *In re K-Dur Antitrust Litig.*, 162 F. Supp. 2d at 689. K-Dur is an immediately dispersing potassium chloride extended release tablet for the treatment of low blood potassium levels. K-Dur Product Information Sheet, *supra* note 120.

223. *In re K-Dur Antitrust Litig.*, 162 F. Supp. 2d at 689. The only subsequent published opinion in this case is an order for pretrial discovery in the district of New Jersey. *See* 2001 WL 1347237 (J.P.M.L. 2001).

224. *See In re* Tamoxifen Citrate Antitrust Litig., 196 F. Supp. 2d 1371 (J.P.M.L. 2001). Some plaintiffs attempted to remand the state causes of action. The court denied the motion because the state causes of action turned on federal patent law. *In re* Tamoxifen Citrate Antitrust Litig., 222 F. Supp. 2d 326, 330-33 (E.D.N.Y. 2002).

225. AstraZeneca Pharmaceuticals LP, Nolvadex Professional Information Brochure (June 2003), *available at* http://www.astrazeneca-us.com/pi/Nolvadex.pdf (last visited Dec. 6, 2003).

226. Complaint at 2, Statewide Senior Action Council v. Barr Laboratories, Inc., No. 01 Civ. 2908 (E.D.N.Y., filed May 9, 2001), *available at* http://www.prescriptionaccesslitigation.org/pdf/20010509-Barr-Class-Action-Complaint.pdf (last visited Dec. 6, 2003) [hereinafter Tamoxifen Complaint]. This case was consolidated into *In re Tamoxifen Antitrust Litigation*.

227. Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co., 991 F.2d 811, 1993 WL 118931 (Fed. Cir. 1993) (unpublished table disposition).

228. Tamoxifen Complaint, *supra* note 226, at 3.

229. 94 F. Supp. 2d 36 (D.D.C. 2000), *vacated as moot*, Pharmachemie B.V. v. Barr Laboratories, Inc., 276 F.3d 627 (D.C. Cir. 2002).

230. Tamoxifen Complaint, *supra* note 226, at 22.

231. *Id*. at 23–24

court's finding of patent invalidity somehow served to un-trigger the 180-day exclusivity period, which would otherwise have been triggered by the finding of invalidity. The FDA agreed with this theory, and stayed the other ANDAs. The District Court for the District of Columbia disagreed with Barr's argument, found the FDA's interpretation to be arbitrary and capricious, and ordered that Barr's 180-day exclusivity period had been triggered by the finding of invalidity and was by then long over.[232] Plaintiffs sought to recover for the continuing harm that resulted from Barr's actions in prolonging the control of the Nolvadex market.[233]

4. In re Neurontin Antitrust Litigation

¶ 70 *In re Neurontin Antitrust Litigation* was consolidated in the District of New Jersey by the Judicial Panel on Multidistrict Litigation in August 2002.[234] Plaintiff individuals, consumer organizations, and benefit and health care plans filed suits against Warner-Lambert and its parent, Pfizer, alleging violation of antitrust laws by excluding generic competition for Neurontin by bringing sham patent infringement actions against a number of generic drug manufacturers.[235] Neurontin is the trade name of gabapentin, which is prescribed for epilepsy. [236]

¶ 71 Plaintiffs alleged that Warner-Lambert listed a number of patents in the Orange Book under gabapentin that do not cover the form of gabapentin marketed as Neurontin and, when the Neurontin patent expired in 2000, used these patents to delay generic entry through sham litigation.[237] Warner had filed infringement suits against Neurontin paragraph IV ANDA filers TorPharm, Purepac Pharmaceuticals, Geneva Pharmaceuticals, Teva Pharmaceuticals USA, Zenith Goldline Pharmaceuticals, and Eon Labs Manufacturing.[238] Plaintiffs alleged that this was sham litigation aimed to prolong Warner-Lambert's market exclusivity for Neurontin, which generated $1.3 billion in revenue in 2000.[239]

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232. *Id.* at 25.
233. *Id.* at 3.
234. *In re* Neurontin Antitrust Litig., 217 F. Supp. 2d 1380 (J.P.M.L. 2002) (consolidating 17 pending cases).
235. *In re Neurontin Antitrust Litig.*, 217 F. Supp. 2d at 1381. In a set of actions separate from those discussed here, consumer groups have also sued Pfizer alleging that it promoted the use of Neurontin for uses for which it was not FDA approved (so called "off-label" use). *See* Liz Kowalczyk, *Pfizer Sued Over Drug Promotion*, BOSTON GLOBE, Feb. 5, 2003, at C2.
236. Pfizer, Neurontin Information Sheet at 10 (Sept. 2003), *available at* http://www.pfizer.com/download/uspi_neurontin.pdf.
237. Complaint at 11–19, Salowe-Kaye v. Pfizer Inc., No. 2:02 Civ. 01527 (D.N.J. filed Apr. 11, 2002), *available at* http://www.prescriptionaccesslitigation.org/pdf/20020411-Pfizer-Amended-Class-Action-Complaint.pdf.
238. *Id.*
239. *Id.*

5. Immodium Advanced

¶ 72 In *Kirsch et al v. McNeil-PPC,*[240] plaintiffs alleged that McNeil-PPC ("McNeil") committed antitrust violations by obtaining patents covering Immodium Advanced and by filing an infringement suit against a generic manufacturer.[241] McNeil sold Immodium A-D, a successful anti-diarrheal drug based on its loperamide patents. When McNeil's loperamide patents expired, it faced generic competition.[242] In response, McNeil obtained patents covering the combination of loperamide with the anti-flatulence drug simethicone, and in October 1997 began to market Immodium Advanced.[243] In November 2000, Perrigo Co. filed a paragraph IV ANDA to market a generic version of Immodium Advanced, and McNeil filed an infringement suit in response.[244] In June 2002, the District Court for the Eastern District of Pennsylvania held that McNeil's patents were invalid.[245] The court sharply criticized McNeil's behavior before the Patent and Trademark Office ("PTO"), saying that it was "careless, irresponsible, and, at the very least, tantamount to studied and deceptive ignorance."[246]

¶ 73 Compared to the other cases described above, this case presents a weaker argument for the proposition that the brand-name abused the FDA's drug approval apparatus. When the patent for Immodium expired, McNeil developed a new product that combined two types of medication. McNeil did not try to keep generic versions of the original formulation of its drug off the market, as occurred in many of the cases above. Rather, McNeil was attempting to capture market share through innovation, which is what the patent laws are designed to promote. While the district court judge had harsh words for McNeil's conduct before the PTO, equally harsh words could be directed to the PTO itself if the patent was as inappropriate as the district court ruled that it was, because unlike the FDA, the PTO does review the scope and validity of patents. Even though the court may have been correct in finding the patent invalid, it is not clear that scenarios such as this one should lead to the kind of antitrust liability that the plaintiffs are urging, and which does seem appropriate in cases where the brand-name abuses the regulatory apparatus to prevent generic competition to drugs whose patents have long expired.[247]

6. Wellbutrin

¶ 74 In *Burrell v. GlaxoSmithKline plc.*,[248] plaintiffs alleged that GlaxoSmithKline ("Glaxo") unlawfully prevented generic competition with its Wellbutrin SR.[249]

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240. Complaint, Kirsch v. McNeil-PPC, Inc., No. 02 Civ. 4387 (E.D. Pa. filed July 2, 2002), *available at* http://www.prescriptionaccesslitigation.org/pdf/20020702-Imodium-Complaint.pdf.
241. *Id.*
242. *Id.* at 10.
243. *Id.* at 11.
244. *Id.* at 12.
245. *Id.*
246. *Id.* at 14.
247. *See infra* Part IV.B for further discussions of improvements to the PTO and FDA procedures.
248. Complaint, Burrell v. GlaxoSmithKline plc, No. 02-4431 (E.D. Pa. filed July 2, 2002), *available at* http://www.prescriptionaccesslitigation.org/pdf/complaint-wellbutrin.pdf (last visited Dec. 1, 2003).
249. *Id.*

Wellbutrin SR contains the antidepressant drug buproprion hydrochloride, the patent for which expired a decade ago, and which has been available in generic form for a number of years.[250] Glaxo obtained a patent for an extended-release formulation of the drug that only needed to be administered two times a day rather than the three or four times for the basic drug, and marketed this formulation as Wellbutrin SR.[251] In 1999, Andrx Pharmaceuticals filed a paragraph IV ANDA to market an extended-release formulation of buproprion hydrochloride based on its own pending patent for pill formulation.[252] Glaxo filed suit for infringement, but the PTO determined that Andrx's formulation was distinct enough to warrant its own patent in April 2001, and in February 2002, the District Court for the Southern District of Florida held that Glaxo's patent was not infringed.[253]

¶ 75 As in the Immodium Advanced case above, it is less clear that the consumer plaintiffs in the Wellbutrin litigation can make out an antitrust violation. Unlike the Cipro, K-Dur, Nolvadex, and Neurontin cases, there was no effort to prevent generic manufacturers from marketing a formulation whose patent had long expired. Rather, Glaxo innovated and created a product that was more useful than the previously available version. Also, Andrx behaved consistently with the incentive scheme of paragraph IV certifications: it successfully designed around Glaxo's patent and defended the infringement action. Glaxo's infringement suit is unlikely to constitute an antitrust violation in and of itself. While the PTO issued Andrx a patent for its own process, we have seen many cases where courts have reversed the PTO's decision.[254] Imposing antitrust liability for Glaxo's actions seems to be contrary to the balance, reached by the Hatch-Waxman Act, between reward for innovation and market choices.

¶ 76 These consumer suits are in their infancy, and may not get past the summary judgment stage. Many of the suits fail to meet the direct buyer rule of *Illinois Brick Co. v. Illinois*,[255] depending on how the purchases were structured between primary care providers, pharmacies, and patients. Nonetheless, the potential liability is likely to affect drug manufacturers on both sides of the Hatch-Waxman Act.

III. CURRENT APPROACHES TO REFORM

¶ 77 The deficiencies in the operation of the Hatch-Waxman Act are being addressed by actors in all branches of government. The Senate recently passed, as part of the Medicare bill, an amendment that significantly reforms the 30-month stay and 180-day exclusivity provisions. The FTC has proposed a series of legislative and regulatory

250. *Id*. at 10.
251. *Id*. at 10-11
252. *Id*. at 11-13.
253. *Id*. at 13. The finding of non-infringement is reported in *Glaxo Wellcome, Inc. v. Andrx Pharms., Inc.*, 190 F. Supp. 2d 1354 (S.D. Fla. 2002).
254. As noted earlier, the generic has prevailed in 73% of the infringement suits. GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, *supra* note 77, at 13.
255. 431 U.S. 720 (1977) (holding that indirect buyers of a manufacturer's goods or services could not recover for the manufacturer's alleged antitrust violations; only direct purchasers could recover).

changes, based on its experiences from enforcement actions. The FDA has responded to the FTC's proposals with a rule of its own. Finally, courts are becoming involved through the consumer class action suits. Change, it seems, is in the air.

A. The Gregg-Schumer Amendments

¶ 78 On June 19, 2003, the Senate voted 94-1 to approve an amendment to the Medicare bill introduced by Senators Gregg and Schumer, which dramatically changes some provisions of the original Hatch-Waxman Act.[256] The lone dissenting vote in the Senate was Senator Hatch.[257] The bill limits the availability of the 30-month stay to those patents already listed in the Orange Book at the time of paragraph IV certification, [258] thus avoiding the multiple-stay scenario from *Andrx Pharmaceuticals v. Biovail*.[259] An ANDA applicant must still file a paragraph IV certification for any later-listed patents, but additional 30-month stays are not available.[260] The generic applicant can file a declaratory judgment action against the brand-name manufacturer within 45 days of filing a paragraph IV certification, thus securing the 180-day exclusivity period.[261] A limited private right of action is available to delist a patent from the Orange Book: only as a counterclaim in an existing infringement suit.[262] The amendment also clarifies that the 180-day exclusivity period is triggered by a final court decision.[263] Finally, the generic applicant risks forfeiting its 180-day exclusivity if it fails to market the drug within 60 days of receiving a favorable court decision, or if the FTC determines that it entered into an agreement with the patent owner that violates the antitrust laws.[264] If the first filer forfeits its 180-day exclusivity, the second ANDA filer can enter the market but will not have a 180-day exclusivity period available.

¶ 79 The Gregg-Schumer Amendment greatly improves the Hatch-Waxman mechanism but falls short in some significant respects. While limiting the availability of 30-month stays is desirable, selecting 30 months as the duration of the stay is arbitrary, as we discuss in Part IV.C, *infra*. The availability of the counterclaim for delisting is

256. S. 1225, 108th Cong. (2003); *see also* Robert Pear & Robin Toner, *Senate Votes to Give Consumers Faster Access to Generic Drugs, Amending Medicare Bill*, N.Y. TIMES, June 20, 2003, at A18. The amendment is titled the "Greater Access to Affordable Pharmaceuticals Act."

257. Senator Hatch explained his disagreement in a floor statement. See Orrin Hatch, *Floor Statement: The Greater Access to Affordable Pharmaceuticals Act* (June 27, 2003), *available at* http://hatch.senate.gov/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=835. Although he agreed with the main provision limiting the number of 30-month stays to one, he disagreed with the creation of the declaratory judgment action and advocated a return to the successful-defense requirement abandoned in *Mova Pharm. Corp. v. Shalala*. *See id.*

258. S.1225 at § 2(a).

259. *See supra* Part I.B.3.

260. S. 1225 at § 2(a). If the generic applicant files an entirely new ANDA in response to a later-issued patent, a new 30-month stay is available, but if the generic applicant does so, it would risk losing its first-filer status. *Id.*

261. *Id.*

262. *Id.* at § 2(b).

263. *Id.* at § 3(a).

264. *Id.*

appropriate and may reduce some needless litigation by causing a brand-name to think twice before bringing suit. The counterclaim creates the risk for the brand-name of losing that patent listing such that later generics will be able to have ANDAs approved with much more ease. Limiting the delisting action to a counterclaim also minimizes the use of judicial resources on an administrative matter that should be within the FDA's domain.[265] The 180-day exclusivity period should remain available to the second filer if the first filer forfeits that exclusivity due to inequitable conduct. Some incentive for generics to develop around existing patents is thus lost, and, as the results of Hatch-Waxman have shown, that added incentive greatly increases the availability of generic drugs.[266] Overall the Gregg-Schumer Amendments are a significant improvement, although they are not likely to be the last word in legislation, litigation, or regulation in this area.

B. The FTC Recommendations

¶ 80 In its study,[267] the FTC proposed five legislative and regulatory changes:

> (1) There should only be one 30-month stay per drug product per ANDA.[268] Under current practice, if the owner of a brand-name drug lists an additional patent covering the drug in the Orange Book, then the generic must make another paragraph IV certification, and if the brand-name company sues within 45 days, another 30-month stay issues.[269] The FTC believes that these later-issued patents may not meet the requirements for listing, but there is no private right of action to challenge the listing and the FDA has claimed that it does not have the expertise or manpower to review the propriety of listing a patent.[270] As a result, it is possible that brand-name companies are abusing the process by listing inappropriate patents to generate additional 30-month stays, further delaying generic entry. To eliminate this potential for abuse, the FTC recommends that only one stay be allowed.
>
> (2) Legislation should be passed to require companies to provide the FTC with copies of agreements made between the first generic ANDA filer with a paragraph IV certification and the brand-name company where the agreement has the potential to keep subsequent ANDAs from being approved due to the 180-day marketing exclusivity provision.[271] Under current practice, it is possible for the first paragraph IV ANDA filer to prevent the

265. *See infra* Part IV.B for improvements to the Orange Book listing process.

266. Generic drugs are now nearly 50% of the market; in 1984, the year the Hatch-Waxman Act was passed, the market share for generics was less than 20%. *See* GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, *supra* note 77, at i.

267. The FTC study was discussed in Part II.A.1, *supra*.

268. GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, *supra* note 77, at ii.

269. *Id.* at iii.

270. *Id.* at iv.

271. *Id.* at vii.

approval of a second ANDA by failing to resolve infringement litigation with the brand-name company. Fourteen of the twenty settlements the FTC analyzed for its study had this potential, although since the FTC investigations became public, first ANDA filers and brand-name companies have not entered into agreements with such potential.[272]

(3) The meaning of "commercial marketing," for purposes of triggering the 180-day exclusivity period, should be clarified in situations in which the first ANDA filer agrees with the brand-name to market the brand-name product as a generic under the brand-name company's NDA, rather than its own ANDA.[273] Under current practice, the FTC is unsure whether such marketing would trigger the 180-day exclusivity provision.[274] If it did not, then if the brand-name did not sue the second ANDA filer, there would never be a triggering event for the 180-day exclusivity period, and the FDA would be unable to approve the second or any subsequent ANDA.

(4) *Any* court finding of invalidity or non-infringement of the patent at issue should serve as a trigger for the 180-day marketing exclusivity period for the first-filed ANDA.[275] This is the current FDA practice,[276] and the FTC would like to see it codified. The alternative interpretation of the court-decision triggering provision[277] is that only a decision in the litigation involving the first ANDA applicant would trigger the period. Under this interpretation, it would be possible for a second applicant to have a court ruling of non-infringement, but be unable to bring the generic to market if there has been no court decision involving the first ANDA filer.

(5) A court decision dismissing a declaratory judgment action for lack of subject matter jurisdiction should serve as a trigger for the 180-day marketing exclusivity period.[278] The D.C. Circuit determined such dismissal constituted a trigger in a situation in which the second ANDA filer brought a declaratory judgment that its ANDA was non-infringing, and the brand-name indicated that

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272. *Id.* at 63.

273. *Id.* at ix. This type of arrangement occurred in *In Re Tamoxifen Citrate Antitrust Litig.*, described in *supra* Part II.C.3.

274. *Id.*

275. *Id.* at ix.

276. *See* Food and Drug Administration, *Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, at 4–5 (June 1998), *available at* http://www.fda.gov/cder/guidance/2576fnl.pdf (last visited Dec. 15, 2003).

277. 21 U.S.C. § 355(j)(5)(B)(iv)(II).

278. GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY, *supra* note 77, at x.

> it would not sue the second ANDA filer for infringement.[279] If other circuits held otherwise, the result would be that if the first ANDA filer neither litigated nor marketed, subsequent filers would be unable to bring the generic to market.

¶ 81 In our view, the FTC's solutions (1), (4), and (5) are correct. Solution (2) should be extended to cover all agreements between ANDA filers and brand-names, as the added administrative burden to the FTC of reviewing those agreements should not be so great, where the FTC found 14 out of 20 such agreements had anticompetitive potential. We disagree with solution (3), due to the effect of solution (4) (with which we agree). A licensing generic manufacturer in the scenario described in solution (3) has not fully earned its 180-day exclusivity period, because a licensed generic will not be as inexpensive as a "true" generic due to licensing costs and higher barriers to market entry. In that scenario, there should still be an incentive for someone to break the NDA patent. Solution (4) means that there will still be incentives for the second filer to pursue final judgment.

C. FDA Proposed Rule

¶ 82 The FDA responded to the FTC report by proposing rule changes for the patent listing and ANDA processes.[280] The proposed rule would do three things: (1) define more clearly what types of patents must and must not be listed in the Orange Book, (2) provide a new checklist-style declaration for the patent listing, designed to help applicants and the FDA ensure that appropriate patents are listed, and (3) allow only one 30-month stay per ANDA.[281]

¶ 83 The proposed rule "would expressly state that information on patents claiming packaging, patents claiming metabolites, and patents claiming intermediates must not be submitted," because these patent types fall outside of the statutory scheme.[282] The rule would also require listing of patents that claim a different form of the NDA drug, "as long as the drug substances are the 'same' active ingredient" as defined by the statute.[283] The reason for this change is that under current practice, ANDA applicants could file for a generic that contains the "same" active ingredient in a different form, and correctly certify that their generic does not infringe the patent listed in the NDA, even in the not uncommon case where the NDA holder actually holds the patent on the alternative form,

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279. *See* Teva Pharms., USA, Inc. v. FDA, 182 F.3d 1003 (D.C. Cir. 1999).

280. Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug is Invalid or Will Not be Infringed, 67 Fed. Reg. 65,448 (proposed Oct. 24, 2002) (to be codified at 21 C.F.R. pt. 314) [hereinafter "FDA Proposed Rule"]. As the cost of prescription drugs is a hot topic in the political field, the proposed regulations were trumpeted by the White House. Press Release, The White House, *President Takes Action to Lower Prescription Drug Prices by Improving Access to Generic Drugs*, (Oct. 21, 2002), *available at* http://www.whitehouse.gov/news/releases/2002/10/20021021-4.html (last visited Dec. 19, 2003).

281. FDA Proposed Rule, 67 Fed. Reg. at 65,448-49.

282. *Id.* at 65,451.

283. *Id.* at 65,452.

but could not list it under the current rules. The NDA holder would then be able to commence successful infringement litigation against the generic manufacturer. This constitutes a waste of resources for the generic manufacturer, the brand-name manufacturer, and the FDA, all of which can be avoided by the increased knowledge of who holds patents for "same" drug ingredients that the proposed rule provides.[284]

¶ 84 The projected economic impact of the decrease in delay of generic competition as a result of the proposed rule is significant. The estimated one-year impact will be gains of $1.1 billion to generic manufacturers through earlier access to the market and $2 billion to consumers in reduced drug prices, with equivalent ($3.1 billion total) losses to brand-name manufacturers.[285] The estimated 10-year total costs are $51.5 billion to brand-name firms, with corresponding benefits of $53.9 billion, split between generic manufacturers and consumers.[286]

¶ 85 The FDA appears to have adopted the FTC's recommendations to the extent of its powers. Clarifying Orange Book practice is useful, but we have further suggestions in Part IV.B, *infra*. The FDA should consider coordinating with the PTO on the applicability of patents to those listed in the Orange Book. The large benefits from such modest changes illustrate the present problems with the Hatch-Waxman Act.

D. Comparison of FTC Enforcement and Consumer Class Action Suits

¶ 86 While the FTC has been successful in pursuing a number of its complaints to consent decrees, some of the limitations of the agency make the consumer class action suit a superior means of enforcement. The FTC cannot pursue punitive damages, limiting its deterrent function, and does not seek refunds of consumer overpayment, limiting its restitutionary function. A consumer class action suit provides the appropriate level of deterrence by allowing for punitive damages in cases of willful misconduct or antitrust violations.[287] The consumer suit also serves restitutionary goals by returning excess payments to consumers.

¶ 87 The FTC's advantage in seeking prospective relief can be replicated by including non-profit consumer groups in the class action litigation. Generally, a consumer class action suit will simply seek damages, allowing the threat of future suits to deter similar behavior in the future. Having consumer groups as part of the lead attorney team helps to alleviate this concern. The consumer group can insist on prospective injunctive relief as part of any settlement. The affiliation of consumer groups and plaintiff class action firms can overcome the deficiencies of either acting alone: the consumer group lacks the financial capacity to litigate vigorously, and the plaintiff class action firm lacks the incentives to seek prospective relief. The incentives of these groups also help to alleviate

284. *See id.* at 65,453.
285. *Id.* at 65,462-63.
286. *Id*. at 65,463.
287. Shavell and Polinsky have suggested that punitive damages promote efficiency when they adjust for the possibility that the inefficient/illegal conduct may not be discovered. *See* A. Mitchell Polinsky & Steven Shavell, *Punitive Damages: An Economic Analysis*, 111 HARV. L. REV. 869 (1998).

some of the burden on state attorney general offices in pursuing these suits.[288]

IV. SOLUTIONS

¶ 88 The suits and settlements discussed in Part II evince serious structural problems in the Hatch-Waxman apparatus. While the current approaches to reform discussed in Part III are generally positive, further changes in three areas would establish an efficient generic drug regime: a duty to litigate, changes in Orange Book Practice, and market-based stay length and damages. The following table presents the problems encountered along with our proposed solution.

Table 1. Evaluation of Possible Settlement Scenarios with Recommendations

Scenario	Effect	Antitrust risks?	Recommendation	Discussion
Brand-name relents, dismisses suit with prejudice.	180-day exclusivity period begins for the first filer.	No		
Brand-name licenses to generic to make the generic drug under its NDA, dismisses without prejudice.	180-day exclusivity period is "lost" on the first generic or possibly prevents the approval of subsequent ANDAs.	Yes: Generic may effectively share brand-name's monopoly profits by keeping a high price and paying a high licensing fee. Consumers do not get the benefit of a "true" generic.	Next ANDA filer should receive 180-day exclusivity period.	See Part III.B, solution (3).
Generic relents, but receives no payment.	180-day exclusivity period shifts to second filer.	No		
Generic relents and receives payment.	180-day exclusivity period shifts to the second filer.	Yes: brand name has used its monopoly profits to pay off potential competitor.	Should be a flat ban.	See Part IV.A.
Generic relents with any kind of side deal.	180-day exclusivity period shifts to the second filer.	Possibly: FTC needs to examine to determine whether side deal is bona fide or is a disguised payment.	Agree with FTC's recommendation to examine settlements in such suits, would go further to say that FTC should examine all such settlements.	See Part III.B, solution (2) and discussion.

288. This team of consumer groups and plaintiff class action firms has had some early success. The aforementioned suits, involving Cipro, BuSpar and others, are the product of an alliance among 75 consumer groups nationwide and the leading plaintiff's class action firms. *See* http://www.prescriptionaccesslitigation.org. This alliance, called the Prescription Access Litigation Project ("PAL"), also has nascent suits in other areas of pharmaceutical law. *See, e.g.*, Prescription Access Litigation Project, Average Wholesale Price Manipulation Lawsuit, *at* http://www.prescriptionaccesslitigation.org/awp.htm (last visited Dec. 9, 2003); Prescription Access Litigation Project, Claritin Lawsuit, *at* http://www.prescriptionaccesslitigation.org/claritin.htm (last visited Dec. 9, 2003). The success of this group provides useful insights for the reform of the Hatch-Waxman Act and serves as a model for consumer class action litigation in other areas.

A. Duty to Litigate: Scope and Meaning

¶ 89 From the examples of collusive settlements examined above, it is clear that judicial monitoring of settlements in the brand-name / generic arena is inadequate. It has been suggested that increased judicial scrutiny of settlements would be more expensive than structural changes to the Hatch-Waxman process, despite the availability of seemingly simple tests such as the direction in which settlement payments are flowing.[289] Due to the demonstrated limits of the scrutiny courts direct to these settlements, we agree that structural changes are preferable. The best structural change would be to prohibit settlements between ANDA filers and the brand-name manufacturer in the ANDA infringement litigation where the brand-name pays the ANDA filer.[290] That is, there should be a duty either to litigate such suits to a judgment of infringement/noninfringement or validity/invalidity or to dismiss them.

¶ 90 The idea of a duty to litigate is anomalous in our legal system, which generally favors the out-of-court settlement of disputes.[291] However, the narrow situation presented in ANDA litigation presents compelling rationales for such a duty. The patent and drug approval laws contain a tradeoff of monopoly for innovation.[292] ANDA practice provides an incentive to find ways around the monopoly, or to demonstrate that the monopoly was improperly granted. Because monopoly profits are greater than competitive profits, there is a greater pie to be divided when the patent is not disturbed. Therefore it will often be to the advantage of both of the parties to ANDA litigation to split the monopoly profits.[293] Because such splitting is contrary to the antitrust laws[294] and the purposes of the Hatch-

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289. *See* Julia Rosenthal, *Antitrust: Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 BERK. TECH. L.J. 317, 332–33 (2002) (discussing suggestion by FTC Commissioner Thomas Leary that "the most straightforward test of the legitimacy of patent settlements … is the presence of payments from the patent holder to the potential challenger. Since these payments flow in the opposite direction of an expected license agreement …, they can be considered evidence of a presumptively anti-competitive agreement."); *see also* FTC Commissioner Thomas Leary, Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes Part II, Speech Before the American Bar Association's Antitrust Healthcare Program (May 17, 2001), *available at* http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm.

290. David Balto suggests that reforming the 180-day exclusivity provision will avoid many of the antitrust risks in brand-name generic settlement. *See* Balto, *supra* note 7, at 339. We disagree, because there are antitrust risks whenever payments go to the generic, even without 180-day exclusivity period.

291. Sometimes litigation of sorts can be compelled, such as shareholder derivative suits. Other commentators have been sharply critical of settlements. *See generally* Owen M. Fiss, *Against Settlement*, 93 YALE L.J. 1073 (1984); David Luban, *Settlements and the Erosion of the Public Realm*, 83 GEO. L.J. 2619 (1995).

292. *See generally* Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1813 (1984) (describing the tension between patent and antitrust law).

293. Even if the generic has a high probability of prevailing, it will be in the generic's interest to settle and share the monopoly profits, especially if other firms can be kept out of the market through misuse of the 180-day exclusivity provision. It is only when the brand-name has a high probability of prevailing that both parties will not want to settle, but based on generic companies' overall rate of success (approximately 75%) in the infringement suits, this scenario is less likely. The fact that the generic filed the ANDA in the first place indicates that the generic anticipates a high probability of success.

294. Justice White, concurring in *United States v. Singer Mfg. Co.*, 374 U.S. 174, 199–200 (1963), wrote: "[The two parties] agreed to settle an interference, at least in part, to prevent an open fight over

Waxman Act,[295] it simply should not be permitted. To the extent that settlement in general allows for parties to avoid uncertainty and create outcomes based on probabilities, it is an inappropriate device for the resolution of ANDA litigation.[296] In ANDA litigation, it is in the public interest to know whether a generic drug is infringing or not, but never in the public interest to allow an ANDA filer to split monopoly profits with a brand-name manufacturer.

¶ 91 The duty to litigate would also have a positive effect on the quality of paragraph IV ANDA certifications. When the generic applicant knows that it will not be able to settle with the brand-name for a payment, there will be no incentive to file ANDAs that are only worthwhile in a regime in which the brand-name will settle with the generic to avoid the uncertainty of a trial on the validity and infringement questions. This discourages the filing of frivolous paragraph IV ANDAs. The purpose of the ANDA incentive is to find genuine ways around a patent or instances of invalid patents, not to extract payments from brand-name manufacturers based on litigation uncertainties over monopoly profits.

¶ 92 It would also be necessary to outlaw a potential work-around of the duty to litigate, which would be for a generic to take its ANDA directly to the brand-name *before* it filed and suggest that the brand-name company make the same payment arrangement that it would have made in litigation. The incidence of such agreements would be harder to detect than settlements to court actions, but banning such agreements would make them unlikely to occur for several reasons. First, as illegal agreements, they would be unenforceable and are consequently less useful. Second, a generic manufacturer would not be sure that the brand-name would not turn the offer over to authorities and incur whatever sanction is established. Third, the generic manufacturer would risk losing its ANDA first filer benefits if another generic files during negotiations. These agreements could also be discovered through whistleblowers and by observing the inflow and outflow of funds, which could be difficult to disguise.

B. Accompanying Changes in Orange Book Practice

¶ 93 Most proposed solutions have centered on revisions to Orange Book practice, and we agree that significant reforms are needed. The potential for multiple 30-month stays has, in some cases, extended market exclusivity far beyond the life of the patent. The

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validity. There is a public interest here … which the parties have subordinated to their private ends — the public interest in granting patent monopolies only when the progress of the useful arts and of science will be furthered because as consideration for its grant the public is given a novel and useful invention. . . . In my view, such collusion to secure a monopoly grant runs afoul of the Sherman Act's prohibitions against conspiracies in restraint of trade — if not bad *per se*, then such agreements are at least presumptively bad."

295. "The [Hatch-Waxman Act] has been turned on its head. We were trying to encourage more generics and through different business arrangements, the reverse has happened." Congressman Henry A. Waxman, *quoted in* Shery1 Gay Stolberg & Jeff Gerth, *How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, at A1 (quoted by Balto, *supra* note 7, at 321).

296. The profit-maximizing decision for both parties in almost all ANDA litigation suits is to share the monopoly profits rather than face the litigation risk. Therefore, allowing companies to assess relative risks and rewards invariably will incorporate calculations of illegal gains from antitrust violations.

180-day market exclusivity granted to the first generic manufacturer can be used to keep other generics off the market for far longer than 180 days. The lessons learned from the abuses of the system point toward certain improvements.

¶ 94 First, listing of drug patents in the Orange Book and certification requirements should be product-specific. Currently, the Hatch-Waxman Act provides that an ANDA filer must make a paragraph IV certification whenever an unexpired patent is listed for the NDA corresponding to the generic filer's ANDA.[297] Orange Book listings contain all drug products and all patents for those products under a single NDA. Therefore, ANDA filers will have to make certifications with respect to patents that may not even be involved in their drug product, which can result in frivolous litigation by the NDA holder to extend market exclusion on a product whose patents have expired.[298] The Orange Book should be listed by drug product, and generic manufacturers should just be required to certify with respect to a given drug product. Any risk that generic drug manufacturers would abuse this system by making equivalents of newer products while claiming to make equivalents of older products with expired patents is mitigated by the requirement that the generic be the bioequivalent of the original product. The FDA is well-equipped to determine whether the generic is equivalent to the original product or one of the more recent products.

¶ 95 Second, the patents listed in an NDA for a particular drug product should be limited to those patents submitted initially and those pending when the NDA is issued. Any patent filed after an NDA is approved must not be able to claim the original drug product of that NDA. If the NDA is approved, then that drug product would be prior art for any subsequent patent.[299] Therefore, the patent applicant would have to disclaim that drug product during patent prosecution. If that drug product has been disclaimed, then the NDA holder would not be able to "reasonably" assert a patent infringement claim if an unlicensed person "engaged in the manufacture, use, or sale of the drug."[300] So, given that no later-filed patents could possibly apply to that drug, no patents other than those issued or pending at the time of approval should be listed for that drug.

¶ 96 Third, the holder of the NDA should be estopped from bringing a patent

297. 21 U.S.C. § 355(j)(2)(A)(vii).

298. An NDA may contain the original formulation of the drug, for example for a drug in capsule form. The manufacturer may file a supplement to its NDA with a new formulation of the drug, for example, containing a patent for the tablet form. Since the patent for the tablet formulation can then be listed under the same NDA, a generic must submit a paragraph IV certification asserting that its generic capsule drug does not infringe the tablet formulation patent (which should be obvious to all parties), even though the patents on the original product have expired. Despite the obvious lack of merit of such a suit, the brand-name manufacturer could bring an infringement suit under the tablet patent, and thus receive the 30-month stay. We should also be concerned with the generic manufacturer's receiving 180 days of exclusivity merely for filing a paragraph IV certification when a paragraph III (patents expired) certification would suffice. Because the generic company did not perform any service such as breaking a meritless patent that may have inhibited generic entry, the generic does not deserve the reward of 180 days of market exclusivity.

299. *See* 35 U.S.C. § 102(b) (such a drug product would be publicly disclosed or for sale).

300. *See* 21 U.S.C. § 355(b)(1).

infringement suit based on any patent that is not listed in the Orange Book for the particular drug product. This requirement will add teeth to the listing requirements of the Orange Book by effecting a use-it-or-lose-it policy. While patent searches may be handled expeditiously using various electronic services,[301] the development of generic drugs will be facilitated by greater disclosure of relevant patents, and the NDA holder is the party with the most ready access to that information. As discussed above, any later patents could not apply to the drug product due to prosecution history estoppel. The generic has asserted that the drug product in its ANDA is the same as the listed drug product, and if it is not, its application will fail because of the FDA's requirement of bioequivalence. Therefore, the only relevant patents are those that the NDA holder asserts for the particular listed drug product.

C. Stay Length and Damages

¶ 97 Choosing the length of stay to be 30 months is arbitrary. If the stay exists to prevent generic manufactures from causing more damage then they can pay for due to the price differential between the brand-name and generic products, then the stay should last as long as the litigation does. This is analogous to obtaining an injunction, as would be required by the Gregg-Schumer bill, but due to the similarity of the situation encountered in every ANDA filing, there is good reason for it to happen automatically. In cases in which the brand-name manufacturer prevails, there is no need to determine compensation for the injunction. Where the generic manufacturer ultimately prevails, however, there are a number of problems. First, both generic manufacturers and consumers have been harmed. Second, due to the fact that the amount of the harm is based on what the market price would have been in the presence of competition, the amount of damages is uncertain and speculative.

¶ 98 We propose that to solve the problem of the harm to the consumers, the portion of the damages that "belongs" to the consumers should be transferred to a government drug-benefit plan, which would inure to the benefit of prescription drug purchasers, if not precisely the same ones who purchased the drug. The damages that should be paid to the generic manufacturers are difficult to determine because of uncertainty regarding how many manufacturers would have entered the market and what the prices would have been. The best way to solve this problem would be to let the market actually run its course, and then award damages based on the results. That is, after the litigation is resolved in the generic's favor, the generic enters the market, as do subsequent manufacturers after the exclusivity period. After an appropriate length of time, the damages will be calculated and distributed according to the profits that the generic manufacturers achieve in the market.

¶ 99 This damages scheme avoids the problem of multiple companies' filing ANDAs in order to get a piece of the damages from the period in which no generic competition

301. *See, e.g.*, http://www.lawmart.com; http://www.micropat.com; http://www.bustpatents.com.

was allowed.[302] Also, tying the award of damages to profits checks the distortion of the market that would occur if the damages were based on the market share achieved by the competing generic firms. In such a scenario, the bonanza of the large damage judgment would cause firms to cut prices more than they would under optimally competitive conditions in order to take as much of the damage award as is profitable. By calculating and distributing the damages based on profit, there is little, if any, distorting effect caused by the lawsuit outcome: the firm's incentive is, as always, to maximize profit.[303] By taking the brand-name's excess profits and distributing them to consumers and competitors, the harmful effect of staying the ANDA during the litigation is removed.

V. CONCLUSION

¶ 100 Abuse of the procedures established by the Hatch-Waxman Act has led to effects that are contrary to the intent of the act. These effects have been well documented by the FTC and have been the impetus for procedural change at the FDA. The consumer suits illustrate that consumers are also real parties in interest in controversies regarding generic drug entry. The FTC recommendations take steps toward incorporating this interest, but further changes are warranted to ensure the timely marketing of generic drugs. Together with the FTC's suggestions, our proposed changes — the duty to litigate ANDA infringement suits, changes in the Orange Book listing practice, and a real-market based disgorgement of excess profits accrued during an automatic injunction — would ensure that brand-name pharmaceutical companies receive their due patent protection, but nothing more. Our health care system deserves nothing less.

302. The requirements of preparing an ANDA, including manufacturing the drug and demonstrating bioequivalence, are also significant barriers to this kind of tag-along activity.

303. Of course, the check that the real-world profits have on distorting market share does not apply to the distortions on profits caused by creative accounting. This, however, is a concern in many areas of the corporate law, and is not unique to this method of computing damages. We expect that less than honest behavior in this corner of accounting will be dealt with by the same mechanisms that govern accounting generally, and we can expect extra scrutiny to be applied by the brand-name firm from whom the payment is being extracted.