IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ROXANE LABORATORIES, INC., 1809 Wilson Road Columbus, Ohio 43228 Plaintiff,	)	
v.	)	Civil Action No. ___-_____
UNITED STATES FOOD AND DRUG ADMINISTRATION, 1007 Switzer Building 330 C St., S.W. Washington, D.C. 20204; and	)	
MARGARET HAMBURG, M.D., in her official Capacity as Commissioner of Food and Drugs, 1007 Switzer Building 330 C St., S.W. Washington, D.C., 20204, Defendants.	)	

COMPLAINT FOR DECLARATORY JUDGMENT
AND INJUNCTIVE RELIEF

Plaintiff Roxane Laboratories, Inc. ("Roxane") brings this action against the Defendant United States Food and Drug Administration and Defendant Margaret A. Hamburg, M.D., in her official capacity as Commissioner of the FDA (collectively "FDA"). In support thereof, Plaintiff states the following:

Nature of the Action

1. This is an action challenging the FDA's imminent grant of 180-day generic drug exclusivity for generic versions of the brand-name hypertension drugs Hyzaar® (losartan HCTZ tablets) and Cozaar® (losartan potassium tablets) (hereafter, "generic losartan").

2. To the best of Roxane's knowledge, there is no obstacle standing in the way of FDA's final approval of Roxane's generic losartan ANDAs on April 6, 2010, the date upon which all patent and statutory exclusivities for the brand company versions of Hyzaar® and Cozaar® have expired, other than an award of generic exclusivity to another ANDA applicant for generic losartan, which would delay Roxane's approval for 180 days.

3. Roxane is prepared to launch its generic losartan product on April 6, 2010.

4. FDA has stated that it intends to award 180 days of market exclusivity with respect to generic losartan, having ruled on March 26, 2010, that the company otherwise entitled to exclusivity has not forfeited such exclusivity due to the expiration of U.S. Patent No. 5,608,075 ("the '075 patent").

5. FDA has stated that this generic exclusivity will be awarded and will begin on April 6, 2010, on which date FDA is expected to approve the first ANDA for generic losartan and to award exclusivity to the applicant that it deems to have qualified for that exclusivity.

6. Teva Pharmaceuticals U.S.A. ("Teva") has claimed that it is the company entitled to generic exclusivity for generic losartan.

7. The effect of this imminent FDA approval and award of exclusivity is that the agency will not approve Roxane's generic losartan product until the expiration of the exclusivity period, which will be at least 180 days from April 6, 2010 – that is, at least until October 6, 2010

– and Roxane will not be able to sell or market its generic losartan product until that time, even though it would otherwise be prepared to launch its generic losartan product on April 6, 2010.

8. As shown below, however, FDA's decision to grant any 180-day exclusivity for generic losartan violates the Federal Food, Drug and Cosmetic Act ("FFDCA") and is arbitrary and capricious, an abuse of discretion and otherwise not in accordance with law, in violation of the Administrative Procedure Act ("APA"), because the expiration of the '075 makes exclusivity unavailable as a matter of law.

Parties

9. Plaintiff Roxane is a corporation organized and existing under the laws of Nevada, with its principal place of business in Ohio.

10. Defendant FDA is a federal administrative agency within the Department of Health and Human Services, with responsibility pursuant to FFDCA for regulating drugs marketed in the United States.

11. Defendant Margaret A. Hamburg, M.D. is the Commissioner of Food and Drugs and is responsible for supervising the activities of FDA. Defendant Hamburg is being sued in her official capacity.

Jurisdiction and Venue

12. 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 ("Hatch-Waxman Amendments" or "Hatch-Waxman") and the Medicare Modernization Act of 2003 ("MMA"), *codified at, inter alia,* 21 U.S.C. § 355; the APA, 5 U.S.C. §§ 551-59, 701, *et seq.*; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1337 (commerce), and 28 U.S.C. § 1361 (relief in the nature of mandamus).

14. Venue is proper in this Court under 28 U.S.C. § 1391(e) because this is a civil action in which Defendants are officers of the United States acting in their official capacities and both of the Defendants maintain offices and conduct business in this judicial district.

Statutory Background

15. Congress enacted the Hatch-Waxman Amendments to the FFDCA to increase the availability of low-cost generic drugs. A generic drug is a version of a brand name drug that contains the same active ingredient as the brand name drug and typically sells at a lower cost than the brand name drug.

16. Under Hatch-Waxman, an applicant that wishes to market a generic drug must submit an abbreviated new drug application ("ANDA") that shows that its product is equivalent to an already approved brand name product, known as the "RLD" or "reference listed drug." 21 U.S.C. § 355(j)(2)(A).

17. Under Hatch-Waxman, brand companies are required to submit patents claiming an approved drug to FDA for inclusion in the agency's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

18. Under Hatch-Waxman, a generic applicant must identify as part of its ANDA any patents listed in the Orange Book for the RLD and must certify as to each such patent (I) that no patent information has been filed with the FDA ("Paragraph I certification"); (II) that the claimed patent has expired ("Paragraph II certification"); (III) the date on which the filed patent will expire ("Paragraph III certification"); or (IV) that the filed patent is invalid, unenforceable, or

will not be infringed by the generic drug for which approval is sought ("Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV); *see also* 21 CFR § 314.94(a)(12).

19. As an incentive for generic applicants to challenge invalid, unenforceable, or uninfringed brand company patents, Hatch-Waxman awards 180 days of exclusivity to the generic applicant that is first to file with, or as an amendment to, its ANDA a Paragraph IV certification with respect to any patent that the brand company asserts claims the RLD. 21 U.S.C. § 355 (j)(5)(B)(iv). The exclusivity recipient is known as the "first filer."

20. FDA regulations state that upon the expiration of a listed patent that is the basis for an ANDA applicant's Paragraph IV certification, the ANDA applicant must change its certification from a Paragraph IV certification to a different certification – a Paragraph II certification, which certifies that the brand company patent has expired (and therefore, for that separate reason, does not block approval of the ANDA). 21 C.F.R. § 314.94(a)(12)(viii)(C)(1).

21. In 2003, Congress amended Hatch-Waxman in the MMA to provide for the forfeiture of generic exclusivity on the occurrence of any of several "forfeiture events." One such forfeiture event is the expiration of the Orange Book-listed brand-company patent that supported the first-filer's Paragraph IV certification. In other words, under the FFDCA if the Paragraph IV certification giving rise to an ANDA applicant's claim of exclusivity expires before the ANDA is approved, the first filer loses its right to exclusivity based on that certification. 21 U.S.C. § 355(j)(5)(D)(i)(VI).

Factual Allegations

22. Merck & Co., Inc. ("Merck") holds the FDA approvals for brand versions of losartan, which it markets under the names Hyzaar® (losartan HCTZ tablets) and Cozaar® (losartan potassium tablets).

23. Merck caused three patents to be listed in FDA's Orange Book in connection with its brand losartan products: U.S. Patent Nos. 5,138,069 ("the '069 patent"), 5,153,197 ("the '197 patent"), and the '075 patent (*supra* ¶ 4).

24. The '069 patent expired on February 11, 2010.

25. The '197 patent expired on October 6, 2009, but Merck is currently enjoying an additional statutory pediatric exclusivity award of six months under that patent which expires on April 6, 2010.

26. The '075 patent was originally scheduled to expire in 2014. In March 2005, Merck requested that FDA delist the '075 from the Orange Book. In response to Merck's request, the FDA delisted the '075 patent (but did not make it publicly known until April 18, 2008). On March 4, 2009, the '075 patent expired because of Merck's failure to pay maintenance fees. Merck confirmed the March 4, 2009, expiration of the '075 patent on March 12, 2010, and FDA subsequently changed the Orange Book reference to the '075 patent to reflect that the patent has expired.

27. Roxane filed its ANDA for generic losartan potassium tablets on December 22, 2004, and for losartan potassium/HCTZ tablets (50mg/12.5mg and 100mg/25mg) on May 31, 2005.

28. When it filed its ANDAs for generic losartan, Roxane included Paragraph IV certifications to the '075 patent. On March 22, 2010, Roxane changed these certifications to Paragraph II certifications in light of the expiration of the '075 patent and the fact that FDA had changed the expiration dates in the Orange Book.

29. Roxane received tentative FDA approval of its ANDA for losartan potassium tablets on May 25, 2006, and tentative approval of its ANDA for losartan potassium/HCTZ

tablets on August 16, 2006. In this case, tentative approval means that Roxane's application is ready for approval and that FDA anticipates approval after the patents to which Roxane has submitted Paragraph II certifications have expired and after the applicable statutory deadline for patents to which Roxane has submitted Paragraph IV certifications have expired. As stated above, there are no longer any Paragraph IV certifications in Roxane's ANDAs for generic losartan.

30. Teva has asserted that it too has filed an ANDA for generic losartin.

31. Teva also claims that it is entitled to 180-day generic exclusivity for its generic losartan ANDA, under which exclusivity it would be allowed to market and sell its product free from other generic competition for 180 days, because it claims it was the first to file an ANDA for generic losartan containing a Paragraph IV certification to the '075 patent.

32. Because Merck's pediatric exclusivity under the '197 patent expires on April 6, 2010, it is anticipated that on that date, FDA will be in a position to approve, and will approve, ANDAs for generic losartan.

33. To the best of Roxane's knowledge, there is no obstacle standing in the way of FDA's final approval of Roxane's generic losartan ANDAs other than an award of generic exclusivity to another ANDA applicant for generic losartan.

34. Roxane is prepared to launch its generic losartan products on April 6, 2010.

35. In a letter to all ANDA applicants for generic losartan dated March 26, 2010, FDA indicated that a generic company otherwise entitled to 180-day exclusivity for generic losartan will not be found to have lost that exclusivity by virtue of the expiration of the '075 patent. In that letter, FDA stated that a determination of no exclusivity (which would have allowed Roxane to market generic losartan on April 6, 2010) was consistent with the "plain

language" of Hatch-Waxman, comported with the statute's "text and goals," and "provide[d] the most reasonable way of administering the statute," but that the reasoning of the D.C. Circuit decision in *Teva Pharms., U.S.A., Inc. v. Sebelius*, No. 09-5281 (D.C. Cir. Mar. 2, 2010) supported a different result, even though that court did not have before it, and did not address, the issue of how patent expiration affects eligibility for the 180-day exclusivity .

36. FDA has stated that it is prepared to award 180-day exclusivity for generic losartan on April 6, 2010, at which time it can first approve ANDAs for generic losartan. On information and belief, the recipient of the exclusivity will launch its generic losartan product immediately upon FDA's approval of its ANDA and award of the exclusivity, on April 6, 2010.

37. Such an award would block Roxane from receiving FDA approval and from marketing its generic losartan products until October 2010 -- 180 days after the launch of generic losartan by the exclusivity recipient, which Roxane expects to occur, and Teva has indicated will occur if it receives esclusivity, on April 6, 2010.

Count I

38. Plaintiff realleges and incorporates herein paragraphs 1 through 37 of this Complaint.

39. Because the '075 patent has expired, all Paragraph IV certifications to that patent must as a matter of law be changed to Paragraph II certifications, and under the FDA's regulations there is no effective Paragraph IV certification on which to base an award of generic exclusivity to any ANDA applicant for generic losartan. 21 C.F.R. § 314.94(a)(12)(viii)(C)(1).

40. Consequently, FDA's decision that an award of 180-day exclusivity for generic losartan is not affected by the expiration of the '075 patent, and its expected refusal on that basis to approve Roxane's ANDA for generic losartan on April 6, 2010, on that basis, violates FDA's

regulations and the FFDCA, 21 U.S.C. § 321 *et. seq.*, and is arbitrary, capricious, an abuse of discretion or not otherwise in accordance with law, and therefore in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A) and (C).

Count II

41. Plaintiff realleges and incorporates herein paragraphs 1 through 37 of this Complaint.

42. Under Hatch-Waxman, as amended in 2003, the expiration of the '075 patent is a "forfeiture event" and operates to strip any generic losartan applicant that would otherwise be eligible for exclusivity of that exclusivity. 21 U.S.C. § 355(j)(5)(D)(i)(VI).

43. Consequently, FDA's decision that an award of 180-day exclusivity for generic losartan is not affected by the expiration of the '075 patent, and its expected refusal on that basis to approve Roxane's ANDA for generic losartan on April 6, 2010, on that basis, violates the FFDCA, 21 U.S.C. § 321 *et. seq.*, and is arbitrary, capricious, an abuse of discretion or not otherwise in accordance with law, and therefore in violation of the Administrative Procedure Act, 5 U.S.C. §§ 706(2)(A) and (C).

Prayer for Relief

WHEREFORE, Roxane respectfully requests that this Court enter judgment:

1. declaring that FDA may not award generic exclusivity to any ANDA applicant for generic losartan;

2. declaring that FDA must approve all otherwise eligible ANDAs for generic losartan, including Roxane's, on the expiration of Merck's pediatric exclusivity period under the '197 patent on April 6, 2010.

3. enjoining FDA from awarding generic exclusivity to any ANDA applicant for generic losartan;

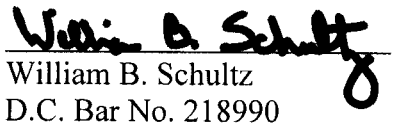
4. ordering FDA to approve Roxane's ANDAs for generic losartan upon the expiration of Merck's pediatric exclusivity period under the '197 patent on April 6, 2010;

5. awarding plaintiffs their costs and reasonable attorney's fees to the extent authorized by law; and

6. awarding plaintiffs such other and further relief as this Court may deem just.

Dated: March 30, 2010

Respectfully submitted,



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