UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, Inc.
1090 Horsham Road
North Wales, PA 19454

Plaintiff,

v.

MICHAEL O. LEAVITT, in his official capacity as Secretary of Health and Human Services,
200 Independence Ave., S.W.
Washington, DC 20204;

ANDREW C. VON ESCHENBACH, M.D., in his official capacity as Commissioner of Food and Drugs,
200 C Street, S.W.
Washington, DC 20204;

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

Defendants.

Case No. _____

TEVA PHARMACEUTICAL USA, INC.'S COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Teva Pharmaceuticals USA, Inc. ("Teva") brings this complaint for declaratory and injunctive relief against Defendants Michael O. Leavitt, in his official capacity as Secretary of Health and Human Services, Andrew C. von Eschenbach, in his official capacity as Commissioner of Food and Drugs, and the United States Food and Drug Administration (collectively "FDA"). In support thereof, Teva states the following:

NATURE OF THE ACTION

1. Teva brings this suit in response to FDA's refusal to relist U.S. Patent No. 5,158,952 ("the '952 patent") in the Agency's official register of drug-related patents, *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book"), and award Teva the 180-day period of marketing exclusivity to which it is entitled under the Hatch-Waxman amendments to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 *et seq.* ("Hatch-Waxman").

2. Teva was the first manufacturer to submit an abbreviated new drug application ("ANDA") containing a "Paragraph IV" certification for a generic version of Janssen Pharmaceutica's brand-name drug Risperdal® in tablet form. Risperidone is the active ingredient in Risperdal® tablets.

3. At the time Teva filed its ANDA, FDA's official Orange Book (and the then-current official monthly supplement to the Orange Book) listed two patents as claiming Risperdal® tablets: the '952 patent and U.S. Patent No. 4,804,663 ("the '663 patent"). As the first ANDA filer to make a Paragraph IV certification to the '952 patent, Teva earned the right to market its generic risperidone tablets for 180 days prior to any other generic competitor. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Congress instituted this 180-day marketing exclusivity period in order to encourage generic manufacturers to challenge drug patents and thereby increase competition in the pharmaceutical industry.

4. Despite the fact that Teva invested significant resources to identify a vulnerable patent and develop a non-infringing generic risperidone product, and then subjected itself to a patent infringement claim by filing its Paragraph IV certification to the '952 patent, *see* 35 U.S.C. § 271(e); despite the fact that the '952 patent continued to appear in FDA's 2001 Orange

Book; and despite the fact that FDA's then-current Cumulative Supplement to the Orange Book did not reflect any change to the official patent-listing information for Risperdal® at the time Teva submitted its ANDA to FDA, FDA asserted Teva that it had "delisted" the '952 patent prior to the submission of Teva's ANDA and informed Teva that it thus would not accept Teva's ANDA for filing unless Teva removed its Paragraph IV certification to the '952 patent from its ANDA.

5. As it has with several other improperly delisted patents, Teva petitioned FDA to restore the '952 patent to the Orange Book, honor Teva's Paragraph IV certification to that patent, and award Teva 180-day exclusivity. *See* Citizen Petition No. 2007P-0316 (filed Aug. 8, 2007).(attached as Ex.1). FDA has refused to do so, effectively nullifying Teva's 180-day exclusivity period.

6. FDA's refusal to relist the '952 patent and award Teva its 180-day exclusivity period violates the plain language of the Hatch-Waxman Act and flouts the D.C. Circuit's binding decision in *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006), which held that FDA may not effectuate the delisting of a patent and thereby deny the first generic Paragraph IV applicant 180-day marketing exclusivity after the generic manufacturer relies on the Orange Book's official patent listings to challenge a listed patent. In addition, FDA's refusal to restore the '952 patent to the Orange Book and award Teva 180-day exclusivity conflicts with the Agency's own regulations and the Orange Book itself. As such, FDA's actions here contravene the Administrative Procedure Act ("APA"), because they fail to embody principles of reasoned agency decision-making and are contrary to settled agency practice, arbitrary, capricious, and otherwise contrary to law. *See* 5 U.S.C. § 706.

7. As a result, Teva seeks immediate declaratory and injunctive relief from this Court to (1) set aside FDA's decision as contrary to law, an abuse of discretion, and arbitrary and capricious; (2) declare unlawful the delisting of the '952 patent prior to the expiration of Teva's exclusivity; (3) restore Teva's Paragraph IV certification to the '952 patent *nunc pro tunc*; and (4) enjoin FDA from approving any ANDA for generic risperidone tablets filed after Teva's ANDA for generic risperidone tablets pending the conclusion of Teva's exclusivity period for generic risperidone tablets.

PARTIES

8. Plaintiff Teva is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva is a wholly-owned, indirect subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), a global pharmaceutical company organized under the laws of Israel with its principal place of business in Israel. Teva distributes the finished pharmaceutical products of Teva Ltd. in the United States and is an industry leader in the development, manufacture, and marketing of generic pharmaceutical in the United States.

9. Defendant Michael O. Leavitt is the Secretary of Health and Human Services ("HHS") and is the official charged by law with administering the Hatch-Waxman Act. Secretary Leavitt is sued in his official capacity. He maintains offices at 200 Independence Ave., S.W., Washington, DC 20204.

10. Defendant Andrew C. von Eschenbach, the Commissioner of the FDA, has the delegated authority to administer the drug approval provisions of the Hatch-Waxman Act. Commissioner von Eschenbach is sued in his official capacity. He maintains offices at 200 C St., S.W., Washington, DC 20204, and 5600 Fishers Lane, Rockville, MD 20857.

11. Defendant FDA is the agency within HHS charged with overseeing, *inter alia,* the human drug approval process, including the portions of that process controlled by the Hatch-Waxman Act.

JURISDICTION AND VENUE

12. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331. This action arises under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), *codified at, inter alia*, 21 U.S.C. § 355; the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 555, 702, and 706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

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

FACTUAL ALLEGATIONS

The Relevant Statutory Framework

14. The approval of generic drugs is governed by the Hatch-Waxman Act. Although the Act has subsequently been amended by the Medicare Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173 § 1101(c)(1), and the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. 110-85, 121 Stat. 823 (2007), the substantive aspects of this case relating to the listing and delisting of Orange Book patents and Teva's entitlement to 180-day exclusivity are governed by the pre-2003 version of the FDCA. *See* 21 U.S.C. §§ 301, *et seq.* (2002).[1]

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[1] Unless otherwise noted, all references to the FDCA and FDA's implementing regulations are to the pre-2003 version of the statute.

15. Generic drugs contain the same active ingredients, and provide the same therapeutic value, as branded drugs. They are, however, generally sold at a lower price to consumers, private insurers, and public insurers. Congress enacted the Hatch-Waxman Act to increase the availability of generic drugs by expediting the process of bringing them to market, and thereby significantly reduce the cost that the public pays for pharmaceuticals. *See* 21 U.S.C. § 355.

16. In order to expedite the approval process for generic drugs, the Hatch-Waxman Act permits generic companies to obtain approval of their generic products so long as they can show them to be bioequivalent to products that the FDA has already deemed safe and effective. Before marketing a generic drug, the manufacturer must submit an abbreviated new drug application, or ANDA, to the FDA. 21 U.S.C. § 355(j). The ANDA establishes the bioequivalence and therapeutic value of the generic product as compared with the branded product. 21 U.S.C. § 355(j)(2)(A). So long as bioequivalence can be established, a generic drug manufacturer need not repeat the safety and efficacy studies that were conducted on the branded version of the drug and included as part of the brand manufacturer's new drug application ("NDA"). *Id.*

17. In the ANDA, the generic manufacturer also must address, and provide a certification concerning, each patent listed in the official Orange Book by the NDA-holder as claiming the drug. The Orange Book, which FDA printed annually during the relevant time period and updated monthly with printed Cumulative Supplements, is intended to reflect the most current information regarding which patents claim a particular branded drug. A generic applicant must certify as to each patent listed in the most recent official Orange Book as claiming

the branded drug. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1350 (Fed. Cir. 2003); *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 31 (D.D.C. 2006).

18. Among other things, generic applicants are allowed certify that a 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. Such a certification is known as a Paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). A Paragraph IV certification signals the generic manufacturer's intent to market its product prior to the expiration of one or more patents listed as claiming the branded drug.

19. By design, the Hatch-Waxman Act encourages generic drug companies to challenge pharmaceutical patents by filing Paragraph IV certifications in order to bring generic products to market faster. The first generic drug company to file a Paragraph IV certification, and thereby challenge a patent, generally bears costs of research and development, legal costs to identify potentially vulnerable patents, as well as the litigation costs that may come from protracted patent infringement litigation. If this generic drug company succeeds in being the first to successfully file a Paragraph IV ANDA, however, the benefits of those investments may ultimately be shared with other generic drug companies, who can benefit from the substantial investments that the first filer has made.

20. Therefore, in order to encourage generic drug companies to bear the costs and litigation risks associated with being the first filer of a Paragraph IV ANDA certification, the Hatch-Waxman Act provides that the first filer will receive the exclusive right to market the pertinent generic product for 180 days following the challenge. 21 U.S.C. § 355(j)(5)(B)(iv). The Act prohibits the FDA from approving the ANDAs of the subsequent filers until the first applicant's 180-day exclusivity period has elapsed.

21. The 180-day exclusivity period runs from the earlier of the date on which the first-filing generic drug company first commercially markets the generic drug or "the date of a decision of a court in an action … holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(II).

22. The FDA may not approve the applications of subsequent ANDA filers until the 180-day exclusivity period expires. Once the 180 day exclusivity period ends, however, other generic manufacturers may be approved to enter the product market.

23. Depriving the first filer of the benefits of exclusivity therefore undermines the incentive system that Congress carefully constructed in the Hatch-Waxman Act to ensure that generic drugs are brought to market as early as possible for the benefit of consumers.

Risperidone Proceedings

24. Risperidone is an atypical antipsychotic medication. Janssen holds the approved NDA for risperidone tablets, No. 20-272, which it commercially markets under the brand name Risperdal®.

25. At the time it filed its NDA for Risperdal® tablets, Janssen caused FDA to list the '663 and '952 patents in the official Orange Book. *See* Orange Book (21st ed. 2001) ("2001 Orange Book"), at ADA 57 (attached as Ex. 2). The '952 patent is set to expire on October 27, 2009. The '663 patent expired on December 29, 2007, but Janssen received an additional six months of exclusivity for studying the effectiveness of Risperdal® in pediatric populations. *See* 21 U.S.C. § 355a. Janssen's period of "pediatric exclusivity" expires June 29, 2008.

26. As of August 2001, both the official Orange Book and the then-current Cumulative Supplement to the Orange Book listed both the '663 and '952 patents as claiming

Risperdal®, *see* 2001 Orange Book at ADA 57; Orange Book 21st ed. Cumulative Supplement 8 (Aug. 2001) at A-14 (attached as Ex. 3).

27. On August 28, 2001, Teva submitted an original ANDA, No. 76-228, seeking approval to market generic risperidone tablets in 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg strengths. In accordance with 21 U.S.C. § 355(j)(2)(A)(vii), Teva's ANDA contained a certification as to each patent listed in the official Orange Book as claiming Risperdal® tablets. Teva thus filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III certification") as to the '663 patent, asserting that Teva would not seek to market its generic risperidone tablets until that patent expired, and a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") as to the '952 patent, asserting that the patent was invalid or would not be infringed by Teva's generic risperidone tablets.

28. Teva was the first generic manufacturer to file a Paragraph IV certification as to the '952 patent. Under the plain terms of the FDCA, Teva was thus entitled to 180 days of market exclusivity to commence upon the first commercial marketing of its generic risperidone products, or a court decision declaring that the '952 patent was invalid or not infringed by Teva's generic risperidone products.

29. On October 12, 2001, FDA for the first time notified Teva that it had "delisted" the '952 patent from the Orange Book. FDA made this statement despite the fact that the official Orange Book continued to list the '952 patent as claiming Risperdal®, *see* 2001 Orange Book at ADA 57, and despite the fact that the then-current Cumulative Supplement reflected no changes to the official patent-listing information for Risperdal®. *See* Orange Book 21st ed. Cumulative Supplement 10 (Oct. 2001) at A-19 (attached as Ex. 4).

30. FDA nevertheless informed Teva that it would not accept Teva's ANDA for filing unless Teva modified its patent certification to reflect FDA's assertion that the '952 patent was no longer listed as claiming Risperdal®. *See* FDA Letter Decision (dated Feb. 26, 2008) at 5 (attached as Ex. 5). Thus, despite the fact that the official Orange Book, and then-current Cumulative Supplements, continued to indicate that the '952 patent claimed Risperdal®, Teva was forced to follow the agency's directive and amend its ANDA.

31. In November 2001 and December 2001, FDA's official monthly supplements to the Orange Book continued to reflect that no changes had been made to the Risperdal® patent-listing information, and thus that the '952 patent continued to be listed as claiming Risperdal® tablets. *See* Orange Book 21st ed. Cumulative Supplement 11 (Nov. 2001) at A-21 (attached as Ex. 6). Orange Book 21st ed. Cumulative Supplement 12 (Dec. 2001) at XA-24 (attached as Ex. 7).

32. In January 2002, FDA released a revised version of the Orange Book, which for the first time indicated the delisting of the '952 patent. *See* Orange Book (22nd ed. 2002), at ADA 64-65 (attached as Ex.8).

33. In November 2006, the D.C. Circuit ruled that the plain text of the FDCA prevented FDA from effectuating the delisting of a patent following the submission of a paragraph IV certification as to that patent. *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006). The court struck down FDA's practice because it "change[d] the incentive structure adopted by Congress," by "depriv[ing] the generic applicant of a period of marketing exclusivity" after the generic manufacturer had expended significant resources in developing a non-infringing generic substitute and undertaken the risk of infringing the patent by filing a Paragraph IV certification. *Id.* at 126. The D.C. Circuit thus held that FDA's approach to

delisting contravened the plain meaning of the FDCA, and invalidated FDA's practice under *Chevron* step one. *Id.*

34. Following the D.C. Circuit's decision, Teva undertook a comprehensive review of its portfolio of pending ANDAs to determine whether FDA's unlawful delisting practices had deprived Teva of its entitlement to 180-day generic exclusivity for any other product. Teva then sought to regain its exclusivity on each of the drug products affected by FDA's unlawful delisting.

35. On August 3, 2007, Teva submitted Citizen Petition No. 2007P-0316 (the "Petition") requesting that FDA relist the '952 patent in the Orange Book for Risperdal® tablets; confirm that Teva's right to 180-day exclusivity with regard to its ANDA had not been affected by FDA's erroneous delisting of the '952 patent; and refrain from granting final approval to any other ANDAs for 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg risperidone tablets until Teva's 180-day exclusivity period expires. *See* Citizen Petition.

36. FDA denied the Citizen Petition on February 26, 2008.

37. Janssen's pediatric exclusivity for Risperdal® is set to expire on June 29, 2008. Unless this Court grants the relief sought by Teva, FDA will on that date be free to grant final approval to any ANDA for generic risperidone tablets, thus permitting other generic manufacturers to market their generic risperidone products and depriving Teva of the 180-day exclusivity period to which it is entitled under the Hatch-Waxman Act.

FIRST CAUSE OF ACTION
(Violation of the FDCA and the APA)

38. FDA's refusal to relist the '952 patent and grant Teva 180-day exclusivity for its generic risperidone tablets violates the plain language of the Hatch-Waxman Act, the D.C. Circuit's decision in *Ranbaxy*, FDA's own regulations, and the Orange Book itself. FDA's

decision is thus in excess of its statutory authority, arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, in violation of 5 U.S.C. § 706.

39. FDA's refusal to relist the '952 patent and grant Teva 180-day exclusivity for generic risperidone tablets constitutes final agency action that is subject to judicial review. Teva has exhausted every available administrative avenue and has no adequate remedy at law.

40. Neither Defendants nor any other entity will suffer cognizable harm if the relief requested herein is granted, and the public interest will be served by such relief.

41. Teva will suffer substantial and irreparable harm absent the granting of the requested relief, in the form of lost sales and decreased market share that can never be recovered.

42. FDA's unlawful conduct has caused, is causing, and will continue to cause substantial harm to Teva unless and until the FDA's actions are declared unlawful pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, and the Hatch-Waxman Act; this Court requires FDA to relist the '952 patent in the Orange Book; and this Court orders FDA to award Teva its 180-day exclusivity period for generic risperidone tablets.

PRAYER FOR RELIEF

WHEREFORE, Teva prays that this Court:

A. Vacate FDA's action as contrary to law, an abuse of discretion, and arbitrary and capricious;

B. Enter an injunction compelling FDA to relist the '952 patent as claiming Risperdal® tablets in the official Orange Book and restore Teva's Paragraph IV certification to the '952 patent *nunc pro tunc*;

C. Declare that Teva is entitled to 180-day exclusivity on its ANDA No. 76-228 for generic risperidone tablets in 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg strengths;

D. Enjoin FDA from granting final approval to any other ANDA for generic risperidone tablets until the expiration of Teva's 180-day exclusivity period; and

E. Provide such further relief as the Court may deem just and proper.

Dated: March 4, 2008

Respectfully submitted,

By: _____

Jay P. Lefkowitz, P.C. (D.C. Bar No. 449280)
Michael D. Shumsky (D.C. Bar No. 495078)
Gregory L. Skidmore (D.C. Bar No. 974024)
KIRKLAND & ELLIS LLP
655 15th Street N.W., Suite 1200
Washington, D.C. 20005
(202) 879-5000
(202) 879-5200 fax

Counsel for Teva Pharmaceuticals USA, Inc.