IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

COBALT PHARMACEUTICALS INC. and COBALT LABORATORIES INC., Plaintiffs, v. BAYER AKTIENGESELLSCHAFT and BAYER PHARMACEUTICALS CORP., Defendants.	07CV5875 JUDGE CASTILLO MAG. JUDGE VALDEZ

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc. (collectively "Cobalt"), for their complaint against Bayer Aktiengesellschaft ("Bayer AG") and Bayer Pharmaceuticals Corporation (collectively, "Bayer"), allege as follows:

Nature Of The Action

1. Cobalt brings—and is entitled by statute to maintain—this action for declaratory judgment of patent non-infringement and invalidity under, *inter alia*, the Declaratory Judgment Act and 21 U.S.C. § 355(j)(5)(C)(i), which is part of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA").

2. This action arises out of, *inter alia*, Cobalt's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Bayer's brand-name drug Precose®, known generically as acarbose.

3. Bayer purports to own U.S. Patent No. 4,904,769 ("the '769 patent"), a true and accurate copy of which is attached hereto as Exhibit A. Upon submission by Bayer, the '769 patent was listed in FDA's list of *Approved Drug Products with Therapeutic Equivalents Evaluations*, more commonly known as the "Orange Book." As a consequence of such listing, Bayer has affirmatively represented to the world that the '769 patent claims the approved drug, Precose®, or a method of using that drug, and that a claim for patent infringement could reasonably be asserted against any generic ANDA applicant, including Cobalt, attempting to market a generic acarbose product before patent expiration. Moreover, Bayer has enforced and continues to vigorously enforce its intellectual property rights against other generic pharmaceutical companies.

4. Cobalt has designed around the '769 patent with its proposed generic acarbose ANDA product and so, as required by statute, has certified to FDA that Cobalt's product will not infringe the '769 patent and has further notified Bayer of the legal and factual bases for that certification. Cobalt's submission of an ANDA containing a so-called "paragraph IV" certification to the '769 patent constitutes an artificial act of patent infringement. This regulatory submission created the necessary case or controversy and subject matter jurisdiction for Bayer to sue Cobalt for patent infringement. It likewise created the necessary case or controversy for Cobalt to file and maintain an action for declaratory judgment of patent non-infringement and invalidity.

5. There is an actual, substantial, and continuing justiciable case and controversy between Cobalt and Bayer regarding infringement and validity of the '769 patent, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

6. Cobalt is entitled by law to bring and maintain this action for declaratory judgment of patent non-infringement and invalidity under the Declaratory Judgment Act and the MMA where, as here, Bayer did not sue Cobalt within 45 days of receipt of Cobalt's notice of paragraph IV certification to the '769 patent, and Cobalt has offered Bayer an Offer of Confidential Access to Cobalt's ANDA for generic acarbose tablets.

7. Cobalt is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Cobalt's proposed generic acarbose product does not and will not infringe the '769 patent and that such patent is invalid.

Parties

8. Plaintiff Cobalt Pharmaceuticals Inc. is a corporation organized and existing under the laws of Canada and having a place of business at 6500 Kitimat Road, Mississauga, Ontario, Canada L5N 2B8.

9. Plaintiff Cobalt Laboratories Inc. is a corporation organized and existing under the laws of Delaware and having a place of business at 24840 South Tamiami Trail, Bonita Springs, FL 34134.

10. On information and belief, Defendant Bayer AG is a corporation organized under the laws of the Federal Republic of Germany, with a place of business at D-51368 Leverkusen, Germany. On information and belief, Defendant Bayer AG, through its various agents, affiliates, representatives, subsidiaries and/or alter egos, develops, manufactures, and sells pharmaceutical products throughout the world, including in the United States and in this District. On information and belief, Bayer AG also allegedly owns United States patents that purport to cover pharmaceutical products sold in the United States and in this District, and from which Bayer AG derives substantial revenue exceeding $5 billion in the United States alone in 2006.

11. On information and belief, Defendant Bayer Pharmaceuticals Corporation is a corporation organized under the laws of the State of Indiana, with a place of business at 400 Morgan Lane, West Haven, Connecticut 06516. On information and belief, Bayer Pharmaceuticals Corporation is the agent, affiliate, representative, subsidiary and/or alter ego of, and/or acts in concert with, Bayer AG, for purposes of marketing, distributing, and selling patented pharmaceutical products within the United States and in this District on behalf of Bayer AG, and from which Bayer AG generates billions of dollars in yearly revenue.

Jurisdiction and Venue

12. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)).

13. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq.*; under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because it is an actual controversy concerning the infringement and validity of the patent-in-suit; and under the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)), because Congress has directed that district courts maintain and exercise jurisdiction in such cases.

14. There exists a substantial and continuing actual, justiciable case or controversy between Cobalt and Bayer regarding infringement and validity of the '769 patent.

15. This Court can and should declare the rights and legal relations of the parties regarding non-infringement of the '769 patent pursuant to, *inter alia*, the Declaratory Judgment

Act, 28 U.S.C. §§ 2201 and 2202, and the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)).

16. Cobalt has the statutory right to bring and maintain this declaratory judgment action under 21 U.S.C. § 355(j)(5)(C)(i). This Court can and should exercise its declaratory judgment jurisdiction over Cobalt's claims pursuant to 35 U.S.C. § 271(e)(5).

17. This Court has personal jurisdiction over Bayer AG and Bayer Pharmaceuticals Corporation because both conduct substantial business in, and have regular and systematic contact with, this District.

18. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

Background

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

19. The approval of new and generic drugs is governed by the applicable provisions of 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) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and subsequently amended by the MMA (codified as amended in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271).

A. New drugs and patent listing requirements.

20. Before marketing an original new drug in the United States, the FFDCA, as amended by Hatch-Waxman and the MMA, requires that an applicant submit, and that FDA approve, a new drug application ("NDA") under 21 U.S.C. § 355(b). The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling relating to the use of the drug for which approval is requested.

21. An NDA applicant is required, within its NDA, to submit information (*e.g.*, the patent number and expiration date) regarding each patent that claims the drug or method of using the drug that is the subject of the NDA and for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product. 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2).

22. FDA publishes patent information submitted by an NDA-holder in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").

23. By filing an NDA and submitting a patent for listing in the Orange Book, the NDA-holder/patent owner, by law, necessarily maintains that the listed patent claims the approved NDA drug, or a method of using that drug, and that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, use, or sale of the drug, and, in particular, against any company that is seeking to make a generic bioequivalent of the NDA drug before patent expiration.

24. Thus, the NDA-holder/patent owner necessarily puts all prospective generic ANDA applicants on notice that a suit for infringement can and will be asserted against any ANDA applicant that attempts to seek approval for and market a generic version of the NDA drug before patent expiration.

B. Generic drugs and patent certification requirements.

25. The FFDCA, as amended by Hatch-Waxman and the MMA, provides for an ANDA approval process that enables generic pharmaceutical manufacturers to obtain regulatory approval of lower-cost generic versions of previously approved brand-name or NDA drugs on an expedited basis, thereby benefiting the U.S. health-care system and American consumers. The

ANDA process is a streamlined version of the full NDA procedure and results in a generic drug product that is normally marketed under the chemical name of the active drug ingredient.

26. An applicant may invoke this procedure for expedited FDA approval of a generic version of an already-approved NDA drug by submitting an ANDA to FDA under 21 U.S.C. § 355(j).

27. Instead of repeating the clinical studies of safety and efficacy conducted for the previously-approved NDA drug, a generic applicant submitting an ANDA is required to establish, among other details, that its proposed generic product is bioequivalent to the already-approved NDA drug (*i.e.*, has no significant difference in rate and extent of absorption) and that it has the same active ingredient, dosage form, dosage strength, route of administration, and labeling (with certain exceptions) as the approved NDA drug. 21 U.S.C. § 355(j)(2)(A).

28. An ANDA applicant also is required to address each patent listed in the Orange Book in connection with the approved NDA drug. In particular, Hatch-Waxman requires an ANDA applicant to submit one of four types of patent certifications: (I) that the NDA-holder/patent owner has not submitted any patent information to FDA; (II) that the listed patent has expired; (III) that the patent will expire on a future date, and that the generic applicant will not market its product until after the expiration date; or, (IV) that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted (commonly referred to as a "paragraph IV certification"). 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(IV). This last type of certification, a paragraph IV certification, signifies that the generic ANDA applicant intends to market its generic product prior to expiration of the subject patent. Such certification constitutes an act of patent infringement. 35 U.S.C. § 271(e).

29. When an ANDA applicant submits a paragraph IV certification for a listed patent, the generic applicant must notify the NDA-holder/patent owner that it has filed an ANDA to obtain regulatory approval of a generic version of the NDA drug, and that the ANDA contains a paragraph IV certification for a listed patent (indicating that the ANDA applicant intends to market its generic product before expiration of the listed patent). 21 U.S.C. § 355(j)(2)(B). This notice must contain a detailed statement of the factual and legal bases for the ANDA applicant's certification that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic applicant's generic drug product. 21 U.S.C. § 355(j)(2)(B)(iv).

30. The submission of a paragraph IV certification has two important consequences.

31. First, an applicant that is first to submit an ANDA containing a paragraph IV certification for a listed patent is entitled to 180 days of generic market exclusivity during which no other ANDA for that drug product will be approved. 21 U.S.C. § 355(j)(5)(B)(iv).

32. Second, the submission of a paragraph IV certification for a listed patent constitutes an act of infringement that creates the necessary case or controversy and subject matter jurisdiction to enable an NDA-holder/patent owner to file, and a district court to resolve, an action for patent infringement—before the generic drug is actually made, used, or sold—to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

33. The submission of a paragraph IV certification likewise creates the necessary case or controversy and subject matter jurisdiction for an ANDA applicant to file a declaratory judgment action against the NDA-holder/patent owner if the ANDA applicant is not sued within the applicable 45-day period, as set forth below.

34. Upon receiving notice of a paragraph IV certification for a listed patent submitted by an ANDA applicant, the NDA-holder/patent owner may file suit for infringement of the listed patent under 35 U.S.C. § 271(e)(2)(A) within 45 days of receiving such notification. Such a suit automatically delays FDA from issuing final approval of the ANDA for up to thirty (30) months. 21 U.S.C. § 355(j)(5)(B)(iii). An ANDA applicant is statutorily prohibited from seeking a declaratory judgment during the 45-day period in which the NDA-holder/patent owner may bring suit after receiving notification of the ANDA and paragraph IV certification. *Id.*

35. If the NDA-holder/patent owner does not file such a suit, the ANDA applicant can file and maintain a suit for declaratory judgment against the NDA-holder/patent owner to obtain patent certainty. Indeed, as explained below, Congress explicitly mandated that an ANDA-filer is entitled to maintain a declaratory judgment action when it is not sued. 21 U.S.C. § 355(j)(5)(C).

36. Congress enacted Hatch-Waxman and the ANDA approval process in order to expedite the marketing of lower-priced generic drug products. Congress intended that the generic manufacturing and marketing of a drug should be allowed as soon as it is determined that the particular generic drug does not violate patent rights.

II. Congress Explicitly Mandated That An ANDA-Filer May Bring And Maintain A Declaratory Judgment Action When The Brand Company Does Not Bring An Infringement Action.

37. On December 8, 2003, the MMA was signed into law. Title XI of the MMA, labeled "Access to Affordable Pharmaceuticals," amended provisions of the FFDCA and, in particular, Hatch-Waxman.

38. Under the MMA, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to institute and maintain an action for declaratory judgment against an

NDA-holder/patent owner if: (1) the 45-day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the NDA-holder/patent owner brought an action for infringement of the patent within the 45-day period; and (3) the notice of paragraph IV certification contains an Offer of Confidential Access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

39. Once these three conditions are met, the MMA specifically and unequivocally provides that an ANDA applicant "may, in accordance with section 2201 of Title 28 [of the United States Code] bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II).

40. An ANDA applicant may exercise its right to file and maintain a declaratory judgment action under the MMA regardless of whether or not the Offer of Confidential Access to Application is accepted.

41. The new declaratory judgment provision contained in the MMA, Section 1101 of the MMA, 117 Stat. 2066, 2454-2456, applies to all ANDAs pending on or after December 8, 2003, which includes these proceedings.

42. Congress' intent in amending 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5) was to extend to ANDA applicants, like Cobalt here, the right to file and maintain a declaratory judgment action for patent non-infringement and/or invalidity against an NDA-holder/patent owner, and grant the court subject matter jurisdiction in such an action.

III. The Patent-In-Suit.

43. On or about February 27, 1990, the U.S. Patent and Trademark Office ("PTO") issued the '769 patent, entitled "Highly Pure Acarbose," to Erich Rauenbusch.

44. Bayer purports and claims to own the '769 patent.

45. Bayer purports and claims to have the right to enforce the '769 patent.

IV. Bayer's Precose® (Acarbose).

46. Bayer is the holder of approved NDA No. 20-482 for acarbose tablets, which are sold under the brand name Precose®.

47. Precose® (acarbose) is indicated for, among other things, the treatment of hyperglycemia in patients afflicted with type-2 diabetes mellitus.

48. FDA approved Precose® in 1995. Today, Precose® remains the only acarbose tablet product on the market.

49. Bayer purports and claims to be the owner of the '769 patent, the term of which expires on or about September 6, 2009, according to FDA's Orange Book.

50. Bayer submitted information regarding the '769 patent to FDA for listing in the Orange Book. By virtue of that submission, FDA listed the '769 patent in the Orange Book in connection with Bayer's approved NDA for Precose® (acarbose) tablets.

51. By listing the '769 patent in the Orange Book, Bayer has affirmatively represented to the world, that the '769 patent claims Precose® (acarbose) tablets, or a method of using that drug, and that an infringement suit could reasonably be asserted against any generic ANDA applicant, including Cobalt, that attempts to seek approval for, and market, a generic version of Precose® before patent expiration.

52. The listing of the '769 patent in the Orange Book alone objectively creates the necessary case or controversy and subject matter jurisdiction for an ANDA-filer to file and maintain a declaratory judgment action if it is not sued by Bayer within the requisite 45-day period.

V. Cobalt's ANDA For Acarbose.

53. Cobalt has submitted an ANDA to FDA seeking approval to market a generic version of Precose® (acarbose) tablets in 25 mg, 50 mg, and 100 mg strengths for the treatment of hyperglycemia in individuals with type-2 diabetes mellitus.

54. Cobalt devoted considerable resources researching, developing, and testing its generic acarbose product, all toward compiling the information necessary to submit its ANDA for generic acarbose tablets.

55. Bayer submitted the '769 patent to FDA for listing in the Orange Book prior to the filing of Cobalt's ANDA for generic acarbose tablets. By law, Cobalt was required to include in its ANDA a certification to the '769 patent.

56. Cobalt ANDA, as originally filed, contains a paragraph IV certification to the '769 patent, stating that the '769 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Cobalt's generic acarbose tablets and/or that the '769 patent is invalid. This certification signified that Cobalt intends to market and commercialize its generic acarbose product prior to the expiration of the '769 patent.

57. Cobalt's ANDA is substantially complete and was accepted for filing by FDA.

58. Cobalt intends, and is prepared, to market its generic acarbose product before expiration of the '769 patent.

59. In accordance with 21 U.S.C. § 355(j)(2)(B), Cobalt provided Bayer with notice that it submitted ANDA and a paragraph IV certification to the '769 patent. This notice included a detailed statement setting forth the factual and legal bases why the '769 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Cobalt's generic acarbose tablets.

60. Upon receipt of Cobalt's notice of paragraph IV certification to the '769 patent, Bayer did not sue Cobalt within the 45-day period for instituting an infringement suit under 21 U.S.C. § 271(e).

VI. Cobalt's Offer Of Confidential Access To Application.

61. Cobalt—by letter and as required under 21 U.S.C. § 355(j)(5)(C)—extended to Bayer an Offer of Confidential Access to Application to access certain information in Cobalt's ANDA for acarbose tablets.

62. By providing this Offer of Confidential Access to Application, and because Bayer did not sue Cobalt within 45 days of receipt of Cobalt's notice of paragraph IV certification, Cobalt is statutorily entitled to file and maintain a declaratory judgment action against Bayer under 28 U.S.C. §§ 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C).

VII. Bayer's Attempt to Delist The '769 Patent From FDA's Orange Book.

63. On information and belief, Bayer has, without justification, attempted to remove the '769 patent from FDA's Orange Book, which removal could deprive Cobalt of any marketing exclusivity Cobalt may be entitled pursuant to the filing of its ANDA for generic acarbose tablets.

64. Bayer cannot lawfully remove the '769 patent from the Orange Book, *inter alia*, in light of marketing exclusivity that may attach to the filing of Cobalt's ANDA.

VIII. There Is A Substantial And Continuing Justiciable Controversy Between Cobalt And Bayer Regarding The '769 Patent.

65. By preparing and filing Cobalt's ANDA No. 77-532, Cobalt has substantially prepared to commercialize generic acarbose tablets in the United States. Cobalt is prepared to begin commercialization of its competing generic product upon issuance of final FDA approval.

66. By submitting its ANDA to commercialize generic acarbose tablets before the expiration of the '769 patent, as well as submitting a paragraph IV certification to said patent, Cobalt has committed an artificial act of patent infringement sufficient to create case or controversy jurisdiction pursuant to 35 U.S.C. § 271(e)(2) and Article III of the Constitution.

67. Bayer's listing of the '769 patent and Cobalt's paragraph IV certification to that patent satisfy Article III of the Constitution by creating the necessary case or controversy between Bayer and Cobalt regarding infringement of the '769 patent.

68. To avoid legal uncertainty, to protect its substantial investment, and to protect its anticipated future investments in its manufacturing process for generic acarbose tablets, Cobalt has initiated this action and is entitled to a declaration of the rights of the parties with respect to the '769 patent.

COUNT I
(Declaratory Judgment of Non-Infringement of the '769 Patent)

69. Cobalt repeats and incorporates by reference the allegations contained in paragraphs 1 through 68 of its Complaint as though fully set forth herein.

70. There is an actual, substantial, and continuing justiciable case or controversy between Cobalt and Bayer regarding infringement of the '769 patent.

71. The manufacture, use, sale, offer for sale, or importation of the acarbose tablets that are the subject of Cobalt's ANDA does not and will not infringe (either literally or under the doctrine of equivalents) any valid and enforceable claim of the '769 patent.

72. Cobalt is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the acarbose tablets that are the subject of Cobalt's ANDA does not and will not infringe (either literally or under the doctrine of equivalents) any valid and enforceable claim of the '769 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '769 Patent)

73. Cobalt repeats and incorporates by reference the allegations contained in paragraphs 1 through 72 of its Complaint as though fully set forth herein.

74. There is an actual, substantial, and continuing justiciable case or controversy between Cobalt and Bayer regarding the validity of the '769 patent.

75. The claims of the '769 patent are invalid for failure to satisfy one or more conditions for patentability under the patent laws.

76. Cobalt is entitled to a judicial declaration that the claims of the '769 patent are invalid.

COUNT III
(Declaratory Judgment Precluding the Delisting of the '769 Patent from FDA's Orange Book)

77. Cobalt repeats and incorporates by reference the allegations contained in paragraphs 1 through 76 of its Complaint as though fully set forth herein.

78. There exists an actual, substantial, and continuing justiciable case or controversy between Cobalt and Bayer regarding the listing of the '769 patent in FDA's Orange Book.

79. Pursuant to statute, Bayer duly submitted the '769 patent for listing in FDA's Orange Book, and certified to FDA that the '769 patent claims the drug (acarbose) or method of using the drug that is the subject of the NDA (acarbose) and for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged

in the manufacture, use, or sale of the drug product. 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2).

80. As a consequence of that listing, Cobalt undertook the risk and expense of challenging the '769 patent by submitting a paragraph IV certification to the '769 patent.

81. Because Cobalt was the first generic applicant to submit an ANDA for acarbose tablets with a paragraph IV certification to the '769 patent, Cobalt is entitled to the 180-day generic marketing exclusivity for acarbose tablets.

82. On in formation and belief, on or about April 16, 2007, Bayer purportedly requested that FDA "delist" the '769 patent as to Precose®.

83. Such delisting, if permitted, could deprive Cobalt of the 180-day exclusivity to which it is lawfully entitled under the FFDCA.

84. By law, Bayer is not permitted to delist the '769 patent because Cobalt has submitted a paragraph IV certification that entitles Cobalt to the 180-day exclusivity.

85. Cobalt is entitled to a judicial declaration that the Bayer's delisting request is improper and that Bayer may not remove the '769 patent from the Orange Book until after the natural expiration of Cobalt's 180-day exclusivity.

WHEREFORE, Cobalt respectfully prays for judgment in its favor and against Bayer Aktiengesellschaft and Bayer Pharmaceuticals Corporation as follows:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of the acarbose tablets that are the subject of Cobalt's ANDA does not and will not infringe (either literally or under the doctrine of equivalents) any valid, enforceable and unexpired claim of the '769 patent;

(b) Declaring that the claims of the '769 patent are invalid;

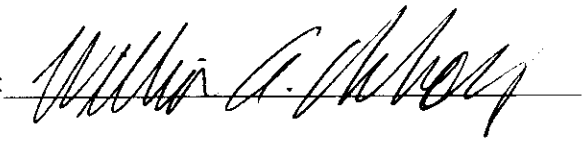
(c) Declaring that Bayer's "delisting" request for the '769 patent is improper and that Bayer may not remove the '769 patent from the Orange Book; and

(d) Awarding Cobalt such other and further relief as the Court may deem just and proper.

Dated: October 17, 2007.

Respectfully submitted,

COBALT PHARMACEUTICALS INC. and
COBALT LABORATORIES INC.

By: 

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