IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

MYLAN PHARMACEUTICALS INC.
781 Chestnut Ridge Road
Morgantown, WV 26505,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20857,

TOMMY G. THOMPSON
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20204,

LESTER M. CRAWFORD
Acting Commissioner of the Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857,

PROCTER & GAMBLE PHARMACEUTICALS, INC., THE PROCTER & GAMBLE COMPANY,
One Procter & Gamble Plaza
Cincinnati, OH 45202, and

WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC.,
311 Bonnie Circle
Corona, CA 92880,

Defendants.

Civil Action No. 1:04cv242

COMPLAINT

Plaintiff Mylan Pharmaceuticals Inc. ("Mylan"), for its Complaint against the Food and Drug Administration ("FDA"); Tommy G. Thompson, Secretary of Health and Human Services;

Lester M. Crawford, Acting Commissioner of FDA; Procter & Gamble Pharmaceuticals, Inc.; The Procter & Gamble Company (collectively, "P&G"); Watson Pharmaceuticals, Inc.; and Watson Laboratories, Inc. (collectively, "Watson"), alleges as follows:

Nature Of The Action

1. This action arises out of the marketing of a so-called "authorized generic" drug during Mylan's Congressionally-mandated 180-day generic exclusivity period.

2. Mylan, a generic drug company, routinely files abbreviated new drug applications ("ANDA") seeking FDA approval to market generic versions of various brand-name drugs prior to the expiration of related brand patents. Mylan is often the first applicant to do so, as with its ANDA seeking immediate approval to market a generic version of P&G's Macrobid® (nitrofurantoin monohydrate/macrocrystals) ("nitrofurantoin"). Nitrofurantoin is a prescription drug widely prescribed for the treatment of acute urinary tract infections ("UTI").

3. Mylan's nitrofurantoin ANDA contained so-called "paragraph IV certifications" to P&G's "Orange Book-listed" patents for Macrobid®, certifying that such patents would not be infringed by Mylan's generic drug. By virtue of—and as a reward for—being the first paragraph IV ANDA-filer (hereinafter "first-filer") for nitrofurantoin, the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by the Hatch-Waxman Amendments, grants Mylan the right to a 180-day period during which time *no* other generic nitrofurantoin product may be marketed and sold. *See* 21 U.S.C. § 355(j)(5)(B)(iv). As FDA has stated:

> [I]t is clear that the statute intends to provide 180 days for the first generic to be on the market as the *sole competitor of the innovator product.*

(Feb. 16, 2001 Hearing Tr. at 67, *Mylan Pharms. Inc. v. Thompson,* Civ. A. No. 1:01CV23 (N.D. W.V.) (emphasis added).)

4. Congress enacted the 180-day generic exclusivity reward as the powerful, market-based incentive needed to encourage generic manufacturers and developers, like Mylan, to undertake the risk and expense of challenging brand-name patents. Congress created this incentive for the purpose of expediting the market entry of lower-priced generic drugs earlier than would otherwise be the case (*i.e.*, before patent expiration). The viability and protection of Congress's exclusivity incentive is absolutely critical to achieving Hatch-Waxman's goal of getting less-expensive generic drugs in the hands of American consumers as quickly as possible.

5. Just as Congress intended when creating the exclusivity incentive, Mylan has regularly invested millions of dollars researching and developing lower-priced generic drugs and filing the first paragraph IV ANDA challenging the many blocking patents on brand drugs like P&G's Macrobid® (nitrofurantoin), Pfizer's Norvasc® (amlodipine besylate), Johnson & Johnson's ("J&J") Levaquin® (levofloxacin), and J&J's Ditropan XL® (oxybutynin chloride). Mylan made these substantial investments and undertook the risk and expense of challenging, and continuing to challenge, the patents for these brand drugs for the purpose of securing eligibility for 180-day generic exclusivity on these products and many others. The exclusivity incentive is an integral part of Mylan's business model, which depends on the additional revenues generated during the exclusivity period to develop new generic drugs and fund additional patent challenges.

6. Here, relying on this 180-day exclusivity, Mylan made substantial investments in anticipation of an exclusive commercial launch of its generic nitrofurantoin product. Shortly before launch, however, Mylan discovered that P&G had entered into an unlawful scheme pursuant to which P&G licensed and authorized Watson to launch an "authorized generic" version of P&G's Macrobid® during Mylan's 180-day generic exclusivity period.

7. The term "authorized generic," as defined by the Food and Drug Administration ("FDA"), means "any marketing by an NDA holder or authorized by an NDA holder, including through a third-party distributor, of the drug product approved under the NDA in a manner equivalent to the marketing practices of holders of an approved ANDA for that drug." (FDA Decision Letter, Docket Nos. 2004P-0075; 2004P-0261, at 2 n.2 (July 2, 2004).) Besides the names and how they are promoted and sold, the only distinction between the brand-name drug and authorized generic drug is "the lowering of the price for this [authorized generic] version of the drug product relative to the price of the brand version." (*Id.*) In other words, an authorized generic is just the brand-name drug disguised and sold as a generic drug during the first-filer's exclusivity period.

8. Mylan petitioned FDA in February 2004 to protect its 180-day generic exclusivity rights for nitrofurantoin and numerous other products. Mylan petitioned FDA to prohibit the marketing of any competing generic drug, regardless of source (NDA or ANDA), during the first-filer's exclusivity period—including the imminent marketing of Watson's authorized generic drug during Mylan's 180-day generic exclusivity period ("Mylan's Petition").

9. Upon receiving final approval from FDA, Mylan commercially launched its nitrofurantoin product on March 23, 2004, thus triggering its 180-day exclusivity period. But, the very next day, Watson announced that it had launched an authorized generic product, depriving Mylan of the 180-day generic exclusivity to which it was statutorily entitled. Watson's product merely is P&G's Macrobid® disguised and sold as a generic drug without the brand-name. Prior to Mylan's launch, Watson was in the marketplace pre-selling and, on information and belief, promoting its generic Macrobid® at prices below Macrobid®'s cost in order to interfere with Mylan's existing and expected business relationships.

10. In a final administrative ruling dated July 2, 2004, FDA denied Mylan's Petition in its entirety, permitting P&G and all other brand companies to market authorized generic versions of their brand drugs during the first-filer's 180-day exclusivity period.

11. FDA's denial of Mylan's Petition has severely harmed, and continues to severely harm, Mylan by depriving it of exclusivity for nitrofurantoin. The unlawful competition by P&G's and Watson's authorized generic product during Mylan's exclusivity period has substantially reduced Mylan's market share for nitrofurantoin by diverting the profits that Mylan would have otherwise received as Congress intended. FDA's administrative ruling also jeopardizes Mylan's eligibility for exclusivity on numerous other drugs, including amlodipine, levofloxacin, and oxybutynin. Should Mylan prevail in the ongoing patent litigation on those products, it likely would face unlawful competition from authorized generic drugs during its exclusivity period.

12. FDA's administrative ruling violates the FFDCA and the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A). As U.S. Representative Henry Waxman, co-author of the Hatch-Waxman Amendments, recently observed, brand companies are "circumventing the intent" of the law by marketing their own generic during the six-month exclusivity period. (S. Sutter, *Congress Needs to Review "Authorized" Generics, Hatch and Waxman Agree*, 16 Health News Daily 195 (Oct. 7, 2004) (emphasis added).) The intent of that law is clear: to provide 180 days for the first generic to be on the market as the *sole competitor of the innovator product*. FDA's interpretation—which admittedly diminishes if not eliminates the exclusivity incentive by permitting unlimited authorized generic competition during this period—is squarely at odds with that intent. It also represents an impermissible departure from

FDA's own interpretation of the generic exclusivity provision, which itself was upheld by a United States district court.

13. FDA's administrative ruling and P&G/Watson's authorized generic scheme gives rise to at least the following claims:

a. FDA's denial of Mylan's Petition violates the FFDCA and the APA, 5 U.S.C. § 706(2)(A).

b. The P&G/Watson nitrofurantoin authorized generic scheme violates the federal and state antitrust and unfair competition laws, including the Sherman Act, 15 U.S.C. §§ 1 and 2; the Clayton Act, 15 U.S.C. § 15; the Robinson-Patman Act, 15 U.S.C. § 13(a); the West Virginia Antitrust Act, W. VA. CODE § 47-18-1 *et seq.*; the West Virginia Unfair Practices Act, W. VA. CODE §§ 47-11A-1 to 47-11A-14; and the West Virginia Pharmaceutical Availability and Affordability Act, W. VA. CODE § 5A-3C-12.

c. By entering into and carrying out the P&G/Watson nitrofurantoin authorized generic scheme, P&G and Watson have tortiously interfered with Mylan's existing and/or prospective contractual and/or advantageous business relationships.

d. By entering into and carrying out the P&G/Watson nitrofurantoin authorized generic scheme, P&G and Watson have been unjustly enriched at Mylan's expense.

14. Based upon the foregoing, and the more detailed allegations below, Mylan is entitled to declaratory and injunctive relief, as well as an award of damages, from this Court.

Parties

15. Plaintiff Mylan is a West Virginia corporation with its principal place of business in Morgantown, West Virginia. Mylan develops, manufactures, and distributes quality generic pharmaceutical products in the United States, including a lower-priced generic version of Macrobid® (nitrofurantoin), for which Mylan holds first-filer status and was entitled to—but did not receive—180-day generic exclusivity. Mylan is also the first-filer on a number of other drug products that are currently in litigation, including Pfizer's Norvasc® (amlodipine besylate)

tablets, J&J's Levaquin® (levofloxacin) tablets, and J&J's Ditropan XL® (oxybutynin chloride) extended-release tablets, for which Mylan is eligible for 180-day generic exclusivity.

16. Defendant FDA is an agency of the United States within the Department of Health and Human Services, with offices at 5600 Fishers Lane, Rockville, MD 20857. FDA has been delegated the authority to administer the FFDCA.

17. Defendant Tommy G. Thompson is the Secretary of Health and Human Services ("HHS") and the official charged by law with administering the FFDCA. He is sued in his official capacity. Secretary Thompson maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20204.

18. Defendant Lester M. Crawford is the Acting Commissioner of FDA. He is sued in his official capacity. Acting Commissioner Crawford has been delegated the authority to administer the drug approval provisions of the FFDCA through FDA. He maintains an office at 5600 Fishers Lane, Rockville, MD 20857.

19. Defendants Procter & Gamble Pharmaceuticals, Inc. and The Procter & Gamble Company (collectively, "P&G") are Ohio corporations with their principal places of business in Cincinnati, Ohio. P&G is engaged in, *inter alia*, the development, manufacture, and marketing of brand-name prescription drugs in this District and throughout the United States, including the brand-name drug Macrobid® (nitrofurantoin) and authorized generic versions of Macrobid®. P&G has regular and systematic business contacts within this judicial District. P&G has also subjected itself to the jurisdiction of this Court in prior litigation.

20. Defendants Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively, "Watson") are Nevada corporations with their principal places of business in Corona, California. Watson is engaged in the marketing of generic drugs in this District and

throughout the United States, including an authorized generic version of Macrobid® (nitrofurantoin) licensed from P&G. Watson has regular and systematic business contacts within this judicial District. Watson has also subjected itself to the jurisdiction of this Court in prior litigation.

21. The acts and conduct complained of herein by P&G were done with the agreement, cooperation, participation, and assistance of Watson. The acts and conduct complained of herein by Watson were done at the direction, and with the authorization, agreement, cooperation, participation, and assistance, of P&G.

Jurisdiction and Venue

22. This action arises under the FFDCA, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"); the APA, 5 U.S.C. § 551 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202; the federal antitrust laws, particularly the Sherman Act, 15 U.S.C. §§ 1 and 2, the Clayton Act, 15 U.S.C. § 15, and the Robinson-Patman Act, 15 U.S.C. § 13(a); the West Virginia Antitrust Act, W. VA. CODE ANN. § 47-18-1 *et seq.*; the West Virginia Unfair Practices Act, W. VA. CODE ANN. §§ 47-11A-1 to 47-11A-14; the West Virginia Pharmaceutical Availability and Affordability Act, W. VA. CODE § 5A-3C-12; and the common law, including, but not limited to, the common law of the State of West Virginia.

23. This Court has subject matter jurisdiction over Mylan's federal claims under 28 U.S.C. §§ 1331, 1337, and 1361, and 15 U.S.C. § 15. This Court has supplemental jurisdiction over Mylan's state law claims under 28 U.S.C. § 1367. The Court also has subject matter

jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the parties are diverse and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

24. This Court has personal jurisdiction over all Defendants because they conduct substantial business in, and have regular and systematic contact with, this District; because they have purposefully availed themselves of the privileges of conducting activities within this District, including subjecting themselves to the personal jurisdiction of this Court in previous litigation; and because the unlawful conduct complained of herein was committed against, and has irreparably harmed and damaged, a party located in this District.

25. Venue is proper in this District under 28 U.S.C. § 1391(c), (e), and 15 U.S.C. §§ 15 and 22.

26. FDA's denial of Mylan's Petition constitutes final agency action and presents an actual and continuing justiciable controversy, for which Mylan is entitled to review and relief under 5 U.S.C. §§ 702, 704, 706.

27. Mylan has standing to maintain this action against FDA, pursuant to the APA, as a legal entity that has suffered a legal wrong and has been adversely affected by final agency action.

Facts Applicable To All Claims

28. This case involves the complex statutory and regulatory framework for the approval and marketing of prescription brand-name drugs and lower-priced generic drugs; and the manner in which those drugs are marketed and sold.

29. P&G and Watson have manipulated this system to their advantage and to the detriment of Mylan, resulting in millions of dollars in damages and other irreparable injury. P&G and Watson engaged in this improper gaming of the system in order to, *inter alia*, harm

Mylan and deprive it of crucial profits and revenues; destroy the critical Congressionally-mandated incentive to challenge suspect brand patents and bring generic drugs to market before patent expiration; and attempt to maintain and/or obtain an anticompetitive hold over the nitrofurantoin market, as well as other innovator drug markets in which P&G currently maintains a monopoly. FDA, for its part, has permitted and enabled P&G and Watson to profit from their unlawful conduct by refusing to enforce its governing statute.

I. Statutory And Regulatory Framework For Approval Of Brand And Generic Drugs

A. Approving Brand-Name Drugs

30. Before marketing a new, brand-name or brand drug in the United States, the FFDCA requires that an applicant submit, and that FDA approve, a New Drug Application ("NDA") under 21 U.S.C. § 355(b). The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling for the use of the drug for which approval is requested. *See* 21 U.S.C. § 355(b)(1).

31. An NDA applicant must also submit information concerning any patent that claims the drug for which the applicant submitted the NDA, or which claims a method of using such drug, and with respect to which a claim for patent infringement could reasonably be asserted if a person not licensed by the owner, engaged in the manufacture, use, or sale of the drug. *See* 21 U.S.C. § 355(b)(1).

32. FDA publishes patent information submitted by the NDA-holder in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(e).

33. Brand companies typically obtain and submit numerous patents to FDA for listing in the Orange Book. Many of these patents, whose terms extend out for decades, are of questionable validity and breadth. Brand companies nevertheless use such patents to protect their lucrative drug monopolies by delaying generic competition.

34. Brand-name drugs typically are sold under a particular brand or trade name, such as Macrobid®, and are directly promoted and advertised to prescribers and consumers. Due to the numerous "blocking" patents, which can delay competition from lower-priced generic drugs for years, brand companies can and do charge very high monopoly prices for their brand-name drugs.

35. Brand companies have rarely, if ever, voluntarily or willingly lowered the prices of their brand drugs in the United States. Nor have brand companies ever willingly or voluntarily licensed their brand-name drugs to others, as P&G has done here for Watson, unless and until faced with patent expiration or the market entry of a generic competitor. The authorized generic practice began, as alleged below, only when the brand companies had no other weapons left to discourage and delay generic competition with their brand-name drugs.

36. All of these factors have led to rising health care costs. Congress sought to address this problem by increasing the availability of lower-priced generic drugs to compete with brand drugs. This case is about how Congress, in its judgment and wisdom, intended to achieve that goal.

B. Hatch-Waxman Creates An Expedited Process For Getting Generic Drugs To Consumers

37. Generic drugs are versions of brand-name prescription drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients as the brand-name drug.

38. Before 1984, a company that wished to make a generic version of an FDA-approved brand drug had to file an application containing new studies showing that the generic drug was as safe and effective as the brand drug. Preparing such an application was almost as time-consuming and costly as the original NDA. In addition, any company that wished to market a competing generic drug had to contend with the numerous blocking patents—many of questionable validity and scope—protecting the brand-name drug. Together, these obstacles, in Congress's judgment, unduly delayed the marketing of lower-priced generic drugs.

39. In 1984, Congress enacted Hatch-Waxman, in part, to address aspects of the drug-approval process that unduly delayed the market entry of lower-priced generic versions of brand-name drugs.

40. To that end, the FFDCA now includes an expedited process under 21 U.S.C. § 355(j) for regulatory approval of less-expensive generic versions of brand-name drugs that FDA has already approved. A generic company's application under this expedited process is known as an ANDA.

41. The ANDA regulatory process is more streamlined than the full NDA procedure and results in a generic drug (referred to herein as an "ANDA generic") that normally is marketed under the chemical name of the active pharmaceutical ingredient rather than a brand-name.

42. Before FDA will approve an ANDA generic drug, the ANDA applicant must establish, *inter alia*, that its proposed generic drug is bioequivalent to the already-approved brand-name drug (*i.e.*, there is no significant difference in the generic drug's rate and extent of absorption) and that it has the same active ingredient, dosage form, dosage strength, route of

administration, and labeling (with certain exceptions) as the approved brand-name drug. *See* 21 U.S.C. § 355(j)(2)(A).

43. An ANDA applicant also is required to address each patent listed in the Orange Book in connection with the approved brand-name drug by submitting one of four types of patent certifications for each listed patent: (I) that no patent information has been submitted to FDA; (II) that the listed patent(s) has expired; (III) that the patent will expire on a future date, and that the generic applicant will not market its product until after the expiration date; or, (IV) that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). This last certification is commonly referred to as a "paragraph IV certification." With certain exceptions not applicable here, an ANDA applicant must file a paragraph IV certification if it seeks FDA approval to market a generic drug before the expiration of any patent listed in FDA's Orange Book in connection with the approved brand-name drug.

44. If an ANDA applicant submits a paragraph IV certification to an Orange Book-listed patent, the applicant must notify the brand company of its intent to seek FDA approval to market its ANDA product before expiration of the listed patent. This notice must include a detailed statement of the factual and legal bases for the ANDA applicant's opinion that the listed patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the proposed, equivalent ANDA generic drug. *See* 21 U.S.C. § 355(j)(2)(B).

45. The submission of a paragraph IV certification for a listed patent constitutes an act of patent infringement that creates the necessary subject matter jurisdiction to enable the brand company to file, and a district court to resolve, an action for patent infringement to

determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent(s). *See* 35 U.S.C. § 271(e)(2)(A).

46. Upon receipt of an ANDA applicant's notice of a paragraph IV certification, a brand company may file suit for alleged infringement of the patent under 35 U.S.C. § 271(e)(2)(A). If the brand company does not file suit within 45 days of receiving notice of the ANDA applicant's paragraph IV certification, the ANDA can be approved immediately. But if the brand company brings an infringement action during that 45-day window, approval of the ANDA automatically is stayed until the earlier of the expiration of 30 months, or until a court decision holding the patent to be not infringed and/or invalid. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

47. Before submitting an ANDA with a paragraph IV certification, a generic ANDA applicant, like Mylan here, invests substantial resources and incurs significant risks, including: research, development, and testing of the proposed generic drug; research to determine whether the patents listed in the Orange Book are valid and enforceable and, if so, whether the applicant can design and manufacture a noninfringing and bioequivalent generic version of the brand drug; whether the applicant can sustain its position in the patent litigation that will likely follow the paragraph IV certification; and, whether the applicant can be the first to file an ANDA with a paragraph IV certification in order to secure 180-day generic exclusivity.

C. Congress Grants The First-Filer 180 Days Of Generic Marketing Exclusivity

48. The ANDA procedure was just one part of Congress's plan to increase access to lower-priced generic drugs. As already noted, Congress recognized that brand-name drugs are protected by numerous patents of questionable validity and breadth that improperly extend brand-name drug monopolies and delay generic competition. The only way for a generic company to market before patent expiration is to challenge the validity or scope of such patents

in court. But these challenges, Congress recognized, are both risky and expensive, especially for generic companies that, prior to Hatch-Waxman, operated in a post-patent, commodity-based generic industry with multiple competitors and relatively low margins and revenues. In this economic environment, companies had no incentive or reason to engage in a long and expensive patent challenge only to win and open the market to numerous competitors. But Congress needed to encourage generic companies to challenge these suspect patents in order to bring lower-priced generic drugs to market years earlier than would otherwise be possible, *i.e.*, before patent expiration.

49. In order to encourage generic drug makers to incur the substantial risks and costs associated with challenging brand company patents, and also understanding and acknowledging the commodity-based nature of the generic drug industry, Congress granted a valuable right and reward to the first generic company to challenge an Orange Book-listed patent. Specifically, Congress gave the first-filer a statutory right to market its product free from all generic competition for 180-days. *See* 21 U.S.C. § 355(j)(5)(B)(iv). This statutory benefit is commonly known as "180-day generic exclusivity."

50. For purposes of awarding exclusivity in this case, the pertinent statutory provision of the FFDCA provides:

> If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection [containing] such a certification, the application shall be made effective not earlier than one hundred and eighty days after--
>
> (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
>
> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv).

51. Congress's intent in establishing this 180-day generic exclusivity is clear: to encourage generic companies to challenge brand patents. *See* 54 Fed. Reg. 28,872, 28,895 (July 10, 1989) ("The purpose of section 505(j)([5])(B)(iv) of the act is to reward the first applicant to test the scope or validity of a patent . . . ."). Even FDA recognizes this fact. In FDA's July 2, 2004 administrative ruling on authorized generics, for example, the Agency unequivocally stated that "Congress established the 180-day exclusivity as an incentive for ANDA applicants to make patent challenges." (FDA Resp. to Mylan and Teva Citizen Petitions, Docket Nos. 2004P-0075/CP1 and 2004P-0261/CP1, at 12 (July 2, 2004).) Similarly, in the prior proceeding before this Court, counsel for FDA also made clear that Congress "gave [180-day exclusivity to generics] as a reward for challenging patents . . . ." (8/27/04 Tr. of Proceedings in *Mylan Pharmaceuticals, Inc. v. FDA et al.*, No. 1:04CV174 (N.D. W.Va.) (Keeley, J.), at 56.)

52. The courts have also recognized Congress's intent in enacting the 180-day generic exclusivity provision: "the Hatch-Waxman Amendments provide an added incentive for generic drug producers to file Paragraph IV certifications . . . a 180-day period of exclusive marketing rights for a generic version of the drug claimed by that patent." *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 33 (D.D.C. 2000), As another court has aptly described:

> As an incentive *to the first generic maker to expose himself to the risk of costly patent litigation*, the Hatch-Waxman regime provides that the first to file a Paragraph IV certified ANDA ("the first filer") is eligible for a 180-day period of marketing protection, commonly known as the 180-day exclusivity period ("the Exclusivity Incentive").

Mylan Pharms. Inc. v. Henney, 94 F. Supp. 2d 36, 40 (D.D.C. 2000) (emphasis added).

53. The courts have also recognized how Congress intended to encourage patent challenges through a true 180-day exclusivity period. As the United States Court of Appeals for

the D.C. Circuit has acknowledged, the 180-day generic exclusivity period provides an "Edenic moment of freedom from the pressures of the marketplace." *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1064 (D.C. Cir. 1998). Another court explained:

> By its terms, *the Exclusivity Incentive affords the first filer protection from competition from subsequent generic makers for 180 days* beginning from the earlier of a commercial marketing or court decision.

Mylan, 94 F. Supp. 2d at 40 (emphasis added); *see also Mylan*, 81 F. Supp. 2d at 33 (holding that Hatch-Waxman provides "a 180-day period of exclusive marketing rights for a generic version of the drug claimed by that patent").

54. FDA has also expressly acknowledged "that the statute intends to provide 180 days for the first generic to be on the market as the *sole competitor of the innovator product.*" (Feb. 16, 2001 Hearing Tr. at 67, *Mylan Pharms. Inc. v. Thompson,* Civ. A. No. 1:01CV23 (N.D. W. Va.) (emphasis added).) FDA has further described Congress's intent as providing "180 days *to reap the economic benefits of being [the brand's] sole competition.*" (FDA Mem. Opp'n at 12, *Mylan Pharms. Inc. v. Thompson*, Civ. A. No. 1:01CV23 (N.D. W. Va.) (emphasis added).); *see also* Brief of Federal Defendants-Appellees in *Mylan Pharms. Inc. v. Thompson*, No. 01-1554 (4th Cir.), 38 ("[180-day exclusivity] was intended to allow a generic manufacturer 180 days of marketing a drug without competition from other generic drugs.").

55. FDA has further acknowledged that the Act "ensures that the Agency will provide" the first-filer with a "specific benefit (marketing exclusivity)" as an incentive and reward for challenging brand patents and promoting competition. (FDA Citizen Petition Response, Docket No. 2004P-0227/CP1, at 4 (July 2, 2004).)

56. In sum, Congress created a critical *quid pro quo* for generic companies—expend the resources necessary to mount the first challenge to a suspect brand patent in exchange for 180

days of sole competition with the brand company. As FDA has acknowledged, "the provision was intended to benefit ANDA applicants, not innovators, to promote competition consistent with a fundamental objective of the Hatch-Waxman amendments." (FDA Citizen Petition Response, Docket No. 2004P-0227/CP1, at 11-12 n.21 (July 2, 2004)); *see also* H.R. Rep. No. 98-857, pt. II (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2692-93 (declaring that one of the principal policy objectives of Hatch-Waxman was to "[get] safe and effective generic substitutes on the market as quickly as possible"). As discussed below, this 180-day period has a unique and irreplaceable value to the first-filer.

D. The 180-Day Generic Exclusivity Period Is *The* Critical Incentive And Economic Reward For First-Filers That Derives Its Value, In Part, From The Practice Of Generic Substitution

57. The 180-day generic exclusivity period is a critical and pro-competitive incentive that expedites the introduction of lower-priced drugs to the consuming public. Without this incentive, generic companies will not, as Congress intended, challenge suspect brand patents.

58. The 180-day generic exclusivity period also constitutes a valuable and protected private right of the first-filer. The economic reward and benefit from this exclusivity period provides the first-filer with the additional revenues and funds necessary for future patent challenges, and, equally important, generates the revenues necessary for the first-filer to supply a full line of other lower-margin generic products that it would not otherwise be able to provide due to the commodity-based nature of, and fierce price competition in, the generic drug industry.

59. The 180-day exclusivity period creates these economic rewards because of the different methods used to sell brand-name drugs and generic drugs. Unlike brand-name drugs, generic drugs generally are not promoted or marketed directly to prescribers and consumers, but rather are sold to the consumer through the practice of generic substitution. As Congress

understood, the first-filer benefits for the exclusivity period only if it is the sole company with the right to take advantage of this practice of generic substitution for 180 days.

60. A generic drug: (a) has the same active chemical ingredient of the same strength, quantity, and dosage form as does the corresponding brand-name drug; (b) generally has a name, or other means of identification, that includes or refers to the relevant active ingredient; (c) is bioequivalent to or the same as the corresponding brand-name drug; and, (d) has a lower list price (frequently referred to as the suggested wholesale price ("SWP") or average wholesale price ("AWP")) than the AWP of the corresponding brand-name drug as reported by pricing compendia such as First Data Bank's PRICE ALERT.

61. The laws of some states will, upon the entry of a generic drug, mandate the substitution of the generic drug for prescriptions of the corresponding brand-name drug in the absence of a direction from the prescribing physician not to do so, and authorize a pharmacist or other dispenser to fill a physician's prescription for the brand-name product with the corresponding generic drug. West Virginia requires such mandatory generic substitution. *See* W. VA. CODE § 30-5-12b (2004).

62. The laws of other states will, upon the listing of a generic drug on the state's list of interchangeable drug products, permit the substitution of the generic drug for prescriptions of the corresponding brand-name drug that appear on the state's list in the absence of a direction from the prescribing physician not to do so, and authorize a pharmacist or other dispenser to fill a physician's prescription for the brand-name product with the corresponding generic drug. Illinois is an example of a state providing for such permissive substitution to be made from the state's list of interchangeable drugs. *See* 410 ILL. COMP. STAT. 620/3.14 (2004) and 225 ILL. COMP. STAT. 85/25 (2004).

63. The laws of still other states will, upon the entry of a generic drug, permit but not mandate the substitution of the generic drug for prescriptions of the corresponding brand-name drug in the absence of a direction from the prescribing physician not to do so, and authorize a pharmacist or other dispenser to fill a physician's prescription for the brand-name drug with the corresponding generic drug. California is one such state. CAL. BUSINESS AND PROFESSIONS CODE § 4073 (West 2004).

64. The laws of many states will, upon the entry of a generic drug, absent an express exemption by the Department of Health or a similar entity or the prescribing physician, mandate the substitution of the generic drug for prescriptions of the corresponding brand-name drug where the consumer cost of the drug is being paid for or subsidized by a government-funded program (*e.g.*, Medicaid), and authorize a pharmacist or other dispenser to fill a physician's prescription with the corresponding generic drug for the brand drug. New York is an example of a state with Medicaid generic substitution. N.Y. SOC. SERV. LAW § 365-a (Consol. 2004).

65. Private insurers, third-party payors, healthcare plans, and managed care entities especially require, or encourage through economic incentives, the substitution of generic drugs for corresponding brand-name drugs in the absence of a direction from the physician not to do so.

66. Many insurance plans issue a formulary that lists drugs that physicians may prescribe and/or that pharmacists may dispense for some or all of the drug price to be reimbursed. If a drug is not included in the formulary, or depending on its status in the formulary, purchase of the drug may require a higher co-payment from the patient or may not be covered by the insurance plan unless the physician obtains prior authorization from the insurance company. After a generic drug product becomes available, reimbursement for the purchase of

the corresponding brand-name drug may be reduced because of inclusion of the generic drug product in the formulary.

67. Generic substitution generally occurs quickly and broadly upon the introduction of a new generic drug, such as when a first-filer proceeds to market with 180-day generic exclusivity. For example, IMS Health, a recognized source for marketing and sales data in the pharmaceutical industry, reports that, on average, generic drugs account for nearly 80% of new prescriptions of the corresponding drug thirteen weeks after the introduction of a new generic drug.

68. The right to the greater profits generated from this generic substitution constitute the economic benefit and reward that Congress created for first-filers.

69. The right to the benefits of 180-day generic exclusivity, however, go well beyond greater revenues and profits generated during the exclusivity period as a result of generic substitution. For example, the exclusivity also allows the first-filer to: sell more generic drugs across all of its product lines; enter into long-term distribution contracts; obtain greater access to more and larger customers; increase resources available to produce other generic products; retain greater market share after the 180-days; and increase customer good will and reputation in the industry.

70. The first-filer realizes these benefits exist only when it receives a true period of 180-day exclusivity. Any additional generic competitor during this period significantly devalues the economic reward to the first-filer. When, depending on the drug and market size, enough generic competitors enter the market during the first 180 days, the first-filer receives no economic benefit, meaning that the company would have been better off not challenging the patents in the first instance.

II. Mylan Regularly Files The First Paragraph IV Patent Challenge To Patents For The Brand Drug

71. Mylan spends millions of dollars and invests substantial resources in researching the applicability and validity of Orange Book-listed patents, and in developing new generic drugs that may be marketed prior to expiration of such patents. As a result of its expenditures and investments, Mylan has been the first-filer with respect to numerous ANDAs, and regularly defends infringement actions brought by brand companies seeking to prevent Mylan from selling its proposed generic products before patent expiration.

72. For its efforts, Mylan has been awarded, or expects to be awarded, 180-day generic marketing exclusivity with respect to the sale of the generic drug at issue.

73. One such drug is Mylan's generic nitrofurantoin product. As described in greater detail below, Mylan filed the first paragraph IV certification to this product. Mylan also filed the first paragraph IV ANDA for numerous generic drugs, including, but not limited to, Pfizer's Norvasc® (amlodipine besylate), J&J's Levaquin® (levofloxacin), and J&J's Ditropan XL® (oxybutynin chloride). If Mylan prevails in its patent litigation against the brand companies on these products, it will be entitled to exclusivity. Indeed, Mylan believes it holds first-to-file paragraph IV ANDAs on drugs representing approximately $11.5 billion in brand sales.

74. FDA's denial of Mylan's Petition directly harmed Mylan by depriving it of the Congressionally-mandated exclusivity for generic nitrofurantoin. Unless set aside by this Court, FDA's administrative ruling will continue to harm Mylan by eliminating the exclusivity for other products as well, including amlodipine, levafloxacin, and oxybutynin.

III. Mylan's First-Filed Generic Nitrofurantoin ANDA

A. Mylan Develops A Noninfringing Generic Nitrofurantoin And Secures 180-Day Generic Exclusivity

75. P&G currently markets the prescription drug nitrofurantoin under the brand-name Macrobid® pursuant to approved NDA No. 20-064.

76. Macrobid® was first approved by FDA on December 24, 1991, for the treatment of acute uncomplicated UTI, and is now one of the most widely prescribed treatments for such indications.

77. P&G obtained and submitted information to FDA on two patents for listing in the Orange Book in connection with Macrobid® and NDA No. 20-064: U.S. Patent Nos. 4,772,473 ("the '473 patent") and 4,798,725 ("the '725 patent"). FDA published this patent information in the Orange Book.

78. Until March 2004, when Mylan launched a competing generic version of nitrofurantoin, P&G's high-priced Macrobid® was the only nitrofurantoin drug product available to U.S. patients and consumers.

79. In 1999, Mylan began to develop a noninfringing generic version of nitrofurantoin. During the next several years, Mylan committed substantial time, skill, and resources to this effort.

80. Mylan made this investment and commitment of resources for the purpose of obtaining and securing the 180-day generic exclusivity period that Congress created to reward such efforts. The economic reward and benefit from this exclusivity would, in turn, provide Mylan with the revenues and funds necessary for future paragraph IV challenges, and also enable Mylan to supply a full line of other generic products that it would not otherwise be able to provide due to the commodity-based nature of, and fierce price competition in, the generic drug

industry. Without this reward, Mylan, like many generic companies, simply would not have the incentive to undertake the substantial burden, expense, and risk of challenging brand patents for the purpose of expediting generic market entry before patent expiration.

81. On January 28, 2003, Mylan submitted ANDA No. 76-648 seeking FDA approval to market generic nitrofurantoin capsules for the treatment of acute uncomplicated UTI. With that ANDA, Mylan submitted paragraph IV certifications to both the '473 and '725 patents.

82. Mylan notified P&G of its ANDA, together with the factual and legal bases for its paragraph IV certifications, on March 19, 2003. Upon receipt of that notice, P&G did not sue Mylan for infringement of the '473 and '725 patents. Instead, as further alleged below, P&G conspired with Watson to destroy Mylan's exclusivity, misappropriate Mylan's profits, and obtain an anticompetitive hold over the nitrofurantoin market.

83. Mylan was the first generic applicant to file an ANDA for nitrofurantoin with paragraph IV certifications challenging P&G's Orange Book-listed patents.

84. In reliance on its first-filer status and the reasonable expectation that it was entitled to the 180-day generic exclusivity provided for by Congress, Mylan invested resources preparing commercial launch quantities of nitrofurantoin, precisely so that it would be in a position to launch its generic nitrofurantoin drug immediately upon receiving final FDA approval of its ANDA.

85. As a reward for undertaking the risk and expense of designing a noninfringing product and challenging P&G's listed patents, FDA recognized Mylan's statutory right to 180 days of generic exclusivity for nitrofurantoin capsules.

86. On March 22, 2004, FDA finally approved Mylan's generic nitrofurantoin product as a safe and effective fully substitutable equivalent to P&G's Macrobid®. In its final

approval letter, FDA stated in part: "Mylan is eligible for 180-days of market exclusivity . . . for Nitrofurantoin."

B. Mylan's Contractual Relationships And Business Expectancies

87. In early 2004, in anticipation of receiving final approval of its nitrofurantoin ANDA and in preparation for its commercial launch, Mylan began promoting its generic nitrofurantoin capsule product to various wholesalers, pharmacies and distributors. During this time, Mylan indicated that it was entitled to 180-day generic exclusivity.

88. Mylan's entire sales effort for this product centered around the fact that it expected to be the first and only generic nitrofurantoin drug on the market for 180 days, thus allowing Mylan to fill the entire generic pipeline for this drug. Mylan also had a reasonable business expectancy that it would maintain a significant portion of the generic market well beyond the expiration of this 180-day period.

89. By early 2004, Mylan already had entered into supply arrangements with some customers, and obtained oral commitments from other customers. Mylan secured these arrangements and oral commitments based on the premise that Mylan's generic nitrofurantoin product would be the only generic product on the market for 180 days after its launch date. Mylan expected to earn at least $41 million in revenues and obtain a substantial portion of the total nitrofurantoin market during its 180-day exclusivity period.

IV. Authorized Generics Are Designed To Destroy The 180-Day Generic Exclusivity Period, Capture Profits Intended For The First-Filer, And Maintain The Brand Company's Anticompetitive Hold Over The Drug

90. Even after Hatch-Waxman, brand companies found ways to manipulate the system Congress designed, stifling generic competition from companies like Mylan.

91. For example, brand companies obtained and listed numerous patents that did not actually claim the listed drug, but were listed in the Orange Book in any event solely to delay generic competition. This practice of so-called "ever-greening" the Orange Book with suspect patents, in turn, allowed brand companies to impose multiple and consecutive 30-month stays of FDA approval. Such practices indefinitely delayed the introduction of generic competition and, in turn, significantly diminished the value of 180-day generic exclusivity.

92. In 2003, Congress enacted the Medicare Prescription Drug, Importation and Modernization Act ("MMA") to address these problems and strengthen the 180-day exclusivity period. Congress, for example, did away with multiple 30-month stays and put other measures in place to ensure that first-filers would actually benefit from the exclusivity reward.

93. Unfortunately, however, brand companies have found another way to stifle generic competition and destroy the 180-day generic exclusivity incentive. As was done here, brand companies, either alone or with a partner, authorize generic versions of the brand-name drug. Unlike the brand companies' past practices however, this authorized generic strategy threatens to eliminate the exclusivity incentive to challenge brand patents altogether.

94. For example, with respect to Macrobid®, P&G entered into a distribution agreement with Watson. Under the agreement, P&G authorized Watson to distribute generic nitrofurantoin subject to P&G's approved NDA. P&G supplies the nitrofurantoin to Watson for distribution, and then Watson markets the drug on a private-label basis under its chemical name at generic prices in the traditional distribution channels for generic drugs. (*See* 8/11/04 P&G Intervention Mem. at 2 (Case No. 04-CV-174); 8/17/04 Watson Intervention Mem. at 2 (Case No. 04-CV-174).) Watson is, therefore, simply distributing the brand-name drug that P&G has

manufactured, packaged and labeled with Watson's name and the generic name for the drug, rather than the brand-name.

95. The purpose of authorized generics is clear: (a) to capture generic sales and profits that otherwise would have gone to the first-filer, as Congress intended; (b) to punish first-filers by eliminating any economic benefit of the exclusivity period; and (c) to eliminate the generic exclusivity incentive in its entirety to discourage and prevent further patent challenges.

96. Brand companies destroy the value of the generic exclusivity period by selling brand-name drugs as authorized generic drugs that qualify for generic substitution. Brand companies sell their brand-name drugs as "generic" drugs by removing the product and company names on the exterior of the brand-name drug and including on the label only the generic name of the drug and the name of a generic subsidiary or of a generic distributor; thus mimicking the labeling used by ANDA generic companies. Brand companies also cause their generic drugs to be listed in industry pricing compendia so that the authorized generic drugs qualify for generic substitution under federal and state laws and under the industry practices of drug purchasers, dispensers, and reimbursers.

97. Just as the brand company planned, an authorized generic and an ANDA generic equally qualify for generic substitution and are otherwise functionally equivalent for all purposes. Purchasers, dispensers, and reimbursers of pharmaceuticals use compendia ("data banks") of drug-pricing information to identify generic drugs that are interchangeable with, and lower priced than, brand drugs for the purpose of generic substitution.

98. Data banks then list the authorized generic as a drug that is bioequivalent to or the same as, and a lower cost alternative to, the brand-name drug. The authorized generic is so listed regardless of whether the drug is made by a brand company or a generic company, or whether

the drug was approved pursuant to an NDA or ANDA. When the authorized generic is so listed, it is treated by dispensers and purchasers as a generic drug that qualifies for generic substitution.

99. Brand companies advise data banks that their authorized generics are equivalent to and interchangeable with their brand-name drugs and will be sold at an SWP or an AWP that is lower than the AWP that the brand companies list for their brand-name drugs. Based upon such representations, the data banks list the authorized generics as equivalent to, interchangeable with, and a lower cost alternative to, the corresponding brand-name drugs. The authorized generics are thereby substituted for the brand-name drugs pursuant to the practice of generic substitution.

100. Authorized generics compete with, and take substantial sales from, ANDA generics before the expiration of the applicable 180-day generic exclusivity period by means of generic substitution. Authorized generics thus intrude upon, and misappropriate, the first filer's rightful and exclusive interest in the 180-day generic exclusivity period. As a result, and as FDA concedes, authorized generics diminish the expected return of generic companies from the expense and risk associated with expeditiously developing a generic drug and challenging brand patents.

101. The relief that Mylan seeks in this case would not prevent brand-name companies from offering lower-priced pharmaceuticals to the public. Brand companies have always been free to, and remain free to, sell their brand-name drugs *at any non-predatory price to any customer*, though by means other than masquerading as a generic drug using generic substitution during the first-filer's exclusivity period. However, brand companies (like P&G) may *not* lawfully deprive an ANDA first-filer of its 180-day generic exclusivity entitlement for the purpose of eliminating the exclusivity incentive, misappropriating generic sales and revenue

belonging to the first-filer, and continuing to charge consumers, the government, and third-party payors inflated prices for brand-name products (such as Macrobid®).

102. Authorized generic agreements do *not* foster competition. To the contrary, they deter competition by discouraging challenges to even the weakest patents—patents that nevertheless stand in the way of generic competition. As the Chief Executive Officer of one brand company acknowledged:

> [A]s we are looking toward the expiry of the patent on Paxil or Wellbutrin, we have picked a partner, and we are getting a very large share of the profits generated during the six months exclusivity period. The idea was somebody has a six months exclusivity. *But we are a king maker; we can make a generic company compete during that very profitable time.* . . . We are not a generic company, and do not wish to become one. If we acquired the most successful generic company in the world, it would barely move the needle on profit.

(Statement of J.P. Garnier, GlaxoSmithKline's CEO, GSK Q4 2003 Earnings Conference Call and Presentation-USA at 7 (Feb. 13, 2004) (emphasis added).) This authorized generic game of "king maker" enables brand companies to eliminate the value that Congress intended to provide to first-filers as an incentive for challenging brand patents and encouraging generic competition before the expiration of weak patents.

103. Indeed, brand companies like P&G are well aware of the detrimental effects of authorized generics on the exclusivity incentive, and know full well that authorized generics can eliminate the exclusivity incentive altogether. For example, when another CEO of a large brand company was asked whether brand companies should consider "giving away" products to generic firms to eliminate the 180-day exclusivity incentive, he replied:

> For this to really work, you'd have to have the whole industry do that systematically each time a patent expires so that you truly eliminate the incentive in the calculation that generic companies would make. . . . [I]t's a very interesting and intriguing idea. Food for thought.

(Statement of Sidney Taurel, Lilly's CEO, *The Pink Sheet*, Dec. 8, 2003.)

104. U.S. Representative Henry Waxman has even observed that brand companies are "circumventing the intent" of the law by marketing their own generic during the six-month exclusivity period. Congressman Waxman declared that, "[a]t a time when not only consumers but businesses and governments are desperate for ways to bring down their prescription drug bills, we must continue to ensure that generics are readily available and to fight attempts to delay their marketing entry." He further noted, "*I don't think we should again allow the frustration of the intent of the law*, which is to bring about more competition, not to allow these loopholes to bring about less." (S. Sutter, *Congress Needs to Review "Authorized" Generics, Hatch and Waxman Agree*, 16 Health News Daily 195 (Oct. 7, 2004) (emphasis added).)

105. U.S. Senate Health Committee Chairman Judd Gregg's office has taken a similar view: "[w]e are very wary of additional gamesmanship that is intended to essentially gut . . . the industry's incentive to sometimes go after some of these blockbuster drugs." (*GPhA Seeks Change on Medicaid "Best Price" for "Authorized Generics,"* The Pink Sheet at 22, Oct. 4, 2004.)

106. But gamesmanship such as this has become a reality. The practice of using authorized generics has become *the* weapon of choice for brand companies to stifle generic competition and destroy the critical exclusivity incentive. Since September 2003, it appears that every commercial launch of a blockbuster generic drug by a first-filer has been met by a competing authorized generic during the exclusivity period. Under FDA's administrative ruling under review here, brand companies will continue to use this strategy to deprive first-filers like Mylan of any economic reward or benefit from the exclusivity.

V. P&G's and Watson's Anticompetitive Scheme To Destroy Mylan's 180-Day Exclusivity And Misappropriate Mylan's Profits

107. While Mylan was preparing to launch its generic nitrofurantoin drug, P&G entered into an agreement with Watson to deprive Mylan of any benefit from the 180-day generic exclusivity for generic nitrofurantoin and to misappropriate Mylan's expected profits.

108. P&G entered into a distribution agreement with Watson, under which P&G authorized Watson to distribute generic nitrofurantoin subject to P&G's approved NDA. P&G would supply the nitrofurantoin to Watson for distribution, and then Watson would market the drug on a private-label basis under its chemical name at generic prices in the traditional distribution channels for generic drugs. (*See* 8/11/04 P&G Intervention Mem. at 2 (Case No. 04-CV-174); 8/17/04 Watson Intervention Mem. at 2 (Case No. 04-CV-174).)

109. On information and belief, the purpose of this agreement was to punish Mylan by destroying the 180-day generic exclusivity incentive and capturing a share of generic sales from Mylan, and to attempt to maintain an anticompetitive hold over the nitrofurantoin market and other innovator drug markets.

110. On information and belief, P&G conditioned its license to Watson upon Mylan actually launching its ANDA generic nitrofurantoin and exercising its 180-day generic exclusivity rights. In other words, Watson's authorized generic would enter the market only if and when Mylan's ANDA generic entered the market.

111. On information and belief, aware of Mylan's entitlement to 180-day exclusivity, and with the specific and malicious intent to steal Mylan's profits during this valuable time, P&G authorized Watson to enter the market with a repackaged and relabeled generic Macrobid® product as soon as Mylan commercially launched its nitrofurantoin product.

112. On information and belief, Watson, with the specific intent to improperly interfere with Mylan's existing or prospective contractual and/or advantageous business relationships, began pre-selling and promoting P&G's authorized generic Macrobid® product in anticipation of a commercial launch by Mylan.

113. Watson, and P&G through Watson, intentionally interfered with Mylan's contractual relationships with respect to its nitrofurantoin product by unlawfully competing during Mylan's exclusivity period and driving the price for generic nitrofurantoin down drastically, forcing Mylan to renegotiate previously accepted pricing agreements with its customers.

114. Because P&G's authorized generic Macrobid® product qualifies for generic substitution under federal and state laws, P&G and Watson intended that their product compete with and be dispensed in place of Mylan's generic nitrofurantoin product, thereby taking away sales that were intended solely for Mylan during its 180-day generic exclusivity period.

115. On March 23, 2004, Mylan launched its generic nitrofurantoin drug. This commercial launch triggered Mylan's exclusivity.

116. On or about the same day that Mylan commercially launched its product, Watson launched its authorized generic version of Macrobid® (under the drug's generic chemical name, "Nitrofurantoin Monohydrate/Macrocrystals") to compete directly with Mylan's generic product during Mylan's 180-day generic exclusivity period.

117. As an authorized generic, Watson's authorized generic nitrofurantoin was intentionally labeled to conceal the fact that it originates from and is manufactured by P&G.

118. P&G manufactures authorized generic Macrobid® capsules for Watson with a different appearance, specifically, a different printed name on the capsule itself. P&G packages

these capsules with labeling that omits any reference to P&G or Macrobid®'s national drug code ("NDC"), and replaces this information with Watson's name and Watson's NDC for generic nitrofurantoin (*i.e.*, Macrobid®).

119. The purpose of P&G's authorized generic Macrobid® is not in dispute: to capture market share that would have otherwise gone to Mylan and maintain the market position of the brand-name product. (8/27/04 Tr. of Proceedings in *Mylan Pharmaceuticals, Inc. v. FDA et al.*, No. 04-174 (N.D. W.Va.), at 72-74.) As counsel for P&G acknowledged in prior litigation, P&G could have lowered the price of Macrobid® in order to compete with Mylan, but instead P&G made a "business decision" to license someone else (here Watson) to offer a lower-priced generic Macrobid® to protect market share and preclude Mylan from supplanting the brand position in the market. (*Id.* at 73.)

120. In that same proceeding, counsel for P&G stated that the price of Macrobid® could not be lowered to compete with Mylan without lowering it to "almost below cost" and that the brand company could not "realistically compete on price" with the generic company because of the brand company's higher cost structure. (8/27/04 Tr. of Proceedings in *Mylan Pharmaceuticals, Inc. v. FDA et al.*, No. 04-174, at 81.) Counsel for P&G explained:

> Actually, unless the price of Macrobid is lowered all the way down to where, you know, it would in effect almost be below cost, lower cost to the generic level, the generic is still going to get the substitution.
>
> * * *
>
> It would be very hard for a brand company that has a cost structure and a research based pharmaceutical to be able to realistically compete on price with a generic product.

(*Id.*) In other words, according to P&G, its cost structure is such that it could not lower the price of Macrobid® to compete with Mylan without selling the drug below cost.

121. Watson's authorized generic Macrobid® is not only "realistically" competing with Mylan, it is being sold at prices so low that it has captured a large portion of Mylan's market share—even though, according to P&G, that could never happen unless Watson was selling P&G's Macrobid® at prices below cost.

122. On information and belief, P&G and Watson are selling P&G's Macrobid® at prices below any reasonable or appropriate measure of cost, and/or at prices lower than are necessary to sell the product, in order to destroy Mylan's exclusivity and drive Mylan from, and attempt to monopolize, the relevant drug markets now and in the future.

123. On information and belief, Watson, acting in combination with P&G pursuant to their arrangement, has sold and/or offered to sell P&G's authorized generic Macrobid® for $25.00 per 100 units of 100 mg capsules. Mylan estimates Watson's fully allocated sales, distribution and general administration costs to be at least $8.00 per 100 units of 100 mg capsules. On information and belief, Watson is not paying P&G any more than its $25.00 sales price less its own fully allocated costs, or no more than $17.00 per 100 units of 100 mg capsules.

124. On information and belief, Mylan estimates that P&G's fully allocated costs for the production and sale of nitrofurantoin to Watson must be at least $19.00 per 100 units of 100 mg capsules. P&G is therefore selling its product to Watson at less than its fully allocated costs, or alternatively, P&G and Watson are collectively distributing authorized generic Macrobid® for less than their combined fully allocated costs of $27.00 per 100 units of 100 mg capsules.

125. P&G and Watson have intentionally concealed the true nature and origin of Watson's generic product. After its launch, Watson continued to market its product as a therapeutic and pharmaceutical generic equivalent to Macrobid®, when in reality it is Macrobid®.

126. Since on or about March 23, 2004, Watson has continued to market its authorized generic Macrobid® as an ANDA generic drug while omitting any references to P&G or the brand-name for the drug.

127. P&G and Watson's intentional, malicious, and improper actions have directly and proximately interfered with Mylan's contractual and/or advantageous business relationships, including the loss of tens of millions of dollars in lost profits from sales of its generic nitrofurantoin product, and an incalculable sum representing lost profits from sales of its other generic product lines.

128. P&G and Watson intentionally, maliciously, and improperly interfered with Mylan's existing and expected advantageous business relationships without privilege or lawful justification. P&G and Watson have instead acted with the improper intent of eliminating the 180-day exclusivity incentive provided by Congress to ANDA applicants who are first to challenge the brand's patents, such as Mylan, resulting in an unlawful restraint on trade.

VI. P&G And Watson Conspire In An Attempt To Monopolize The Nitrofurantoin Market

129. While P&G listed two patents in the Orange Book in connection with Macrobid®, on information and belief, P&G knew that its patent position was weak and thus unlikely to block generic competitors because companies like Mylan could invent around P&G's patents.

130. However, by conspiring and entering into an agreement with Watson to introduce an authorized generic nitrofurantoin product, P&G would destroy Mylan's 180-day generic exclusivity period, while capitalizing on P&G's market power by distributing authorized generic nitrofurantoin through Watson. By introducing this authorized generic drug during Mylan's exclusivity period, there is a dangerous probability that P&G will be able to obtain monopoly power in the relevant markets. This conspiracy thus raises an independent barrier to generic

entry, because, *inter alia*, by destroying the property interest first-filers have in securing a 180-day exclusivity period, all ANDA applicants will have a permanent disincentive to enter this, as well as other, innovator drug markets.

131. The agreement with Watson has allowed P&G to segment the market, discriminate in price, and preserve its ability to charge monopoly prices for its brand-name Macrobid®. P&G, on information and belief, has priced its authorized generic Macrobid® below cost to punish Mylan for entering the market with a competing generic drug, and to deter generic companies such as Mylan from further and future patent challenges and generic entry.

132. P&G created and licensed its authorized generic Macrobid® and has also engaged in other exclusionary acts for the purpose of attempting to obtain a monopoly in the market for nitrofurantoin and other innovator drug markets. These other acts include, *inter alia*, the following.

133. P&G launched its authorized generic Macrobid® to punish Mylan for pursuing that product. On information and belief, P&G is foregoing highly profitable sales of Macrobid® in order to license Watson to sell authorized generic Macrobid®. On information and belief, the only economic reason for P&G doing so is to unlawfully attempt to obtain a monopoly over, and reduce competition in, the relevant markets.

134. On information and belief, P&G intended to use the terms of its agreement with Watson to demand higher prices from consumers for Macrobid®, while allowing Watson to sell Macrobid® below cost in a different segment of the market, *i.e.*, the generic substitution segment that should have been exclusively reserved for Mylan.

135. The reported wholesale price of Macrobid® is $1.95 per pill. *See* http://www.ipcrx.com. However, P&G's authorized generic Macrobid® is sold into the market at

25¢ per pill, nearly 90% less than the wholesale price. Through this predatory pricing scheme, P&G's nitrofurantoin product is able to retain a majority share of the nitrofurantoin market.

136. The purpose of P&G's and Watson's predatory pricing scheme is to destroy Mylan's ability to secure any value from its 180-day market exclusivity period, and to discourage all future first-filers who are similarly situated from designing around and challenging weak and invalid patents.

137. In addition, by gutting the value of Mylan's 180-day exclusivity for Macrobid®, P&G is attempting to monopolize the market for other current and future P&G drugs that will open up to, or be at risk of, generic competition. P&G and Watson's anticompetitive scheme to launch an authorized generic is designed and has the effect of taking away from Mylan and other generic companies the means to develop generic drugs that will compete with P&G's brand drugs in the future. P&G's and Watson's exclusionary acts, as described herein, are reasonably capable of creating a dangerous probability that P&G will obtain a monopoly in other drug markets, such as Asacol® (mesalamine), that could drive Mylan to remove such drugs from its pipeline based on the risk of competition from authorized generics.

138. P&G has attempted to monopolize the relevant markets by engaging in exclusionary, unfair, anticompetitive and unlawful acts, as alleged herein, which were not honestly undertaken and which were designed to endanger, injure, and/or destroy competition in the relevant markets.

139. P&G has willfully attempted to acquire monopoly power in the relevant markets as distinguished from the acquisition of market power as a consequence of superior product, business acumen, or historic accident.

140. On information and belief, P&G acted with specific intent in an attempt to monopolize the relevant markets by conspiring with Watson to implement a scheme to allow P&G to market its own product under the label of a different generic pharmaceutical company, and to thereby destroy the value of Mylan's 180-day market exclusivity period.

141. The P&G and Watson agreement, and actions contemplated under its terms, have an effect on interstate commerce.

142. P&G benefits from its conspiracy with Watson using an authorized generic. Such an anticompetitive strategy destroys Mylan's 180-day exclusivity. It also deters future competitors in other markets, future competitors in the same market, and current competitors in the same or different markets. These effects, combined with the greater staying power of P&G, provide a clear signal to actual and potential rivals that they will be punished if they enter the market. P&G has signaled to competitors, including Mylan, that it is willing to "discipline" competitors, thus creating an anticompetitive effect to the benefit of P&G, even if Mylan is not driven completely from the market.

143. P&G's and Watson's exclusionary, anticompetitive, and unlawful actions have harmed competition and consumers by attempting to exclude generic competitors, including Mylan, from the relevant markets.

144. As a result of the foregoing exclusionary, anticompetitive and unlawful actions, including the conspiracy between P&G and Watson, Mylan has suffered and will continue to suffer antitrust injury to its business and property, including lost profits, and lost business opportunities, of the type that the antitrust laws were intended to prevent.

145. Unless enjoined, there is a dangerous probability that P&G will succeed in monopolizing the market for nitrofurantoin for use in the treatment of acute UTI, as well as other innovator drug markets controlled by P&G.

VII. Having Exhausted Its Administrative Remedies, Mylan Has No Choice But To Seek Relief From This Court Because FDA Has Acted Arbitrarily, Capriciously, And Contrary To Law In Its Handling Of Authorized Generics

A. FDA Denies Mylan's Citizen Petition

146. On February 17, 2004, Mylan filed a Citizen Petition (Docket No. 2004P-0075) with FDA, pursuant to 21 C.F.R. §§ 10.30 and 10.35, requesting that FDA prohibit the marketing and distribution of authorized generic versions of brand-name drugs until the expiration of any first-filer's 180-day generic exclusivity.

147. Mylan did so in order to protect its Congressionally-authorized eligibility for 180-day exclusivity on the numerous drugs for which Mylan is the first-filer, including for example, nitrofurantoin, amlodipine, levofloxacin, and oxybutynin. Because of the anticipated launch of Watson's authorized generic Macrobid® and the devastating harm it would cause to Mylan's nitrofurantoin exclusivity, Mylan requested expedited consideration of its Petition.

148. Other generic companies, Apotex Corp. and Teva, as well as the Generic Pharmaceutical Association, submitted comments in support of Mylan's Petition.

149. On June 9, 2004, Teva filed a similar Citizen Petition (Docket No. 2004P-0261) with FDA, also seeking to prohibit the marketing and distribution of authorized generic versions of brand-name drugs until the expiration of any first-filer's 180-day generic exclusivity.

150. On June 29, 2004, due to FDA's delays in responding to its Petition, Mylan filed a supplement that, among other things, requested an immediate response from FDA in order to

prevent the continuing irreparable harm that Mylan is suffering as a direct result of Watson's marketing of generic Macrobid®.

151. On July 2, 2004, FDA issued a final administrative ruling denying Mylan's and Teva's Petitions on "law and policy" grounds, including, *inter alia*, FDA's purported lack of authority under the FFDCA to delay the marketing of authorized generics during the 180-day generic exclusivity period, and because, FDA said without any support, authorized generics allegedly promote competition in furtherance of the objectives of Hatch-Waxman.

B. FDA's Administrative Ruling Refusing To Prohibit The Marketing Of Authorized Generics During The First-Filer's Exclusivity Must Be Set Aside As Arbitrary, Capricious, And Contrary To Law

152. FDA's administrative ruling, dated July 2, 2004, must be vacated and set aside as arbitrary, capricious, and contrary to law. FDA failed to enforce the FFDCA's 180-day generic exclusivity provision as Congress intended consistent with the underlying purpose of Hatch-Waxman. FDA has adopted an interpretation that is squarely at odds with Congressional intent and eliminates the exclusivity incentive. FDA also impermissibly substituted its judgment for that of Congress, and acted arbitrarily and capriciously by disregarding its own precedent without reasoned justification.

1. FDA's Interpretation Ignores Congressional Intent And Eliminates The Exclusivity Incentive

153. FDA has violated the FFDCA and the APA by refusing to prohibit the marketing of any competing generic drug, regardless of origin and whether approved under an NDA or ANDA, during the first-filer's exclusivity period. Properly construed in view of Congressional intent and the purpose of the statute, Hatch-Waxman's 180-day generic exclusivity provision, 21 U.S.C. § 355 (j)(5)(B)(iv), prohibits the marketing and sale of any competing generic drug,

whether a subsequent ANDA generic drug or an authorized generic drug, during the first-filer's 180-day generic exclusivity period.

154. Congress established the 180-day generic exclusivity period to temporarily delay the marketing of all competing generic products, except for the first-filer's generic product, for the purpose of providing a market-based reward and incentive for undertaking the risk and expense of challenging the brand company's patent(s). This reward consists of the opportunity to be the first and *sole* party to market a generic version of the brand-name drug for a period of 180 days from the date of generic market entry.

155. A company that attempts to circumvent another company's 180-day generic exclusivity, as P&G and Watson have done, defeats the very purpose of Hatch-Waxman by depriving ANDA generics of the incentive mandated by Congress to promote challenges to brand company patents.

156. An authorized generic licensee (and the licensing brand company) unlawfully benefit from limited generic competition during the 180-day generic exclusivity period without having assumed any of the many burdens and risks of challenging brand patents.

157. Nothing in the language or the legislative history of the FFDCA suggests that Congress ever intended for a brand company or its licensee to circumvent, and ultimately destroy, the first-filer's 180-day generic exclusivity in this manner. Indeed, in the recent MMA, Congress affirmed that the sale of an authorized generic is legally and functionally equivalent to the sale of an ANDA generic for purposes of applying and implementing the 180-day generic exclusivity period.

158. FDA's interpretation eliminates the generic exclusivity's incentive to challenge brand patents. Such an interpretation is squarely at odds with Congressional intent, as previously

acknowledged by both FDA and the courts, that the first-filer be rewarded with 180 days as the sole competition with the brand drug.

159. As Congressman Waxman observed, brand companies are "circumventing the intent" of the law, "which is to bring about more competition, not to allow these loopholes to bring about less," by marketing their own generic during the six-month exclusivity period. (S. Sutter, *Congress Needs to Review "Authorized" Generics, Hatch and Waxman Agree*, 16 Health News Daily 195 (Oct. 7, 2004).)

160. FDA and the courts have also explicitly determined that Hatch-Waxman, and in particular the 180-day generic exclusivity provision, must be interpreted to preserve and further three core principles:

> [T]he *Mylan* court identified three factors to consider in interpreting the 180-day exclusivity provision of Hatch-Waxman. **First**, the statute is to be interpreted in a manner consistent with 'the statute's interest in affording market access and incentives for both generic and non-generic makers,' and to maintain 'an incentive for the parties to fulfill the purposes of Hatch-Waxman.' **Second**, FDA should avoid an interpretation that excessively favors the first generic and the innovator parties' 'anticompetitive hold' over the drug. The court observed that 'Hatch-Waxman intended to provide an incentive for drug companies to explore new drugs, not a market 'windfall' for crafty, albeit industrious, market players.' **Finally**, FDA should avoid interpreting Hatch-Waxman so the decision on whether a generic applicant is entitled to exclusivity rests entirely in the patent holder's hands.

(FDA Citizen Petition Response, Docket No. 00P-1446/CP1, at 5 (Feb. 6, 2001) (emphasis added) (citations omitted)); *see also Mylan Pharms.*, 94 F. Supp. 2d at 53-54.

161. FDA's interpretation of the statute here—which permits the marketing of any number of authorized generics during the 180-day generic exclusivity period—violates these core principles because, *inter alia*, it:

- improperly awards the brand company, and other third-party sellers of the authorized generic, a portion of the 180-day generic exclusivity benefit and, as a consequence, destroys the critical Hatch-Waxman incentive to challenge brand patents;

- excessively favors the brand company by allowing it to unilaterally reduce the incentives offered by 180-day generic exclusivity and to maintain its "anticompetitive hold" over the relevant drug markets; and

- impermissibly allows the brand company, which approves and controls the sale of an authorized generic by a licensee, to control whether, to what extent, and for what period of time the first-filer receives the true statutory benefit and reward of 180-day generic exclusivity.

162. To uphold the underlying purpose and objective of Hatch-Waxman, the 180-day generic exclusivity provision must be interpreted to give the first-filer a 180-day "head start" in the generic substitution market over *all* generic versions of the brand drug. This is the only interpretation that can be reconciled with the underlying intent and purpose of Hatch-Waxman to afford "market access and incentives for both generic and non-generic makers" by "avoid[ing] an interpretation that excessively favors the first generic and the innovator parties' 'anticompetitive hold' over the drug."

163. FDA's interpretation here eliminates the Congressional mandate of 180-day generic exclusivity. It is only a matter of time before a brand company licenses two, three, four or more authorized generics, thus completely gutting any exclusivity benefit, and punishing *all* first-filers that successfully challenge brand patents. Congress did not intend such a result, which would lead to the demise of the whole Hatch-Waxman scheme for expediting the market entry of lower-priced generic drugs before brand patent expiration.

164. FDA has both the statutory authority and the obligation to regulate authorized generics by prohibiting such marketing until the expiration of the first-filer's 180-day generic exclusivity period. Contrary to FDA's administrative ruling, it makes no difference whether such regulation has anything to do with public health and safety or efficacy.

2. FDA Impermissibly Substituted Its Judgment For That Of Congress

165. FDA impermissibly substituted its own judgment for that of Congress by adopting an interpretation of the FFDCA, that, by allowing the marketing of authorized generics during the exclusivity period, admittedly "diminish[es] the economic benefit" of 180-day generic exclusivity.

166. Congress enacted the 180-day generic exclusivity incentive to promote long-term competition by awarding market exclusivity to the first-filer. FDA has no authority or discretion to adopt an interpretation of the statute that diminishes in any respect the benefit that Congress sought and intended to provide.

3. FDA Acted Arbitrarily And Disregarded Its Own Precedent

167. FDA has also violated the APA by disregarding its own longstanding interpretation, policies, and precedents regarding Hatch-Waxman and 180-day generic exclusivity. FDA previously determined that an authorized generic is the "functional equivalent" of an ANDA generic product for purposes of 180-day generic exclusivity. FDA may not lawfully disregard that past interpretation and precedent.

168. FDA and the courts have construed the 180-day generic exclusivity provision in a manner that prohibits the marketing of authorized generics during a first-filer's exclusivity period.

(a) *Nifedipine*: FDA Interprets the Term "Application" In § 355(j)(5)(B)(iv) Broadly To Mean Both NDA And ANDA

169. In 2001, FDA issued a final administrative ruling in which it granted a Citizen Petition filed by Teva seeking a determination that an authorized generic is, and must be treated as, functionally and legally equivalent to an ANDA generic for purposes of implementing and applying the 180-day generic exclusivity period.

170. Teva requested that FDA determine that Mylan's launch of an authorized generic version of Pfizer's Procardia® (nifedipine) was legally and functionally equivalent to the marketing of an ANDA generic product for purposes of triggering the 180-day generic exclusivity period under 21 U.S.C. § 355(j)(5)(B)(iv)(I). (Teva Citizen Petition, Docket No. 00P-1446/CP1, at 2 (Aug. 9, 2000).)

171. FDA agreed and granted Teva's Petition. In reaching this conclusion, FDA determined that:

> *Whether Mylan markets the product approved in its ANDA or the product approved in Pfizer's NDA is of little import to the statutory scheme*; Mylan has begun commercial marketing of generic nifedipine. Permitting Mylan to market nifedipine without triggering the beginning of exclusivity would be inconsistent with the intent of the statutory scheme.

(FDA Citizen Petition Response, Docket No. 00P-1446/CP1, at 7-8 (Feb. 6, 2001) (emphasis added).)

172. FDA reached this conclusion even though the "plain language" of the exclusivity provision refers only to an "application" under § 355(j), *i.e.*, an ANDA, *not* an NDA. In other words, FDA read and interpreted the exclusivity provision broadly in conjunction with Congressional intent and the purpose of the statutory scheme, concluding that the term "application" in the exclusivity provision must be interpreted to mean both an ANDA and an NDA.

173. Mylan challenged FDA's administrative ruling and interpretation before this Court (Stamp, J.) on the ground that the plain language of the statute does not support FDA's interpretation. In particular, Mylan repeatedly pointed out that § 355(j)(5)(B)(iv) only refers and applies to an "application" under § 355(j), which is an ANDA, and not an NDA. As such, Mylan argued, FDA could not construe the exclusivity provision, and specifically the term

"application," to mean both an ANDA and an NDA. Notably, this is the same position and interpretation that FDA has taken in the administrative ruling under review here.

174. In the prior *Nifedipine* matter, however, this Court (Stamp, J.) ultimately rejected Mylan's plain meaning interpretation and upheld FDA's expansive interpretation of the exclusivity provision to cover both ANDA and NDA drugs. During the hearing before Judge Stamp, FDA unequivocally stated that "Mylan's marketing of Pfizer's 30 milligram nifedipine product [under an NDA] was a *functional equivalent* of marketing their own drug under their own ANDA." (Feb. 16, 2001 Hearing Tr. at 67, *Mylan Pharms. Inc. v. Thompson*, Civ. A. No. 1:01CV23 (N.D. W. Va.).) When questioned by Judge Stamp about the plain language of the statute and where it refers to such "functional equivalents," FDA replied:

> FDA takes that from the case law . . . . So with . . . guidance from the D.C. Circuit, FDA in looking at the facts of this case found that the marketing by Mylan of 30 milligrams of nifedipine as a generic under its own label as the sole competitor to Pfizer for more than 180 days was the functional equivalent. That is what Congress intended when they set out a provision that gave the first in line 180 days to be the sole competitor to the innovator company.

(Feb. 16, 2001 Hearing Tr. at 67-68, *Mylan Pharms. Inc. v. Thompson*, Civil Action No. 1:01CV23 (N.D. W. Va.).)

175. Judge Stamp agreed with FDA, ruling that authorized generics are legally and functionally equivalent to ANDA generics for purposes of the 180-day generic exclusivity period. *See Mylan Pharms.*, 207 F. Supp. 2d at 488. In doing so, this Court explicitly endorsed FDA's statutory construction:

> [W]hether Mylan markets the produc[t] approved in its ANDA or the product approved [in] Pfizer's NDA is of little import to the statutory scheme; Mylan has begun commercial marketing of generic nifedipine . . . . [P]ermitting Mylan to market nifedipine without triggering the beginning of exclusivity would be inconsistent with the intent of the statutory scheme.

Id. Stated otherwise, the Court upheld FDA's interpretation that the term "application" in the exclusivity provision must be interpreted to mean both ANDA and NDA in order to effectuate Congressional intent.

176. Mylan appealed the district court's decision. On appeal, FDA stated that, for the purpose of applying the 180-day generic exclusivity period, it made "no difference" whether Mylan marketed the generic product approved under its ANDA or the authorized generic produced by Pfizer under its NDA. (Brief for Federal Defendants in *Mylan Pharms., Inc. v. Thompson,* No. 01-1554 (4th Cir.), at 34-35.) FDA further stated that the 180-day generic exclusivity period "was intended to allow a generic manufacturer 180 days of marketing a drug *without competition from other generic drugs.*" (*Id.* at 38 (emphasis added).)

177. FDA also made clear that this interpretation and rule—equating authorized generics with ANDA generics for purposes of applying 180-day generic exclusivity—carries the force and effect of law, having been adopted and promulgated through FDA's formal citizen petition process prescribed in the regulations. (Brief for Federal Defendants in *Mylan Pharms., Inc. v. Thompson,* No. 01-1554 (4th Cir.), at 20-21.) Congress, in fact, recently codified the *Nifedipine* decision in the MMA, providing that generic exclusivity begins to run on the "date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant." 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2004).

(b) *July 2, 2004 Administrative Ruling*: FDA Reverses Itself—"Application" Means Only An ANDA In One Part Of § 355(j)(5)(B)(iv), But An ANDA *And* NDA In Another

178. In the administrative ruling under review, FDA now interprets the exclusivity provision to apply only to ANDA drugs, and not NDA drugs, because the term "application," as used in § 355(j)(5)(B)(iv), means only ANDA. This, of course, is precisely the opposite of what

FDA told Judge Stamp in *Nifedipine*. FDA has provided no basis for this departure from its prior expansive interpretation of the exclusivity provision. This is arbitrary and capricious agency action.

179. But FDA has also interpreted the same term ("application") to mean different things in different parts of the same sentence. In particular, FDA states that the term "application" in the first clause of § 355(j)(5)(B)(iv) means only ANDA, while that same term in subclause (I) means ANDA *or* NDA. FDA's current interpretation is set forth below in brackets after each term:

> If the application **[ANDA]** contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application **[ANDA]** has been submitted under this subsection [containing] such a certification, the application **[ANDA]** shall be made effective not earlier than one hundred and eighty days after--
>
> (I) the date the Secretary receives notice from the applicant under the previous application **[ANDA or NDA]** of the first commercial marketing of the drug under the previous application **[ANDA or NDA]**, or
>
> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv). According to FDA now, the term "application" means something different depending on where in the same sentence it is found.

180. This, too, is arbitrary and capricious. Statutory terms that are part and parcel of the same provision, and in this case the very same sentence, must be interpreted consistently unless Congress has provided an explicit basis for interpreting them differently. Congress has given FDA no reason or cause to interpret the term "application" differently depending on where it is found in § 355(j)(5)(B)(iv).

Claims For Relief

First Claim For Relief
(Violation of the FFDCA and APA by FDA)

181. Mylan repeats and realleges the allegations of paragraphs 1 through 180, as if fully set forth herein.

182. Mylan was the first applicant to submit a nitrofurantoin ANDA containing a paragraph IV certification to P&G's Orange Book-listed patents. Under 21 U.S.C. § 355(j)(5)(B)(iv), Mylan alone was entitled to 180-day generic exclusivity for generic nitrofurantoin.

183. Mylan was also the first applicant to submit ANDAs containing a paragraph IV certification to the Orange Book-listed patents for a number of other products, including, but not limited to, Pfizer's Norvasc® (amlodipine besylate) tablets, J&J's Levaquin® (levofloxacin) tablets, and J&J's Ditropan XL® (oxybutynin chloride) extended-release tablets. Under 21 U.S.C. § 355(j)(5)(B)(iv), Mylan alone is eligible for 180-day generic exclusivity for these products.

184. The FFDCA prohibits the marketing and sale of any competing generic drug, regardless of origin and whether approved under an NDA or ANDA, during the first-filer's 180-day generic exclusivity period.

185. FDA's administrative ruling, dated July 2, 2004, denying Mylan's Petition and refusing to prohibit the marketing of authorized generics during the first-filer's 180-day generic exclusivity period is arbitrary, capricious, and not in accordance with the law, within the meaning of the APA, 5 U.S.C. § 706(2)(A), and in violation of the FFDCA.

186. As a direct result of that administrative ruling, Mylan was denied 180-day generic exclusivity for generic nitrofurantoin. FDA refused to prohibit Watson from marketing an

authorized generic Macrobid® product during the 180-day period in which Mylan was entitled to be the sole generic competition to P&G's Macrobid®. As such, Mylan did not receive the 180-day exclusivity period to which it was statutorily entitled.

187. As a direct result of that administrative ruling, Mylan is also in serious jeopardy of losing its eligibility for 180-day generic exclusivity on Pfizer's Norvasc® (amlodipine besylate) tablets, J&J's Levaquin® (levofloxacin) tablets, and J&J's Ditropan XL® (oxybutynin chloride) extended-release tablets.

188. Pfizer has already publicly announced that authorized generics are now part of its business plan and model when faced with the onset of generic competition. The Vice President and General Manager of Greenstone, Ltd., a Pfizer subsidiary responsible solely for distributing authorized generic versions of Pfizer's brand products, stated that "in order to operate on the same playing field as other generic competitors to the name brand, Pfizer must market its own unbranded version of the drug." (10/12/04 Kennally Decl. ¶ 22, *Teva Pharm. Indus. Ltd. v. Crawford*, No. 04-1416 (D.D.C.).) In a subsequent hearing in another case, Pfizer reiterated that it will launch authorized generics after exhausting its legal options against generic competitors. (*See* 10/13/04 Tr. at 45, 50-51, *Teva Pharm. Indus. Ltd. v. Crawford*, No. 04-1416 (D.D.C.).) Unless FDA's administrative ruling is set aside, if Mylan prevails in its patent litigation with Pfizer on amlodipine, Pfizer will likely launch its own authorized generic Norvasc®, thus depriving Mylan of its Congressionally-mandated exclusivity on this product.

189. J&J also supports the authorized generic strategy and even went so far as to oppose Mylan's Citizen Petition to FDA seeking to prohibit the marketing of authorized generics. Mylan's eligibility for 180-day exclusivity for levofloxacin and oxybutynin is likewise in jeopardy if Mylan prevails in its patent litigation against J&J. Under FDA's administrative

ruling, J&J will be free to launch its own authorized generic drugs to compete with Mylan during, and deprive Mylan of, the 180-day exclusivity. J&J has launched authorized generics during the 180-day exclusivity period on its own products.

190. The substantial harm and damage that Mylan has already suffered on nitrofurantoin, and the imminent harm that Mylan will likely suffer on amlodipine, levofloxacin, and oxybutynin, is redressible only by declaratory and injunctive relief from this Court setting aside FDA's administrative ruling as arbitrary, capricious and contrary to law.

191. FDA's denial of Mylan's Citizen Petition constitutes final agency action and presents an actual and continuing justiciable controversy, for which Mylan is entitled to review and relief under 5 U.S.C. §§ 702, 704, 706.

192. Mylan has standing to maintain this action, pursuant to the APA, as a legal entity that has suffered a legal wrong and has been adversely affected by final agency action.

193. There exists an actual, substantial, and continuing controversy between Mylan and FDA regarding FDA's failure to enforce the provisions of the FFDCA that require the Agency to prohibit the marketing of authorized generics during Mylan's 180-day generic exclusivity period.

194. This Court may declare the rights and legal relations of the parties regarding FDA's arbitrary and capricious refusal to prohibit the marketing of authorized generics during Mylan's 180-day generic exclusivity period pursuant to, *inter alia*, 28 U.S.C. §§ 2201, 2202.

195. Mylan has properly exhausted its administrative remedies.

196. Mylan has no adequate remedy at law.

WHEREFORE, Mylan respectfully prays that this Honorable Court enter judgment in its favor and against Defendant FDA, as follows:

(a) Issuance of a declaratory judgment setting aside FDA's administrative ruling of July 2, 2004, as arbitrary, capricious, and not in accordance with the law, all in violation of the pertinent provisions of the FFDCA and APA;

(b) Issuance of a declaratory judgment that FDA has violated the FFDCA and the APA by permitting, and refusing to prohibit, the marketing of a generic drug, approved under an NDA or ANDA, during Mylan's 180-day generic exclusivity period for that drug;

(c) Entry of an injunction enjoining and directing FDA to withdraw its administrative ruling of July 2, 2004;

(d) Entry of an injunction enjoining and directing FDA to prohibit the marketing and sale of any generic drug, whether approved under an ANDA or NDA, during any first ANDA applicant's 180-day generic exclusivity period for that drug;

(e) Entry of an order awarding Mylan a full 180-day period of exclusive marketing for its generic nitrofurantoin product free from all generic competition, regardless of source;

(f) Entry of an order awarding Mylan its reasonable attorneys' fees and costs of prosecuting this action; and

(g) Such other and further relief as this Honorable Court deems just and proper.

Second Claim For Relief
(Attempted monopolization by P&G
in violation of the Sherman Act, 15 U.S.C. § 2)

197. Mylan repeats and realleges the allegations of paragraphs 1 through 196, as if fully set forth herein.

198. On information and belief, P&G has willfully engaged in anti-competitive conduct with the intent of attempting to monopolize, and preventing Mylan from fairly competing in, the relevant nitrofurantoin market for use in the treatment of acute UTI, as well as other drug markets monopolized by P&G.

199. Prior to March 23, 2004, P&G was the only entity in the United States marketing nitrofurantoin for use in the treatment of acute UTI. There are no acceptable substitutes for

nitrofurantoin when prescribed for this use. There are also substantial barriers to entry into this relevant market, including regulatory approval requirements.

200. The relevant geographic markets in this case include West Virginia and the United States.

201. The relevant and economically meaningful product markets in this case include: (a) the market for generic nitrofurantoin during the 180-day generic exclusivity period; (b) the market for the production and sale of nitrofurantoin (including brand-name Macrobid®, the authorized generic nitrofurantoin distributed by Watson, and true generic bioequivalents); (c) the submarket for brand-name Macrobid®; (d) the submarket for generic nitrofurantoin (including the authorized generic nitrofurantoin distributed by Watson and true generic bioequivalents); and (e) other innovator drug markets controlled by P&G, including, but not limited to, Asacol® (mesalamine).

202. Prior to March 23, 2004, P&G controlled one hundred percent (100%) of the relevant markets. As such, there exists a dangerous probability that P&G will obtain a monopoly in the relevant markets through, *inter alia*, its ability to raise and/or control prices and/or exclude competition and/or restrict output without losing substantial business.

203. After March 23, 2004, P&G has maintained a large share of the relevant markets for nitrofurantoin. P&G also continues to control one hundred percent (100%) of other innovator drug markets, including, but not limited to, Asacol® (mesalamine). P&G's anticompetitive conduct has assured that there is a dangerous probability that P&G will obtain and control at least a predominant share of these relevant markets even after the entry of generic competition.

204. P&G has willfully engaged in anticompetitive conduct with the specific intent to attempt to monopolize the relevant markets in violation of § 2 of the Sherman Act by destroying

Mylan's 180-day generic exclusivity by introducing an authorized generic nitrofurantoin drug product simultaneously with Mylan, and by unlawfully attempting to obtain a monopoly for nitrofurantoin to further destroy competition.

205. On information and belief, P&G has willfully engaged in anticompetitive conduct with the specific intent to attempt to monopolize the relevant markets in violation of § 2 of the Sherman Act by eliminating the 180-day generic exclusivity incentive intended by Congress to promote challenges to brand patents. P&G has harmed Mylan and consumers by eliminating that incentive.

206. On information and belief, P&G has willfully engaged in anticompetitive conduct with the specific intent to attempt to monopolize the relevant markets in violation of § 2 of the Sherman Act by engaging in a price discrimination scheme under which the same drug, Macrobid® and authorized generic Macrobid®, are sold to identically situated buyers at different prices.

207. On information and belief, P&G has willfully engaged in anticompetitive conduct with the specific intent to attempt to monopolize the relevant markets in violation of § 2 of the Sherman Act by engaging in predatory pricing by, on information and belief, selling authorized generic Macrobid® below cost in order to drive competitors from the market, obtain a monopoly, destroy Mylan's exclusivity, and destroy the incentive for Mylan to engage in future challenges to P&G's patents on other drugs.

208. On information and belief, P&G intended to use the terms of its agreement with Watson to demand higher prices from consumers for Macrobid®, while allowing Watson to sell authorized generic Macrobid® below cost in a different segment of the market, *i.e.*, the generic substitution segment that should have been exclusively reserved for Mylan.

209. P&G's actions in entering into the agreement with Watson evidence P&G's specific intent to attempt to monopolize the relevant markets by introducing a competing generic drug during Mylan's exclusivity period and effectively destroying that exclusivity. The conduct of P&G has posed, and continues to pose, a dangerous probability that such monopolization will succeed.

210. P&G's conduct constitutes an unlawful attempt to monopolize the relevant markets in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

211. As a result of P&G's unlawful conduct, Mylan has suffered, and will continue to suffer, antitrust injury to its business and property, including, without limitation, lost profits stemming from the destruction of Mylan's 180-day generic exclusivity period, lost business opportunities, lost first-mover advantages, lost market share and position, and lost business relationships and good will.

212. P&G, by willfully and unlawfully attempting to obtain a monopoly in the relevant nitrofurantoin market, has directly and proximately caused injury to consumers and competition by undermining the effectiveness of Mylan's entry into, and otherwise reducing competition in, the relevant markets.

213. P&G, by willfully and unlawfully attempting to obtain a monopoly in the relevant nitrofurantoin market, has directly and proximately caused injury to consumers and competition by eliminating the critical exclusivity incentive created by Congress to challenge brand patents and promote increased generic competition in the relevant markets.

214. P&G's unlawful conduct has caused injury to Mylan's business and competition in general, of the type that the antitrust laws were designed to prevent, and which flow directly from P&G's unlawful acts.

WHEREFORE, Mylan respectfully prays that this Honorable Court enter judgment in its favor and against P&G, as follows:

(a) An award of the actual damages suffered by Mylan in the amount to be proved at trial, to be trebled as provided by law;

(b) Injunctive relief prohibiting P&G and Watson from engaging in the unlawful acts alleged in this Complaint;

(c) Entry of an order awarding Mylan its reasonable attorneys' fees and costs of prosecuting this action; and

(d) Such other and further relief as this Honorable Court deems just and proper.

Third Claim For Relief
(Conspiracy to monopolize by P&G and Watson in violation of the Sherman Act, 15 U.S.C. § 1)

215. Mylan repeats and realleges the allegations of paragraphs 1 through 214, as if set forth fully herein.

216. On information and belief, P&G and Watson, through the above-described conduct, have conspired and combined in a plan, common design, and understanding with specific intent to eliminate competitors for nitrofurantoin in the United States, to eliminate the critical exclusivity incentive to challenge brand patents, and to prevent competition in other innovator drug markets controlled by P&G.

217. On information and belief, P&G and Watson have conspired in an attempt to monopolize the market for nitrofurantoin in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

218. On information and belief, P&G and Watson have contracted, combined, and conspired with each other to unreasonably restrain trade, to obtain a market monopoly and to prevent Mylan from competing in the relevant market, all in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

219. As a result of the unlawful conspiracy and combination between P&G and Watson, Mylan has suffered, and will continue to suffer, antitrust injury to its business and property, including, without limitation, lost profits stemming from the destruction of Mylan's 180-day generic exclusivity period, lost business opportunities, lost first-mover advantages, lost market share and position, and lost business relationships and good will.

220. P&G and Watson's unlawful conspiracy has also directly and proximately caused injury to consumers and competition by undermining the effectiveness of Mylan's entry into, and otherwise reducing competition in, the relevant markets, as well as by eliminating the critical exclusivity incentive created by Congress to challenge brand patents and promote increased generic competition in the relevant markets.

WHEREFORE, Mylan respectfully prays that this Honorable Court enter judgment in its favor and against P&G and Watson, as follows:

(a) An award of the actual damages suffered by Mylan in the amount to be proved at trial, to be trebled as provided by law;

(b) Injunctive relief prohibiting P&G and Watson from engaging in the unlawful acts alleged in this Complaint;

(c) Entry of an order awarding Mylan its reasonable attorneys' fees and costs of prosecuting this action; and

(d) Such other and further relief as this Honorable Court deems just and proper.

Fourth Claim For Relief
(Predatory and discriminatory pricing by P&G and Watson in violation of the Robinson-Patman Act, 15 U.S.C. § 13(a))

221. Mylan repeats and realleges the allegations of paragraphs 1 through 220, as if fully set forth herein.

222. On information and belief, P&G and Watson have willfully engaged in predatory and discriminatory pricing in violation of the Robinson-Patman Act, 15 U.S.C. § 13(a).

223. On information and belief, P&G and Watson have engaged in unlawful price discrimination by selling the same drug, Macrobid® and authorized generic Macrobid®, to different but identically situated buyers at different prices.

224. On information and belief, P&G and Watson have sold authorized generic Macrobid® at pricing below any appropriate measure of P&G's costs and/or at pricing below the level necessary to sell the product.

225. On information and belief, P&G intended to use the terms of its agreement with Watson to demand higher prices from consumers for Macrobid®, while allowing Watson to sell authorized generic Macrobid® below cost in a different segment of the market, *i.e.*, the generic substitution segment that should have been exclusively reserved for Mylan.

226. On information and belief, P&G and Watson have priced their products in an unfair manner with the object of eliminating or purging competition in the relevant markets.

227. There is a reasonable probability that the predatory and discriminatory pricing charged by P&G and Watson may harm competition in the relevant markets.

228. P&G has a reasonable probability of recouping its investment in below-cost pricing by obtaining higher than competitive prices in the relevant markets, including the other innovator drug markets exclusively controlled by P&G.

229. P&G's actions in entering into the agreement with Watson evidence P&G's specific intent to substantially harm and lessen competition in the relevant markets by destroying the exclusivity incentive to challenge patents through discriminatory and predatory pricing.

230. As a result of P&G's and Watson's unlawful conduct, Mylan has suffered, and will continue to suffer, antitrust injury to its business and property, including, without limitation, lost profits stemming from the destruction of Mylan's 180-day generic exclusivity period, lost

business opportunities, lost first-mover advantages, lost market share and position, and lost business relationships and good will.

WHEREFORE, Mylan respectfully prays that this Honorable Court enter judgment in its favor and against P&G, as follows:

(a) An award of the actual damages suffered by Mylan in the amount to be proved at trial, to be trebled as provided by law;

(b) Injunctive relief prohibiting P&G and Watson from engaging in the unlawful acts alleged in this Complaint;

(c) Entry of an order awarding Mylan its reasonable attorneys' fees and costs of prosecuting this action; and

(d) Such other and further relief as this Honorable Court deems just and proper.

Fifth Claim For Relief
(Violation of the West Virginia Antitrust Act,
W. VA. CODE §§ 47-18-3 and 47-18-4, by P&G and Watson)

231. Mylan repeats and realleges the allegations of paragraphs 1 through 230, as if fully set forth herein.

232. Under the West Virginia Antitrust Act, "[e]very contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce in this state shall be unlawful." W. VA. CODE § 47-18-3(a). Likewise, "[t]he establishment, maintenance or use of a monopoly or an attempt to establish a monopoly of trade or commerce, any part of which is within this state, by any persons for the purpose of excluding competition or controlling, fixing or maintaining prices is unlawful." W. VA. CODE § 47-18-4.

233. On information and belief, P&G has willfully engaged in anticompetitive conduct with the specific intent to attempt to monopolize the relevant markets and to exclude competition therefrom by, *inter alia*, unlawfully introducing an authorized generic product into the market during Mylan's 180-day generic exclusivity period for the purpose of destroying and eliminating

that exclusivity and incentive, and by selling its Macrobid® product at a price below production cost. P&G and Watson have also intentionally engaged in a conspiracy in restraint of trade by agreeing to destroy and eliminate Mylan's exclusivity and to prevent Mylan from competing in the relevant markets through these same tactics.

234. As a result of the unlawful conspiracy and competition between P&G and Watson, Mylan has suffered, and will continue to suffer, antitrust injury to its business and property, including, without limitation, lost profits stemming from the destruction of Mylan's 180-day generic exclusivity period, lost business opportunities, lost first-mover advantages, lost market share and position, and lost business relationships and good will.

235. P&G and Watson's unlawful conspiracy has also directly and proximately caused injury to consumers and competition by undermining the effectiveness of Mylan's entry into, and otherwise reducing competition in, the relevant markets, as well as by eliminating the critical exclusivity incentive created by Congress to challenge brand patents and promote increased generic competition in the relevant markets.

WHEREFORE, Mylan respectfully prays that this Honorable Court enter judgment in its favor and against P&G and Watson, as follows:

(a) An award of the actual damages suffered by Mylan in the amount to be proved at trial, to be trebled as provided by law;

(b) Injunctive relief prohibiting P&G and Watson from engaging in the unlawful acts alleged in this Complaint;

(c) Entry of an order awarding Mylan its reasonable attorneys' fees and costs of prosecuting this action; and

(d) Such other and further relief as this Honorable Court deems just and proper.

Sixth Claim For Relief
(Violation of the West Virginia Unfair Practices Act,
W. VA. CODE §§ 47-11A-1 to 47-11A-14, by P&G and Watson)

236. Mylan repeats and realleges the allegations of paragraphs 1 through 235, as if fully set forth herein.

237. The purpose of the West Virginia Unfair Practices Act "is to safeguard the public against the creation or perpetuation of monopolies and to foster and encourage competition, by prohibiting unfair and discriminatory practices by which fair and honest competition is destroyed or prevented." W. VA. CODE § 47-11A-14.

238. Under the West Virginia Unfair Practices Act, any "offer to sell, or sale . . . at less than cost . . . for the purposes of unfairly diverting trade from or otherwise injuring competitors and destroying competition, is an unfair method of competition contrary to public policy." W. VA. CODE § 47-11A-1.

239. The West Virginia Unfair Practices Act makes it "unlawful for any person, partnership, firm, corporation, joint-stock company, or other association engaged in business as a retailer or wholesaler within this state, to sell, offer for sale or advertise for sale any article, product or item of merchandise at less than the cost thereof . . . for the purposes of unfairly diverting trade from or otherwise injuring one or more competitors, and destroying competition." W. VA. CODE § 47-11A-2.

240. On information and belief, the distribution agreement between P&G and Watson effectuates a predatory pricing scheme in violation of the West Virginia Unfair Practices Act, W. VA. CODE §§ 47-11A-1 – 47-11A-14 (the "Unfair Practices Act").

241. The Unfair Practices Act prohibits P&G and Watson from advertising, selling, or offering for sale Macrobid® at below cost.

242. On information and belief, under the Agreement, the price for which P&G advertises, promotes, sells, and/or offers to sell Macrobid® to distributors and other customers is higher than the price P&G charges Watson for the identical authorized generic version of Macrobid®. Further, on information and belief, Watson in turn advertises, promotes, sells, and/or offers for sale the authorized generic version of Macrobid® below the cost of Macrobid®.

243. On information and belief, P&G and Watson intentionally and unlawfully advertise, promote, sell, and/or offer for sale the generic version of Macrobid®, which is identical to Macrobid®, to purchasers or vendors for the purpose of unfairly diverting trade from and otherwise destroying competition and injuring their competitor, Mylan, by, among other things, taking sales that would have otherwise gone to Mylan.

244. On information and belief, P&G and Watson intentionally and unlawfully sell or offer to sell authorized generic Macrobid® below cost and, in doing so, have injured competitors in the generic nitrofurantoin market, including Mylan, and destroyed competition in the nitrofurantoin market. Such actions by P&G and Watson serve only to punish and deter competition by Mylan and other potential manufacturers of true generic nitrofurantoin.

245. The arrangement between P&G and Watson is not necessary to achieve any recognized procompetitive benefit because P&G could just as easily drop the price of its branded Macrobid®. As such, there are no countervailing considerations that weigh against the adverse economic effects to future innovation and development of generic drugs. The arrangement is therefore anticompetitive and an unfair practice.

246. P&G's and Watson's actions are contrary to public policy and are in direct contravention of the Unfair Practices Act.

247. As a direct and proximate result of the actions of P&G and Watson, Mylan has been irreparably damaged in an amount that includes, among other things, lost sales of nitrofurantoin, lost profits on sales of nitrofurantoin, and Mylan's reduced ability to innovate, develop and market future generic products.

WHEREFORE, Mylan respectfully prays that this Honorable Court enter judgment in its favor and against P&G and Watson, as follows:

(a) An award of the actual damages suffered by Mylan in the amount to be proved at trial, to be trebled as provided by law;

(b) Entry of a declaration that the distributor agreement between P&G and Watson for the sale of the authorized generic version of Macrobid® is an illegal contract;

(c) An injunction prohibiting P&G and Watson from engaging in the unlawful acts contemplated under the terms of their agreement;

(d) Entry of an order awarding Mylan its reasonable attorneys' fees and costs of prosecuting this action; and

(e) Such other and further relief as this Honorable Court deems just and proper.

Seventh Claim For Relief
(Violation of the West Virginia Pharmaceutical Availability and Affordability Act, W. VA. CODE § 5A-3C-12, by P&G and Watson)

248. Mylan repeats and realleges the allegations of paragraphs 1 through 247, as if fully set forth herein.

249. In March of 2004, the West Virginia legislature enacted the West Virginia Pharmaceutical Availability and Affordability Act for the purpose of controlling the rising costs of health care and to provide affordable prescription drugs for state residents. *See* W. VA. CODE § 5A-3C-2.

250. Under the West Virginia Pharmaceutical Availability and Affordability Act, "[a] contract, combination or conspiracy . . . [f]or the purpose or with the intent to fix, control or maintain the market price, rate or fee of pharmaceuticals; or [a]llocate or divide customers or

markets, functional or geographic, for any pharmaceutical" is considered to "restrain trade or commerce unreasonably and shall be unlawful." W. VA. CODE § 5A-3C-12(a)(1)(A)-(B).

251. Also considered an unlawful and unreasonable restraint of trade or commerce is "[t]he establishment, maintenance or use of a monopoly or an attempt to establish a monopoly of trade or commerce, any part of which is within [West Virginia], by any persons for the purpose of or with the intent to exclude competition or control, fix or maintain pharmaceutical prices." W. VA. CODE § 5A-3C-12(a)(2).

252. On information and belief, P&G and Watson have conspired and combined in a common plan and design to allocate and divide the nitrofurantoin market so that P&G could control the market price of both brand and generic nitrofurantoin, and thereby preserve its overall share of nitrofurantoin sales. P&G's and Watson's scheme has enabled P&G to continue to price its brand-name Macrobid® at monopoly levels, while pricing its authorized generic Macrobid® at below-cost levels in order to destroy the value of Mylan's 180-day exclusivity period and punish Mylan for entering the market and competing with P&G's brand product. P&G's and Watson's conspiracy also has the effect of deterring other generic companies from engaging in future challenges to P&G's patents, and competing in other markets dominated by P&G.

253. In addition to conspiring with Watson to control the price of brand and generic Macrobid® and divide the nitrofurantoin market, P&G has acted with the specific intent to attempt to monopolize the relevant markets, including the market for generic nitrofurantoin during the 180-day exclusivity period, the market for the production and sale of nitrofurantoin (including both brand and generic nitrofurantoin), the submarket for brand Macrobid®, the submarket for generic nitrofurantoin (including authorized generic Macrobid®), and other innovator drug markets controlled by P&G.

254. On information and belief, P&G has acted with willful intent to exclude competition in the relevant markets by introducing an authorized generic nitrofurantoin product into the market during Mylan's 180-day exclusivity period for generic nitrofurantoin, by continuing to sell its brand-name Macrobid® product at monopoly prices, and by selling authorized generic Macrobid® at a price below production cost. P&G's conduct eliminates the exclusivity incentive for Mylan and other generic competitors and deters future challenges to P&G's patents on other drugs.

255. As a result of the unlawful conspiracy between P&G and Watson, and P&G's willful and unlawful attempt to monopolize the relevant markets and exclude competition, Mylan has suffered, and will continue to suffer, injury to its business and property, including, without limitation, lost profits stemming from the destruction of Mylan's 180-day generic exclusivity period, lost business opportunities, lost first-mover advantages, lost market share and position, and lost business relationships and good will.

WHEREFORE, Mylan respectfully prays that this Honorable Court enter judgment in its favor and against P&G and Watson, as follows:

(a) An award of the actual damages suffered by Mylan in the amount to be proved at trial, to be trebled as provided by law;

(b) Entry of an order awarding Mylan its reasonable attorneys' fees and costs of prosecuting this action; and

(c) Such other and further relief as this Honorable Court deems just and proper.

Eighth Claim For Relief
(Tortious interference against P&G and Watson)

256. Mylan repeats and realleges the allegations of paragraphs 1 through 255, as if fully set forth herein.

257. P&G and Watson have tortiously interfered with Mylan's current and prospective contractual and/or advantageous business relationships in an intentional, improper, and malicious manner, resulting in significant financial damages to Mylan.

258. Prior to receiving final approval of its nitrofurantoin ANDA and commercially marketing its generic product, Mylan established business relationships with wholesalers, pharmacies, and distributors for the supply and sale of its generic nitrofurantoin product.

259. Prior to the commercial launch of Mylan's nitrofurantoin product, P&G and Watson acted with the specific and malicious intent to misappropriate Mylan's profits during this valuable time by knowingly and intentionally interfering with Mylan's existing and prospective business relationships through the improper promotion and offer for sale of P&G's authorized generic Macrobid® product.

260. On information and belief, P&G's and Watson's conduct forced Mylan to renegotiate previously accepted pricing agreements with its customers and drop its prices for generic nitrofurantoin.

261. Moreover, during Mylan's 180-day exclusivity period, P&G and Watson intentionally and improperly marketed P&G's authorized generic Macrobid® product, knowing that such marketing was in direct violation of the statutory grant of generic marketing exclusivity awarded to Mylan.

262. Due to P&G's and Watson's intentional, malicious, and improper interference with Mylan's existing and prospective contractual and/or advantageous business relationships, Mylan has suffered a loss of tens of millions of dollars in lost profits from sales of its generic nitrofurantoin product.

263. P&G and Watson intentionally, maliciously, and improperly interfered with Mylan's existing and prospective contractual and/or advantageous business relationships without privilege or lawful justification. P&G and Watson have acted with the improper intent of eliminating the 180-day exclusivity incentive provided to first-filers, like Mylan, and for the purpose of maintaining artificially high prices on P&G's brand-name Macrobid® product and attempting to obtain a monopolistic hold on the nitrofurantoin market—resulting in an unlawful restraint on trade.

WHEREFORE, Mylan respectfully prays that this Honorable Court enter judgment in its favor and against P&G and Watson, as follows:

(a) Awarding Mylan any and all profits P&G and Watson have obtained from P&G's and Watson's intentional and improper sale of the authorized generic version of Macrobid® during Mylan's 180-day generic exclusivity period for nitrofurantoin;

(b) Awarding Mylan punitive damages for the losses it has suffered as a direct result of P&G's and Watson's malicious and wanton promotional and marketing activities;

(c) Awarding Mylan its reasonable attorneys' fees and costs of prosecuting this action; and

(d) Awarding Mylan such further relief as this Court deems just and proper.

Ninth Claim For Relief
(Unjust enrichment against P&G and Watson)

264. Mylan repeats and realleges the allegations of paragraphs 1 through 263, as if fully set forth herein.

265. This count is pleaded in the alternative to the previous claims for relief, as permitted by Rule 8(e)(2) of the Federal Rules of Civil Procedure.

266. P&G and Watson have been unjustly enriched insofar as they have benefited, and continue to benefit, at Mylan's expense from the unlawful and inequitable conduct complained of herein.

267. The benefits P&G and Watson have improperly obtained include, among other things, the sales and profits of generic nitrofurantoin obtained during Mylan's 180-day generic exclusivity period to which Mylan was solely entitled, and that P&G and Watson would not have otherwise obtained but for their unlawful and inequitable acts.

268. P&G and Watson have improperly retained these benefits to the detriment of Mylan.

269. Mylan's losses as alleged herein are a direct and proximate cause of P&G's and Watson's unlawful and inequitable conduct.

270. As a result, P&G and Watson have been unjustly enriched in violation of the fundamental principles of justice, equity, and good conscience.

271. Under these circumstances, it would be inequitable and unjust for P&G and Watson to retain this benefit.

WHEREFORE, Mylan respectfully prays that this Honorable Court enter judgment in its favor and against P&G and Watson, as follows:

(a) A determination that P&G and Watson have been unjustly enriched in an amount to be determined at trial;

(b) An order awarding Mylan restitution, together with interest thereon;

(c) Entry of an order awarding Mylan its reasonable attorneys' fees and costs of prosecuting this action; and

(d) Such other and further relief as this Honorable Court deems just and proper.

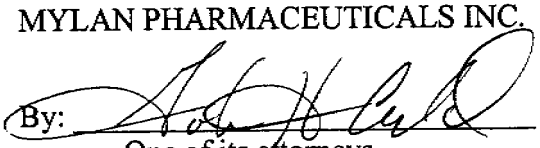
JURY DEMAND

Plaintiff Mylan hereby demands a trial by jury on all claims and issues so triable.

Dated: November 12, 2004.

Respectfully Submitted,

MYLAN PHARMACEUTICALS INC.

By: 
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