IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COBALT LABORATORIES INC. 24840 South Tamiami Trail Bonita Springs, Florida 34134, and COBALT PHARMACEUTICALS, INC. 6500 Kitimat Road Mississauga, Ontario, Canada, L5N 2B8 Plaintiffs, v. FOOD AND DRUG ADMINISTRATION 5600 Fishers Lane Rockville, Maryland 20857, MICHAEL O. LEAVITT Secretary of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201, and ANDREW C. VON ESCHENBACH, M.D. Commissioner of Food and Drugs 5600 Fishers Lane Rockville, Maryland 20857, Defendants.	)	Case No.

COMPLAINT

Plaintiffs Cobalt Laboratories Inc. and Cobalt Pharmaceuticals, Inc. (collectively, "Cobalt"), for their Complaint against the United States Food and Drug Administration; Michael O. Leavitt, in his official capacity as the Secretary of Health and Human Services; and Andrew C. von Eschenbach, M.D., in his official capacity as the Commissioner of the United States Food and Drug Administration (collectively, "FDA"), allege as follows:

Nature Of The Action

1. Cobalt respectfully brings this action for declaratory and injunctive relief to enjoin FDA's unlawful forfeiture of Cobalt's Congressionally-mandated 180-day marketing exclusivity for a generic version of the prescription drug product acarbose, and to require FDA to withdraw the approval of, and refrain from approving, any subsequent applications for generic acarbose until the natural expiration of Cobalt's 180-day exclusivity.

2. Cobalt indisputably submitted the first abbreviated new drug application ("ANDA") for a generic version of acarbose tablets—a prescription drug approved for the treatment of type 2 diabetes and currently marketed by Bayer Pharmaceuticals under the brand-name Precose®. Cobalt's ANDA contains a so-called "paragraph IV certification" to the only Orange Book-listed patent: U.S. Patent No. 4,904,769 ("the '769 patent"). As such, Cobalt is the "first applicant" entitled by statute to the critical 180-day generic marketing exclusivity that Congress created as a reward and incentive for undertaking the risk and expense of launching the first challenge to a brand company's listed patent. Cobalt's exclusivity remains intact and has not been triggered or otherwise forfeited. Thus, FDA cannot lawfully approve any other paragraph IV ANDA for generic acarbose.

3. On May 7, 2008, however, FDA determined that Cobalt purportedly had "forfeited" its exclusivity and, on the same date, the Agency approved a subsequent ANDA applicant in violation of the exclusivity to which Cobalt is statutorily entitled. Such agency action is arbitrary, capricious, an abuse of discretion, and contrary to law, in violation of both the Federal Food, Drug, and Cosmetic Act ("FFDCA") and the Administrative Procedure Act ("APA").

4. To prevent devastating and irreparable harm and the loss of its exclusivity, Cobalt is entitled to immediate injunctive relief from this Court enjoining FDA from forfeiting Cobalt's exclusivity or approving subsequent acarbose applicants.

Parties

5. Plaintiff Cobalt Laboratories Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 24840 South Tamiami Trail, Bonita Springs, Florida 34134. Cobalt Labs markets, sells and distributes quality generic medicines.

6. Cobalt Pharmaceuticals Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 6500 Kitimat Road, Mississauga, Ontario, Canada, L5N 2B8. Cobalt Pharms develops and manufactures quality generic medicines.

7. Defendant Michael O. Leavitt 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 Leavitt maintains offices at 200 Independence Avenue, S.W., Washington, D.C. 20201.

8. Defendant Andrew C. von Eschenbach, M.D. is the Commissioner and senior official of FDA. He is sued in his official capacity. Commissioner von Eschenbach has been delegated the authority to administer the drug approval provisions of the FFDCA through FDA. He maintains offices at 5600 Fishers Lane, Rockville, Maryland 20857.

9. Defendant FDA is an agency within the Public Health Service and is a part of HHS. FDA maintains offices at 5600 Fishers Lane, Rockville, Maryland 20857.

Jurisdiction and Venue

10. 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. § 271) ("Hatch-Waxman") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1102(b)(1), Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) ("MMA"); the APA, 5 U.S.C. § 551 *et seq.*; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1361.

11. This Court has personal jurisdiction over the federal Defendants because they are either located and/or conduct substantial business in, or have regular and systematic contact with, this District. Venue is proper in this District under 28 U.S.C. § 1391(e).

12. FDA's agency action constitutes an actual controversy, for which Cobalt is entitled to review and relief under 5 U.S.C. §§ 702, 704-706. Cobalt has standing to maintain this action, pursuant to the APA, as a legal entity that has been adversely affected by final agency action.

13. There exists an actual, substantial, and continuing controversy between the parties regarding FDA's application of the FFDCA, and in particular the MMA's exclusivity forfeiture provisions. This Court may declare the rights and legal relations of the parties under 28 U.S.C. §§ 2201, 2202.

Background

I. Statutory Framework For Approval Of New And Generic Drugs.

A. New Drugs—NDAs And Patent Listing Requirements.

14. A company seeking to sell an original, new drug must file a new drug application ("NDA") containing 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 use of the drug for which approval is requested. *See* 21 U.S.C. § 355(b)(1).

15. An NDA applicant also must submit information to FDA with respect to any patent that "claims the drug for which the applicant submitted the application or which claims a method of using such drug . . . ." 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2). After approving the NDA, FDA publishes this patent information in the "Orange Book." *See id.*; 21 C.F.R. § 314.53(e).

B. Generic Drugs—ANDAs And Patent Certifications.

16. A company seeking FDA approval to market a generic version of a previously-approved NDA drug may file an ANDA without repeating the comprehensive and extensive human clinical studies conducted for the NDA drug. A generic ANDA applicant must, however, establish that its proposed product is bioequivalent to the already-approved NDA drug and, with certain exceptions, that it has the same active ingredient, dosage form, dosage strength, route of administration, and labeling as the approved NDA drug. *See* 21 U.S.C. § 355(j)(2)(A).

17. An ANDA also must include one of four certifications with respect to each Orange Book-listed patent for the NDA drug: (I) that there is no patent information; (II) that the listed patent has expired; (III) that the ANDA applicant will not market its generic drug until after the expiration of the listed patent; or (IV) that the listed patent is invalid and/or will not be infringed by the proposed generic drug, a so-called "paragraph IV certification." *See* 21 U.S.C. § 355(j)(2)(A)(vii).

18. With certain exceptions not applicable here, an ANDA applicant seeking FDA approval to market its generic drug before expiration of the Orange Book-listed patent must submit a paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B). Submitting a paragraph IV ANDA has two important consequences.

19. First, submitting a paragraph IV certification constitutes a technical act of infringement under 35 U.S.C. § 271(e)(2)(A), thereby vesting the district courts with subject matter jurisdiction to adjudicate whether the proposed generic drug infringes the subject patent before the drug has actually been marketed.

20. Second, the first applicant to submit an ANDA for a drug product containing a paragraph IV certification for any listed patent is entitled to market its generic product free from generic competition for 180 days. *See* 21 U.S.C. § 355(j)(5)(B)(iv). This statutory benefit and period of marketing exclusivity is commonly known as the "180-day exclusivity" period.

C. 180-Day Exclusivity.

21. Congress created the 180-day exclusivity period to "encourage generic drug makers to incur the potentially substantial litigation costs associated with challenging pioneer drug makers' patents." *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 33 (D.D.C. 2000).

22. The exclusivity provision operates by preventing FDA from approving subsequent generic competitors during the exclusivity period, and reads:

> (iv) ***180-DAY EXCLUSIVITY PERIOD***-
>
> (I) EFFECTIVENESS OF APPLICATION – Subject to subparagraph (D), if the application contains a [paragraph IV certification] . . . and is for a drug for which a ***first applicant*** has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including commercial marketing of the listed drug) by any first applicant.

21 U.S.C. § 355(j)(5)(B)(iv) (emphasis added). The statute further defines "180-day exclusivity period" and "first applicant" as follows:

> (aa) ***180-DAY EXCLUSIVITY PERIOD*** – The term '180-day exclusivity period' means the 180-day period ending on the day before the date on which an application submitted by an applicant other than the first applicant could become effective under this clause.

> (bb) ***FIRST APPLICANT*** – As used in this subsection, the term 'first applicant' means an applicant that, on the first day on which a substantially complete application containing a [paragraph IV certification] is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [paragraph IV certification] for the drug.

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

23. The statute therefore endows the first applicant to file a paragraph IV ANDA with a 180-day period free from other generic competition that does not begin to run until first commercial marketing by the first applicant. The "purpose of the exclusivity incentive and the entire ANDA regime is to make available more low cost generic drugs." *Apotex, Inc. v. Shalala*, 53 F. Supp. 2d 454, 461 (D.D.C. 1999).

24. In addition to triggering by first commercial marketing, the 180-day exclusivity period can be "forfeited" in certain limited circumstances if a so-called "forfeiture event" occurs. *See* 21 U.S.C. §§ 355(j)(5)(D)(i) and (ii).

II. Factual Background.

A. Bayer's NDA No. 20-482 For Precose® (Acarbose) Tablets.

25. The reference listed, or brand-name, drug at issue is Bayer's prescription diabetes medication, Precose® Tablets 25 mg, 50 mg, and 100 mg—which is known generically as "acarbose."

26. Bayer submitted information to FDA on one patent for listing in the Orange Book in connection with Precose® (Acarbose) Tablets: the '769 patent, which does not expire until September 6, 2009. By virtue of that submission, information for the '769 patent was listed, and to date remains listed, in FDA's Orange Book, and has not been de-listed or withdrawn.

B. Cobalt Submits The *First* Paragraph IV ANDA For Acarbose Tablets And Secures 180-Day Exclusivity, Which Has Not Been Triggered Or Otherwise Forfeited.

27. On January 10, 2005, Cobalt submitted the first ANDA for Acarbose Tablets in 25 mg, 50 mg, and 100 mg strengths that included, and has lawfully maintained, a paragraph IV certification to the listed '769 patent. Cobalt was and is the "first applicant" to submit a Paragraph IV ANDA for acarbose tablets and thus is statutorily entitled to the 180-day generic marketing exclusivity for all strengths of acarbose tablets. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I).

28. Cobalt's 180-day exclusivity has not yet expired. Nor has any so-called "forfeiture event" occurred with respect to Cobalt's exclusivity. Because Cobalt's exclusivity remains intact and has not been forfeited, FDA cannot lawfully approve any subsequent paragraph IV ANDA for acarbose tablets.

C. FDA Requests Comments Regarding The Forfeiture Of Cobalt's Exclusivity.

29. Despite the fact that Cobalt's exclusivity has not expired or otherwise been forfeited, on or about September 24, 2007, FDA informed Cobalt that its exclusivity could be forfeited and that subsequent applicants could be eligible for approval.

30. On or about September 26, 2007, FDA posted a public letter on its web site seeking comments on whether Cobalt has forfeited its exclusivity and whether subsequent acarbose ANDAs are eligible for final approval. FDA did so despite the fact that Cobalt's 180-day exclusivity remains intact and has not been forfeited.

31. On October 17, 2007, Cobalt submitted detailed comments to FDA explaining that Cobalt's Congressionally-mandated exclusivity has not been forfeited, and that approval of all subsequent acarbose ANDAs must be delayed by such exclusivity, which remains intact. With those comments, to prevent devastating and irreparable harm and the loss of its exclusivity,

Cobalt submitted an emergency petition for stay of agency action requesting that FDA stay all subsequent acarbose approvals until the expiration of Cobalt exclusivity, or at the very least until all issues regarding Cobalt's exclusivity are resolved and subject to any necessary judicial review. Cobalt supplemented those comments on November 6, 2007.

32. On May 7, 2008, after the close of business and without prior notice to Cobalt, FDA issued an administrative decision concluding that Cobalt has forfeited its 180-day exclusivity for acarbose tablets. FDA also issued a separate decision that same day denying Cobalt's request for a stay of approval for all subsequent applicants.

33. That same day, FDA also approved the acarbose ANDA of Roxane Laboratories, Inc., a subsequent applicant, in violation of Cobalt's Congressionally-mandated 180-day exclusivity. Upon information and belief, Roxane has commercially launched its acarbose products in all three strengths. FDA's unlawful agency action is causing Cobalt devastating and irreparable harm by destroying the 180-day exclusivity to which it is statutorily entitled. FDA issued this approval decision in violation of Cobalt's exclusivity after the close of business and without any advance warning or notice, and before Cobalt could seek meaningful judicial review.

34. Cobalt has exhausted its administrative remedies. Any additional effort to seek administrative relief from the Agency would result in irreparable prejudice and harm to Cobalt.

Count I
(Violation of the FFDCA and APA)

35. Cobalt repeats and realleges the foregoing paragraphs as though fully alleged herein.

36. Cobalt is the "first applicant" entitled by statute to the critical 180-day generic marketing exclusivity that Congress created as a reward and incentive for undertaking the risk

and expense of launching the first challenge to a brand company's listed patent. Cobalt's exclusivity blocks the approval of all subsequent acarbose ANDAs until at least 180 days after first commercial marketing by Cobalt.

37. Cobalt has not forfeited its exclusivity, which remains intact.

38. FDA has no lawful basis or authority under the FFDCA to forfeit Cobalt's 180-day exclusivity for acarbose tablets, or otherwise to approve any subsequent ANDA for generic acarbose tablets until the natural expiration of Cobalt's exclusivity.

39. FDA's decision to forfeit Cobalt's exclusivity and to approve a subsequent acarbose ANDA is arbitrary, capricious, an abuse of discretion, and not in accordance with the law within the meaning of 5 U.S.C. § 706(2)(A), in excess of statutory authority within the meaning of 5 U.S.C. § 706(2)(C), and in violation of the FFDCA.

40. Cobalt is suffering, and will continue to suffer, devastating and irreparable harm from the unlawful forfeiture of its exclusivity and the approval of subsequent acarbose ANDAs before the natural expiration of Cobalt's exclusivity.

41. Cobalt has no adequate remedy at law.

Count II
(Relief Pending Review, 5 U.S.C. § 705)

42. Cobalt repeats and realleges the foregoing paragraphs as though fully alleged herein.

43. Under 5 U.S.C. § 705, to prevent devastating and irreparable harm to Cobalt and its exclusivity, Cobalt is entitled to immediate interim injunctive relief staying any and all approvals of, or other agency action on, subsequent acarbose ANDAs pending resolution of this matter on the merits, including an appeal to the D.C. Circuit.

Request for Relief

WHEREFORE, Cobalt respectfully prays that this Honorable Court enter judgment in its favor and against the federal Defendants, as follows:

(a) Entry of judgment declaring that FDA's decision forfeiting Cobalt's 180-day exclusivity for generic acarbose tablets is arbitrary, capricious, an abuse of discretion, and contrary to law;

(b) Entry of judgment declaring that any FDA decision or agency action approving any subsequent ANDA for generic acarbose tablets, before the natural expiration of Cobalt's 180-day exclusivity, is arbitrary, capricious, an abuse of discretion, and contrary to law;

(c) Entry of an injunction enjoining FDA from forfeiting Cobalt's 180-day exclusivity for generic acarbose tablets;

(d) Entry of an injunction requiring FDA to immediately stay or withdraw approval of any acarbose ANDA, except Cobalt's ANDA, to which the Agency has granted final approval, including the approval granted to Roxane on May 7, 2008;

(e) Entry of an injunction requiring FDA to immediately order a recall of any and all acarbose products shipped and/or sold by Roxane in violation of Cobalt's exclusivity;

(f) Entry of an injunction enjoining FDA from approving any subsequent ANDA for generic acarbose tablets until the natural expiration of Cobalt's 180-day exclusivity;

(g) In the alternative, entry of an interim injunction staying all approvals of subsequent acarbose ANDAs, and staying any approvals of subsequent applicants already granted (including Roxane), pending resolution of this action, including, if necessary, an appeal to the D.C. Circuit;

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

(i) Such other and further relief as the Honorable Court deems just and proper.

Dated: May 8, 2008.

Respectfully submitted,

COBALT LABORATORIES INC. and
COBALT PHARMACEUTICALS, INC.

By: _____
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