IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., 1090 Horsham Road, North Wales, PA 19454, Plaintiff, v. LESTER M. CRAWFORD, Acting Commissioner of Food and Drugs, 5600 Fishers Lane, Rockville, MD 20857, FOOD AND DRUG ADMINISTRATION, 5600 Fishers Lane, Rockville, MD 20857, and TOMMY G. THOMPSON, Secretary of Health and Human Services, 200 Independence Ave., SW, Washington DC 20204, Defendants.	)	Civil Action No. _____

COMPLAINT

Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva"), for its Complaint against Defendants Lester M. Crawford, Acting Commissioner of Food and Drugs, the Food and Drug Administration, and Tommy G. Thompson, Secretary of Health and Human Services (collectively, the "FDA"), hereby alleges as follows upon personal knowledge as to Teva and upon information and belief as to persons other than Teva and matters unrelated to Teva:

PRELIMINARY STATEMENT

1. By this action, Teva seeks judicial review of the FDA's July 2, 2004 decision (the "FDA Decision" or "Decision") denying a Citizen Petition (the "Petition,"

attached hereto as Exhibit A) filed by Teva in which Teva requested the FDA take administrative action to prevent the marketing of so-called "brand (or authorized) generic" drug products in violation of certain congressionally mandated generic-drug exclusivity rights. Teva also seeks appropriate declaratory and injunctive relief against the FDA on the ground that the FDA's denial of Teva's Petition was arbitrary, capricious, an abuse of agency discretion, contrary to law, and/or in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "FDCA" or the "Act"), and the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.* (the "APA").

2. At issue here is the FDA's failure to interpret and implement properly an Act of Congress, codified at 21 U.S.C. § 355(j)(5)(B)(iv) (the "FDCA Exclusivity Provision"), that confers a 180-day period of generic-drug marketing exclusivity (the "Generic Exclusivity Period") upon the first generic-drug manufacturer ("generic company") to file an Abbreviated New Drug Application ("ANDA") challenging as inapplicable, invalid, or unenforceable patents that purportedly cover brand drugs.

3. More specifically, the issue that Teva presented in its Petition to the FDA, and that is the subject of this action, is whether the FDA has properly construed and applied the FDCA, including among other provisions the FDCA Exclusivity Provision, 21 U.S.C. § 355(j)(5)(B)(iv), in concluding that the FDA is powerless to, and should not, prevent the marketing of brand generics (as defined below) during the Generic Exclusivity Period when such brand generics are manufactured and/or marketed by a company that was not the first ANDA applicant to file a "Paragraph IV" certification (as defined below) for the drug at issue.

4. The FDA Decision (attached hereto as Exhibit B) rules erroneously (1) that the FDA is powerless to prevent the sale of brand generics during a Generic Exclusivity

Period, and (2) that such marketing of brand generics is consistent with the purpose of the FDCA Exclusivity Provision.

5. The FDA Decision is arbitrary, capricious, an abuse of agency discretion, contrary to law, and should be overturned because it contravenes, and is irreconcilable with, the fundamental purpose of the FDCA Exclusivity Provision. In particular:

(a) The FDA and many courts have confirmed that the purpose of the FDCA Exclusivity Provision is to encourage, specifically by means of the expressly provided Generic Exclusivity Period, generic companies to market and sell generic drugs before the expiration of inapplicable, invalid, or unenforceable patents that purportedly protect brand drugs. Effectuating that purpose requires the application of the FDCA Exclusivity Provision to brand generics and ANDA generics (as defined below) alike.

(b) The FDA Decision exempts brand generics from the application of the FDCA Exclusivity Provision and permits brand generics — in unlimited number — to intrude upon the Generic Exclusivity Period. The FDA Decision thereby permits brand-drug manufacturers ("brand companies") to eliminate entirely the Generic Exclusivity Period and the accompanying incentives provided by Congress to generic companies to challenge brand-drug patents that are inapplicable, invalid, or unenforceable. The FDA Decision thus contravenes the fundamental purpose of the FDCA Exclusivity Provision and violates an established principle of statutory interpretation directly applicable to that Provision: Brand companies

cannot control whether, or to what extent, a generic company obtains the benefit of the Generic Exclusivity Period.

(c) The FDA Decision runs counter to established precedent of the FDA itself, as affirmed by a federal district court and recently endorsed by Congress, that, in interpreting and applying the FDCA Exclusivity Provision, brand generics must be treated as functionally and legally equivalent to ANDA generics. That principle, which was established prior to a recent statutory amendment and when the FDCA Exclusivity Provision was entirely silent as to brand generics, requires the application of the FDCA Exclusivity Provision — and the Generic Exclusivity Period provided thereby — to brand generics and ANDA generics alike.

(d) The FDA Decision improperly intrudes upon Congress's prerogative to establish the quantum and type of economic incentive for generic companies to challenge brand-drug patents. The FDA does so based upon economic considerations and conclusions that are outside the scope of the FDA's congressional mandate and expertise and that are not supported by substantial evidence on the record considered as a whole. The FDA improperly considered, and wrongly answered, the question whether the full incentive provided by Congress through the Generic Exclusivity Period is economically necessary to encourage generic companies to police the quality of, and challenge, patents that purportedly protect brand drugs from generic competition.

(e) The beneficiaries of the FDA Decision are brand companies whose patent portfolios Congress intended to police by means of the FDCA Exclusivity Provision and the Paragraph IV certification process. Brand companies are thereby wrongly permitted both to protect their patent portfolios from scrutiny and attack by generic companies and to benefit economically by marketing brand generics when subsequently filed ANDA generics must await the expiration of the Generic Exclusivity Period.

6. Teva accordingly seeks judicial review of the FDA Decision by this Court, a judgment declaring the FDA Decision to be arbitrary, capricious, an abuse of agency discretion, and/or contrary to law, and an order (a) setting the FDA Decision aside under the APA, 5 U.S.C. § 706, (b) directing the FDA to withdraw the FDA decision, (c) directing the FDA to prohibit the sale of brand generics before the expiration of an applicable Generic Exclusivity Period, and (d) remanding the matter to the FDA to determine the appropriate form of agency action to prohibit such sale of brand generics.

PARTIES

7. Teva Pharmaceuticals USA, Inc. is incorporated under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva develops, manufactures, and sells generic drugs in the United States and regularly seeks and earns the right to Generic Exclusivity Periods with respect to generic drugs that it manufacturers. Teva filed a Citizen Petition with the FDA on June 9, 2004 seeking a determination that brand generics may not be sold before the expiration of an applicable Generic Exclusivity Period.

8. Lester M. Crawford, D.V.M., Ph.D., is Acting Commissioner of Food and Drugs, and is the senior official of the FDA. He is sued in his official capacity. Dr. Crawford maintains offices at 5600 Fishers Lane, Rockville, Maryland 20857 and 200 C Street, SW, Washington, DC 20204.

9. The Food and Drug Administration is an administrative agency within the United States Department of Health and Human Services, with offices at 5600 Fishers Lane, Rockville, Maryland 20857 and 200 C Street, SW, Washington, DC 20204. The FDA has been delegated the authority to administer the FDCA.

10. Tommy G. Thompson is Secretary of Health and Human Services and is the official charged by law with administering the FDCA. He is sued in his official capacity. Secretary Thompson maintains an office at 200 Independence Avenue, SW, Washington, DC 20204.

JURISDICTION, VENUE, AND INTERSTATE COMMERCE

11. This Court has jurisdiction pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, the FDCA, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (commonly known as the "Hatch-Waxman Amendments"), the APA, 5 U.S.C. § 701 *et seq.*, and 28 U.S.C. §§ 1331 and 1361.

12. Defendants are subject to personal jurisdiction in this judicial district.

13. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(e).

14. The FDA Decision denying Teva's Citizen Petition constitutes final agency action for which Teva is entitled to judicial review and from which Teva is entitled to judicial relief.

15. As a direct and proximate result of the FDA Decision, Teva has suffered and will continue to suffer a legal wrong and has been and will continue to be adversely affected and aggrieved.

16. The FDA Decision presents an actual, substantial, and continuing justiciable controversy subject to proper resolution by this Court pursuant to the Declaratory Judgment Act and the APA.

THE APPLICABLE REGULATORY SCHEME

HATCH-WAXMAN AMENDMENTS

17. Congress passed the "Hatch-Waxman Amendments" to the Act in 1984 after concluding, among other things, that the Act's then-current drug-approval process unduly delayed the entry of relatively inexpensive generic drugs into the marketplace.

18. The drug product that the FDA approves for manufacture, marketing, and sale pursuant to a New Drug Application ("NDA") is referred to as the "brand drug," or the "listed drug." *See* 21 U.S.C. § 355(b)(1).

19. The Hatch-Waxman Amendments permit the filing of an Abbreviated New Drug Application (previously defined as an "ANDA") that need not establish the safety and efficacy of the drug through animal and human testing. An ANDA instead relies on the safety and efficacy data submitted pursuant to the NDA process in connection with the brand drug to which the generic drug is bioequivalent.

20. Drugs that are approved for sale pursuant to an ANDA are typically referred to as "generic" drugs and are herein referred to as "ANDA generics."

21. In some cases, brand companies offer for sale, or license others to sell, non-ANDA generic drugs ("brand generics") that were approved pursuant to an NDA.

22. Brand generics are sold in the same commercial manner as generic companies offer for sale their ANDA generics and thereby benefit from rules and incentives contained in state laws and third-party payer plans that require, permit, or encourage the substitution of generic drugs for brand drugs (generally defined as "Generic Substitution" below).

"PARAGRAPH IV" AND "PARAGRAPH III" CERTIFICATIONS

23. An ANDA applicant is required to submit to the FDA one of four certifications with respect to any patent that the brand drug manufacturer has listed as purportedly covering the brand drug in the FDA publication entitled APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (the "Orange Book").

24. If an ANDA applicant seeks approval to market a generic drug *only after* the expiration of a patent listed in the Orange Book, the ANDA applicant must certify, according to 21 U.S.C. § 355(j)(2)(A)(vii)(III), "the date on which such patent will expire." Such a certification is known as a "Paragraph III" certification. No marketing exclusivity is awarded to the first (or any) ANDA applicant to file a Paragraph III certification.

25. If an ANDA applicant seeks approval to market a generic drug *before* the expiration of a patent listed in the Orange Book, the ANDA applicant must certify, according to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Such a certification is known as a "Paragraph IV" certification.

26. Before making a Paragraph IV certification, a generic company invests substantial resources and incurs significant risk. The resources and risk include research and development to determine whether the patents listed in the Orange Book are valid and enforceable; if so, whether the subject drug can be manufactured in a non-infringing and

bioequivalent manner; whether the generic company can sustain its position in the patent litigation that will likely follow the Paragraph IV certification; and whether the generic company can be the first ANDA applicant to file a Paragraph IV certification.

27. The filing of a Paragraph IV certification permits the holder of the challenged patent to assert a cause of action for patent infringement against the ANDA applicant.

28. The Paragraph IV ANDA applicant must successfully defend, at substantial expense, the ensuing patent litigation or face an injunction against the sale of the generic drug until the expiration of the subject patent. If the Paragraph IV ANDA applicant is enjoined from selling the generic drug until the expiration of the patent, the Paragraph IV applicant is in the same position as it would have been had it filed a Paragraph III certification except that the applicant has incurred the substantial additional cost of a Paragraph IV certification.

29. In filing a Paragraph IV certification, the generic company advances at its own expense a congressional policy and the public interest by seeking to introduce, through a lawful though costly and time-consuming procedure, lower cost drugs before the time that the brand company claims the generic drugs can be legally sold.

THE GENERIC EXCLUSIVITY PERIOD

30. To encourage generic companies to invest the resources necessary to make a Paragraph IV certification, challenge brand-drug patents, and incur the consequent risk, Congress granted a valuable right to the first generic company to file a Paragraph IV certification with respect to a given Orange Book-listed patent ("first filers"). That right is the right for first filers to enjoy a 180-day period (previously defined as the "Generic Exclusivity

Period") in which the first filer is entitled to be the *only* provider of generic versions of the drug at issue.

31. In the FDA Decision, the FDA interpreted the FDCA Exclusivity Provision that applied to Paragraph IV ANDAs that were submitted on or before December 8, 2003. The FDCA Exclusivity Provision, as then written, provided in pertinent part as follows:

> If the [ANDA] contains a [Paragraph IV] certification . . . and is for a drug for which a previous [ANDA] has been submitted . . . [containing] such a certification, the [ANDA] shall be made effective not earlier than one hundred and eighty days after . . . the first commercial marketing of the drug under the previous [ANDA].

21 U.S.C. § 355(j)(5)(B)(iv)(I).

32. In 2003, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (the "MMA"), P.L. 108-173, § 1102(a)(1), altered the language of the FDCA Exclusivity Provision. The FDCA Exclusivity Provision now provides in pertinent part:

> [I]f the [ANDA] contains a [Paragraph IV] certification . . . and is for a drug for which a first applicant has submitted an [ANDA] containing such a certification, the [ANDA] shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed [i.e., brand] drug) by any first applicant.

21 U.S.C. § 355(j)(5)(B)(iv)(I).

33. The FDA stated in the FDA Decision that the MMA "did not . . . substantively alter the statutory language upon which the Agency has based its determination that it is permissible to market an authorized [or brand] generic during a 180-day exclusivity period applicable to that drug product under an ANDA." FDA Decision, at 1 n.1. The FDA has accordingly decided, as a final agency action, that brand generics may be sold prior to the expiration of a Generic Exclusivity Period regardless of whether the Generic Exclusivity Period is based upon the text of the FDCA Exclusivity Provision as written before or after the MMA

amendment. By way of this action, Teva challenges as arbitrary, capricious, an abuse of agency discretion, and/or contrary to law the FDA's interpretation of the FDCA Exclusivity Provision as written both before and after the MMA amendment.

34. Prior to the FDA Decision, the FDA had established a policy whereby the marketing of a brand generic is subject to the provisions of the Generic Exclusivity Period to the same extent as an ANDA generic. That policy was upheld by a federal district court and has never been rescinded or modified by the FDA.

35. The purpose of the FDCA Exclusivity Provision is to provide the first filer with a 180-day period before the expiration of which the applicant has the right to be the *sole* seller of the subject generic drug as a reward for being the first ANDA applicant to challenge the patent that purportedly insulates the brand drug from generic competition.

36. Congress's provision of the Generic Exclusivity Period constitutes an important public policy that expedites the introduction of lower cost drugs to the consuming public where brand-company assertions of patents would otherwise preclude generic competition.

DIFFERENCES BETWEEN PARAGRAPH IV AND PARAGRAPH III CERTIFICATIONS

37. Paragraph IV certifications and Paragraph III certifications thus differ insofar as the Paragraph IV applicant (1) seeks to sell its generic drug before the purportedly applicable brand-drug patent expires, (2) risks costly and extended patent-infringement litigation, and (3) obtains the right to a Generic Exclusivity Period if the applicant is the first to file a Paragraph IV certification as to the subject patent. The Paragraph III applicant, in contrast, (1) seeks to sell the generic drug only after the purportedly applicable patent expires, (2) incurs no risk of patent-infringement litigation, and (3) can obtain no marketing exclusivity

but rather will likely face competition from numerous other generic drugs upon the expiration of the brand-drug patent and the launch of its own generic drug.

TEVA REGULARLY FILES PARAGRAPH IV CERTIFICATIONS

38. Teva spends millions of dollars and invests many human resources in researching the applicability and validity of patents listed in the Orange Book that purportedly cover brand drugs and in developing generic-drug formulations on an expedited basis and, often, so as not to infringe the brand-drug patent. As a result of those expenditures and investments, Teva has been the first filer with respect to numerous ANDAs and regularly defends infringement actions by brand companies seeking to prevent Teva from selling ANDA generics before the expiration of patents purportedly covering brand drugs.

39. Upon receipt of final FDA approval as a first filer, Teva is awarded the Generic Exclusivity Period with respect to the sale of the generic drug at issue.

40. Teva is the first Paragraph IV filer with respect to numerous pending ANDAs for which it will be eligible for Generic Exclusivity Periods. Teva expects to be directly harmed by the FDA Decision denying its Citizen Petition to prevent the sale of brand generics before the expiration of an applicable Generic Exclusivity Period.

THE FDCA EXCLUSIVITY PROVISION PROHIBITS THE SALE OF BRAND GENERICS AS WELL AS SUBSEQUENTLY FILED ANDA GENERICS BEFORE THE EXPIRATION OF THE GENERIC EXCLUSIVITY PERIOD.

41. The FDA, the judiciary, and Congress have all construed brand generics and ANDA generics as legally and functionally equivalent under the FDCA Exclusivity Provision and with respect to the operation of the Generic Exclusivity Period, regardless of whether the generic product at issue was approved via an ANDA or an NDA.

42. In 2001, the FDA issued a final administrative ruling in which it granted a Citizen Petition filed by Teva that sought a determination that a brand generic must be treated as

functionally and legally equivalent to an ANDA generic for purposes of the FDA's implementation of the Generic Exclusivity Period. Specifically, Teva requested that the FDA establish that the marketing of a brand generic for nifedipine by a first filer was legally equivalent to the marketing of an ANDA generic product for purposes of triggering the Generic Exclusivity Period under the FDCA Exclusivity Provision. Teva Pharmaceuticals USA, Inc. Citizen Petition, Docket No. 00P-1446/CP1, at 2 (Aug. 9, 2000) (the "Nifedipine Petition").

43. The language of the FDCA Exclusivity Provision at the time that the FDA granted Teva's Nifedipine Petition did not indicate that the sale of a brand drug pursuant to an NDA, whether or not labeled as a generic drug, would trigger the running of the Generic Exclusivity Period. As alleged above, the FDCA Exclusivity Provision then provided in pertinent part:

> If the [ANDA] contains a [Paragraph IV] certification . . . and is for a drug for which a previous [ANDA] has been submitted . . . [containing] such a certification, the [ANDA] shall be made effective not earlier than one hundred and eighty days after . . . the first commercial marketing ***of the drug under the previous [ANDA]***.

21 U.S.C. § 355(j)(5)(B)(iv)(I) (emphasis added).

44. Despite the silence of the FDCA Exclusivity Period as to brand generics and its express reference to marketing "under the previous [ANDA]," the FDA granted Teva's Nifedipine Petition and held 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*." Food and Drug Administration Nifedipine Petition Response Letter, Docket No. 00P-1446/CP1, at 7-8 (Feb. 6, 2001) ("Nifedipine Petition Response") (emphasis added).

45. In rendering its decision, the FDA followed established judicial precedent that holds that the "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." Nifedipine Petition Response, at 5.

46. The United States District Court for the Northern District of West Virginia upheld the FDA's determination that brand generics are legally equivalent to ANDA generics for purposes of triggering the Generic Exclusivity Period despite the silence of the FDCA Exclusivity Provision as to brand generics and its express reference to marketing "under the previous [ANDA]." *Mylan v. Thompson*, 207 F. Supp. 2d 476, 482-83 (N.D. W. Va. 2001). Specifically, the district court endorsed the core principle established by the FDA in its Nifedipine Petition Response by quoting with approval the FDA's decision:

> [W]hether 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[. P]ermitting Mylan to market nifedipine without triggering the beginning of exclusivity would be inconsistent with the intent of the statutory scheme.

Mylan v. Thompson, 207 F. Supp. 2d 476, 488 (N.D. W. Va. 2001) (quoting Nifedipine Petition Response, at 7-8) (emphasis added).

47. Mylan appealed the district court's decision. On appeal, the FDA further explained that, for the purpose of applying the Generic Exclusivity Period, it made "no difference" whether Mylan marketed the generic product approved in its ANDA or the brand generic produced by Pfizer. (Brief for Federal Defendants [FDA] at 34-35, *Mylan v. Thompson*, No. 01-1554 (4th Cir. 2001) ("FDA Nifedipine Appeal Brief"). The FDA explained that the Generic Exclusivity Period "was intended to allow a generic manufacturer 180-days of

marketing a drug *without competition from other generic drugs*." FDA Nifedipine Appeal Brief at 38 (emphasis added).

48. Although the Mylan appeal was dismissed voluntarily, Congress recently affirmed the District Court and FDA holdings that brand generics are legally and functionally equivalent with respect to the Generic Exclusivity Period. As alleged above, Congress amended the FDCA Exclusivity Provision establishing the Generic Exclusivity Period in 2003. In response to the specific issue presented two years before in the Teva Nifedipine Citizen Petition, Congress clarified that the Generic Exclusivity Period is triggered by the first Paragraph IV ANDA filer's sale of a brand generic just as the Generic Exclusivity Period is triggered by the first filer's sale of its ANDA generic:

> [I]f the [ANDA] contains a [Paragraph IV] certification . . . and is for a drug for which a first applicant has submitted an [ANDA] containing such a certification, the [ANDA] shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug ***(including the commercial marketing of the listed [i.e., brand] drug)*** by any first applicant.

21 U.S.C. § 355(j)(5)(B)(iv)(I) (emphasis added). Congress thereby confirmed that the sale of a brand generic is legally and functionally equivalent to the sale of an ANDA generic drug with respect to the Generic Exclusivity Period.

PERMITTING THE SALE OF BRAND GENERICS IS DIRECTLY CONTRARY TO THE CONGRESSIONAL PURPOSE IN PROVIDING THE GENERIC EXCLUSIVITY PERIOD.

49. The sale of a brand generic before the expiration the Generic Exclusivity Period and at or about the time the first Paragraph IV filer launches its ANDA generic deprives the first filer of the exclusivity that it rightly deserves. Under the FDA's erroneous ruling, the brand company could launch or license numerous brand generics on the first day of the Generic Exclusivity Period. The FDA's improper interpretation permits the brand company to produce a

market structure that is indistinguishable from that in which multiple generic companies, by way of Paragraph III certifications, market and sell their generic drugs upon the expiration of applicable brand-drug patents with no marketing exclusivity whatsoever.

50. The launch or licensing by the brand company of numerous brand generics, which is expressly permitted by the FDA Decision, would eliminate *entirely* the Generic Exclusivity Period and the accompanying incentives by which Congress intended to encourage the filing of Paragraph IV certifications instead of Paragraph III certifications. Contrary to judicial mandate and established agency policy, the FDA Decision thereby permits brand companies to control entirely whether, and to what extent, the first Paragraph IV ANDA filer receives the benefit of the Generic Exclusivity Period expressly provided by the FDCA Exclusivity Provision.

51. The sale of a brand generic before the expiration of the Generic Exclusivity Period also improperly allows the brand company, or other seller of the brand generic, to obtain a portion of the exclusivity benefit intended for the first Paragraph IV filer. Under the FDA Decision, the brand generic is permitted to proceed directly to market while subsequently filed ANDA applicants must await the expiration of the Generic Exclusivity Period.

52. The brand company's seizure of the first filer's benefits from the Generic Exclusivity Period is particularly unlawful and inequitable given that those benefits are the first filer's reward for stopping the brand company from reaping unwarranted monopoly profits through the assertion of an inapplicable, invalid, or unenforceable patent. By poaching some or all of the first filer's reward, the brand company will both take what is rightfully the first filer's

and discourage other generic companies from vindicating the public interest through additional Paragraph IV certifications.

53. Prohibiting the sale of brand generics before the expiration of the Generic Exclusivity Period is not inconsistent with the language of the FDCA Exclusivity Provision. The FDCA Exclusivity Provision does not authorize, explicitly or implicitly, the sale of brand generics prior to the expiration of the Generic Exclusivity Period.

54. In connection with the MMA amendment process, Congress was confronted with the question whether the FDCA Exclusivity Provision applies to the sale of brand generics with respect to the *commencement* of the Generic Exclusivity Period. Congress answered that question affirmatively by including a specific reference to brand generics in the MMA amendment. The applicability of the FDCA Exclusivity Provision to brand generics is now at issue with respect to their sale *during* the Generic Exclusivity Period. Teva proposes the same affirmative answer that Congress adopted in the MMA amendment. The FDA's negative answer ignores congressional intent and thwarts the purpose of the FDCA Exclusivity Provision.

BRAND COMPANIES UNDERMINE THE VALUE OF THE GENERIC EXCLUSIVITY PERIOD BY SELLING BRAND DRUGS AS GENERIC DRUGS THAT QUALIFY FOR GENERIC SUBSTITUTION.

55. Brand companies sell brand drugs as generic drugs by replacing the product and company names on the exterior of the brand drug with only the generic name of the drug and the name of a generic subsidiary or of a generic distributor so as to mimic the labeling used by generic companies. Brand companies also cause their generic drugs to be listed in industry pricing compendia so that the generic drugs qualify for Generic Substitution (as

defined below) under federal and state laws and under the industry practices of drug purchasers, dispensers and reimbursers.

GENERIC DRUGS ARE SUBSTITUTED QUICKLY AND WIDELY FOR EQUIVALENT BRAND DRUGS.

56. For commercial purposes, "generic drugs" are products that contain the same active ingredient as a referenced or corresponding brand drug and that are sold in a manner that qualifies for substitution by dispensing pharmacists (or other qualified dispensers) for the corresponding brand drug, pursuant to state law, federal law, and/or industry practice, unless the prescribing physician expressly prohibits such substitution.

57. A generic drug: (a) has the same active chemical ingredient of the same strength, quantity, and dosage form as does the corresponding brand drug; (b) 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 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 drug as reported by pricing compendia such as First Data Bank's PRICE ALERT.

58. 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 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 product with the corresponding generic drug ("Mandatory Generic Substitution"). For example, Massachusetts requires such Mandatory Generic Substitution. MASS. GEN. LAWS ch. 112, § 12D (2004).

59. 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 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 product with the corresponding generic drug ("State Listing-Based Generic Substitution"). Illinois is an example of a state providing for such permissive substitution to be made from the state's list of interchangeable drugs. 410 ILL. COMP. STAT. 620/3.14 (2004) and 225 ILL. COMP. STAT. 85/25 (2004).

60. 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 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 drug with the corresponding generic drug ("Permissive Generic Substitution"). California is one such state. CAL. BUSINESS AND PROFESSIONS CODE § 4073 (West 2004).

61. 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 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 ("Medicaid Generic Substitution".) New York is an example of a state with Medicaid Generic Substitution. N.Y. SOC. SERV. § 365-a (Consol. 2004).

62. Private insurers, third-party payers, healthcare plans, and managed care entities will require, or encourage through economic incentives, the substitution of generic

drugs for corresponding brand drugs in the absence of a direction from the physician not to do so ("Industry Generic Substitution").

63. 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 drug may be reduced because of inclusion of the generic drug product in the formulary.

64. Mandatory Generic Substitution, State Listing-Based Generic Substitution, Permissive Generic Substitution, Medicaid Generic Substitution, and Industry Generic Substitution are collectively referred to herein as "Generic Substitution." Generic Substitution occurs quickly and broadly upon the introduction of a new generic drug. For example, IMS Health reports that, on average, generic drugs account for nearly 80% of new prescriptions of the corresponding drug molecule thirteen weeks after the introduction of a new generic drug.

65. A brand generic and an ANDA generic equally can qualify for Generic Substitution and are otherwise functionally equivalent for all commercial purposes.

66. 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.

67. Manufacturers and distributors of generic drugs submit information to data banks that specify that a subject drug: (a) has the same active chemical ingredients of the same

strength, quantity, and dosage form as the corresponding brand drug; (b) is bioequivalent to or the same as a brand drug (either as approved by the FDA through the ANDA process or by marketing the brand drug, approved through the NDA process, as a generic drug); and (c) has an SWP or AWP that is materially (*i.e.*, approximately 10% or more) lower than the AWP for the brand drug.

68. Upon receipt of the information specified in the immediately preceding paragraph, data banks list the subject drug as a drug that is bioequivalent to or the same as, and a lower cost alternative to, the brand drug. The subject drug 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 subject drug is so listed, it is treated by dispensers and purchasers as a generic drug that qualifies for Generic Substitution.

BRAND COMPANIES DEVALUE THE GENERIC EXCLUSIVITY PERIOD BY SELLING BRAND DRUGS AS GENERIC DRUGS THAT QUALIFY FOR GENERIC SUBSTITUTION.

69. Brand companies advise data banks that their brand generics are equivalent to and interchangeable with their brand 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 drugs. Based upon such representations, the data banks list the brand generics as equivalent to, interchangeable with, and a lower cost alternative to, the corresponding brand drugs. The brand generics are thereby substituted for the brand drugs pursuant to Generic Substitution.

70. Brand generics compete with, and take substantial sales from, ANDA generics before the expiration of the applicable Generic Exclusivity Period by means of Generic Substitution. Brand generics thereby intrude upon, and misappropriate, the first filer's rightful and exclusive interest in the Generic Exclusivity Period. As a result, brand generics diminish

the expected return of generic companies from the expense and risk associated with expeditiously developing, submitting, and defending Paragraph IV certifications.

71. The relief that Teva seeks would not restrict brand companies from offering low-priced pharmaceuticals to the public or undermine the more general purposes of the Hatch Waxman Amendments. Brand companies would remain free to sell their brand drugs *at any price to any customer*, though by means other than Generic Substitution, prior to the expiration of an applicable Generic Exclusivity Period. Brand companies would also remain free to offer brand generics in the absence, or following the expiration, of an applicable Generic Exclusivity Period.

THE FDA HAS FAILED TO PROTECT THE GENERIC EXCLUSIVITY PERIOD FROM BRAND GENERICS.

72. The FDA Decision denied two Citizen Petitions, one filed by Teva and the other by Mylan Pharmaceuticals Inc., which requested that the FDA take regulatory action to prohibit the unlawful marketing and sale of brand generics until the expiration of an applicable Generic Exclusivity Period. The FDA summarized its decision as follows:

> Not only does FDA lack authority to justify delaying the marketing of authorized generics solely to protect 180-day exclusivity, the Agency does not believe their marketing should be delayed in this manner, as this marketing appears to promote competition in the pharmaceutical marketplace, in furtherance of a fundamental objective of the Hatch-Waxman amendments.

FDA Decision, at 2.

73. The FDA Decision was arbitrary, capricious, an abuse of agency discretion, and/or contrary to law in its statement that the FDA lacks authority to delay the marketing of brand generics until the expiration of an applicable Generic Exclusivity Period.

74. In fact, and contrary to the FDA Decision, the FDA has broad authority to make rules and regulations, and does make rules and regulations, "for the efficient enforcement"

of the FDCA. 21 U.S.C. § 371; 21 C.F.R. § 5.10. Similar authority to promulgate regulations "necessary for the administration" of the Act, including the sale of brand generic drugs approved pursuant to NDAs, has been specifically granted under the Hatch-Waxman Amendments. *See* 21 U.S.C. § 355, *et seq.* & note, Pub. L. No. 98-417, § 105, 98 Stat, 1585, 1597 (1984). *See also* 21 U.S.C. § 356a; 21 C.F.R. § 314.70 (authorizing FDA to regulate manufacturing changes).

75. The FDA Decision was arbitrary, capricious, an abuse of agency discretion, and/or contrary to law in its statement that the marketing of brand generics should not be delayed until the expiration of the applicable Generic Exclusivity Period because such marketing "promote[s] competition in the pharmaceutical marketplace" in furtherance of "a fundamental objective of the Hatch Waxman amendments." FDA Decision, at 12.

76. The FDA and the federal courts have established that the FDA must interpret and implement the FDCA Exclusivity Provision to "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 (nifedipine), Docket No. 00P-1446 (Feb. 6, 2001), at 5 (citing *Mylan Pharm. v. Henney*, 94 F. Supp. 2d 36, 54 (D.D.C. 2000)). The FDA Decision directly contravenes that principle.

77. The FDA and courts adopt a statutory construction favorable to those for whom a statutory benefit is chiefly intended. The FDA has expressly acknowledged that the FDCA Exclusivity Provision is intended to benefit the first Paragraph IV filer and has construed the FDCA Exclusivity Provision favorably to such first filers. FDA Citizen Petition Response (gabapentin), Docket No. 2000P-0227, at 6-7 (citing *Mova Pharm. Corp. v. Shalala*, 140 F.3d

1060, 1074-75 (D.C. Cir. 1998)). The FDA Decision harms such first filers and directly contravenes the foregoing principle.

78. The FDA established a policy to treat brand generics as the legal and functional equivalents of generic drugs approved through the ANDA process with respect to the interpretation and application of the FDCA Exclusivity Provision. The FDA Decision directly contravenes that principle.

79. The FDA has refused to adopt an interpretation of the FDCA Exclusivity Provision in which "the value of 180-day exclusivity would be significantly reduced and, in some cases, could be eliminated." FDA Citizen Petition Response (gabapentin), Docket No. 2000P-0227, at 12 (footnote omitted). Contrary to that agency policy, the FDA Decision adopts an interpretation of the FDCA Exclusivity Provision that will "significantly reduce[] and, in some cases, . . . eliminate[]" the "value of 180-day exclusivity."

80. The FDA similarly must examine the practical effect of the challenged action on the intended purposes and goals of the FDCA Exclusivity Provision. The practical effect of a brand company's marketing and sale of brand generics prior to the expiration of the Generic Exclusivity Period is the reduction or elimination of the Generic Exclusivity Period, the congressionally mandated incentive for generic companies to police and challenge brand-drug patents as inapplicable, invalid, or unenforceable. As a result, the FDA's Decision alters an Act of Congress and, contrary to the ANDA certification process, permits brand companies to eliminate any difference in the market structure that the first Paragraph IV filer and Paragraph III applicants face.

81. The FDA has made no findings and has developed no factual or evidentiary record on which to base its conclusion that the marketing of brand generics before

the expiration of an applicable Generic Exclusivity Period promotes the purpose of the FDCA Exclusivity Provision, 21 U.S.C. § 355(j)(5)(B)(iv). The record before the FDA on the Teva Citizen Petition is to the contrary and precludes any such conclusion.

82. The FDA has made no findings, has developed no factual or evidentiary record, and has no expertise on which to base its conclusion that the marketing of brand generics before the expiration of an applicable Generic Exclusivity Period promotes competition in the pharmaceutical marketplace. The record before the FDA on the Teva Citizen Petition is to the contrary and precludes any such conclusion.

83. The FDA Decision constitutes final agency action that is arbitrary, capricious, an abuse of agency discretion, and/or contrary to law insofar as it failed to prohibit the sale of brand generics before the expiration of any applicable Generic Exclusivity Period.

CLAIM FOR RELIEF
FOR JUDICIAL REVIEW, DECLARATORY JUDGMENT, AND INJUNCTIVE RELIEF

84. Teva repeats and realleges Paragraphs 1 through 83 as though fully set forth herein.

85. Teva asserts this claim for declaratory judgment pursuant to 28 U.S.C. § 2201, *et seq.* and 5 U.S.C. § 701, *et seq.*

86. A justiciable controversy exists between the parties hereto as to whether the FDA Decision is arbitrary, capricious, an abuse of agency discretion, and/or contrary to law.

87. Teva is an interested party within the meaning of 28 U.S.C. § 2201(a).

88. Teva requests, and is entitled to, a judicial determination and declaration that the FDA Decision is arbitrary, capricious, an abuse of agency discretion, and contrary to law.

89. Teva requests, and is entitled to, an order

(a) setting aside the FDA Decision;

(b) directing the FDA to withdraw the FDA Decision;

(c) directing the FDA to prohibit the sale of brand generics prior to the expiration of any applicable Generic Exclusivity Period; and

(d) remanding the matter to the FDA to determine the appropriate form of agency action to prohibit such sale of brand generics.

WHEREFORE, by reason of the foregoing allegations, Teva Pharmaceuticals USA, Inc. respectfully demands that the Court enter judgment against Defendants and in favor of Plaintiff, that the Court grant the relief requested in the Claim for Relief set forth above, and that the Court order such other, further, and different relief as the Court may deem just, proper, and equitable.

Dated: August 20, 2004

Respectfully submitted,

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