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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS CORPORATION and NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. COBALT LABORATORIES, INC. and COBALT PHARMACEUTICALS INC., Defendants.	Civil Action No. _____ **COMPLAINT**

Plaintiffs Novartis Corporation and Novartis Pharmaceuticals Corporation (collectively, "Novartis"), by their attorneys White & Case LLP and Gibbons P.C., for their Complaint against Defendants Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals Inc. (hereinafter, "Cobalt"), herein allege:

RELATED ACTION

A related action involving the same parties hereto, the same patent, but different dosage strengths of the same product, captioned *Novartis Corporation et al. v. Cobalt Laboratories, Inc. et al.*, Civil Action No. 08-3256 (HAA)(ES), was filed on June 27, 2008, and is currently pending before this Court ("Related Action"). A copy of the Complaint from that case is attached hereto as Exhibit A.

THE PARTIES

1. Plaintiff Novartis Corporation is a New York corporation having a principal place of business at 180 Park Avenue, Florham Park, New Jersey.

2. Plaintiff Novartis Pharmaceuticals Corporation is a Delaware corporation having a principal place of business at One Health Plaza, East Hanover, New Jersey.

3. On information and belief, Cobalt Laboratories, Inc. is a Delaware corporation having a principal place of business at 24840 S. Tamiami Trail, Ste. 1, Bonita Springs, FL 34134.

4. On information and belief, Cobalt Pharmaceuticals Inc. is a Canadian corporation having a principal place of business at 6500 Kitimat Road, Mississauga, Ontario, Canada L5N 2B8.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338.

6. On information and belief, Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals Inc. are in the business of making and selling generic drug products.

7. On information and belief, Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals Inc. conduct business in New Jersey and sell various drug products in the United States, including the State of New Jersey.

8. Cobalt Pharmaceuticals Inc. is the holder of approved Abbreviated New Drug Applications ("ANDA"), such as ANDA No. 76-685 for simvastatin, ANDA No. 76-818 for metformin hydrochloride, and ANDA No. 77-280 for glimepiride.

9. Cobalt Laboratories, Inc. is the holder of approved ANDAs, such as ANDA No. 77-532 for acarbose, ANDA No. 77-063 for albuterol sulfate/ipratropium bromide, ANDA No. 76-939 for pravastatin sodium and ANDA No. 76-549 for ramipril.

10. On information and belief, Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals Inc. have previously been sued in the United States District Court for the District of New Jersey.

11. On information and belief, Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals Inc. have submitted to the jurisdiction of the United States District Court for the District of New Jersey.

12. Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals Inc. submitted to the jurisdiction of the United States District Court for the District of New Jersey in *Novartis Corp. et al. v. Cobalt Labs, Inc. et al., Civil Action No. 08-3256 (D.N.J.) (HAA)(ES).*

13. On information and belief, Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals Inc. have availed themselves of the jurisdiction of the United States District Court for the District of New Jersey by asserting counterclaims in lawsuits filed in this Court.

14. Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals Inc. asserted counterclaims in *Novartis Corp. et al. v. Cobalt Labs, Inc. et al. Civil Action No. 08-3256 (D.N.J.) (HAA)(ES)*.

15. On information and belief, Cobalt Laboratories, Inc. is registered to do business in New Jersey as a foreign profit corporation, with business identification number 100961623.

16. On information and belief, Cobalt Laboratories, Inc. has appointed National Registered Agents, Inc. of Princeton, New Jersey, as its registered agent for the receipt of service of process.

17. On information and belief, Cobalt Pharmaceuticals Inc. designated Cobalt Laboratories, Inc. as its United States agent, and Cobalt Laboratories, Inc. acts as the agent of Cobalt Pharmaceuticals Inc.

18. Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals Inc. are subject to personal jurisdiction in this judicial district.

19. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The '802 Patent

20. On December 19, 2000, the United States Patent and Trademark Office (the "PTO") issued United States Patent No. 6,162,802 (the "'802 patent"), entitled "Synergistic Combination Therapy Using Benazepril and Amlodipine for the Treatment of Cardiovascular Disorders and Compositions Therefor." The '802 patent has been assigned to, and continues to be owned by, Novartis Corporation. The '802 patent will expire on December 19, 2017. A copy of the '802 patent is attached hereto as Exhibit B.

21. Novartis Corporation has exclusively licensed the '802 patent to Novartis Pharmaceuticals Corporation.

22. The '802 patent is directed to and claims, inter alia, a pharmaceutical composition consisting essentially of a range of ratios of specified amounts of benazepril and amlodipine (or pharmaceutically acceptable salts of either or both), as well as a method of treating a condition selected from a group consisting of, inter alia, hypertension, in a human, consisting of administering a daily dose of a range of ratios of specified amounts of benazepril and amlodipine (or pharmaceutically acceptable salts of either or both).

Lotrel®

23. Novartis Pharmaceuticals Corporation holds an approved New Drug Application for amlodipine besylate and benazepril hydrochloride combination capsules, in 2.5/10 mg (amlodipine/benazepril hydrochloride), 5/10 mg, 5/20 mg, 10/20 mg, 5/40 mg, and 10/40 mg dosage strengths, which it sells under the brand name Lotrel®.

24. Pursuant to 21 U.S.C. § 355(b)(1) and attendant United States Food and Drug Administration ("FDA") regulations, the '802 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Lotrel®.

Cobalt's ANDA

25. On information and belief, Cobalt submitted an Abbreviated New Drug Application ("ANDA") to the FDA pursuant to 21 U.S.C. § 355(j) (the "Cobalt Lower Strength ANDA"), seeking approval to market amlodipine besylate and benazepril hydrochloride capsules in one or more of the following dosage strengths: 2.5/10 mg (amlodipine/benazepril hydrochloride), 5/10 mg, 5/20 mg and 10/20 mg (the "Cobalt Lower Strength ANDA Products").

26. On information and belief, the Cobalt Lower Strength ANDA refers to and relies upon Novartis Pharmaceutical Corporation's NDA for Lotrel® and purports to contain data showing bioequivalence of Cobalt's proposed amlodipine besylate and benazepril hydrochloride capsules with Lotrel®.

27. On information and belief, in connection with the Cobalt Lower Strength ANDA, Cobalt certified pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the ?802 patent is invalid and/or will not be infringed by the manufacture, use, offer to sell, sale, or importation into the United States of the Cobalt Lower Strength ANDA Products.

28. On information and belief, in connection with the Cobalt Lower Strength ANDA, Cobalt submitted to the FDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) stating that the ?802 patent is invalid and/or will not be infringed by the manufacture, use, offer to sell, sale, or importation into the United States of the Cobalt Lower Strength ANDA Products.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,162,802

29. Novartis hereby realleges and incorporates by reference the allegations of paragraphs 1-28 of this Complaint.

30. Cobalt has infringed, induced the infringement, and contributed to the infringement of the '802 patent pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA the Cobalt Lower Strength ANDA, which, on information and belief, includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the '802 patent and which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Cobalt Lower Strength ANDA Products for the treatment of hypertension prior to the expiration of the '802 patent.

31. Upon information and belief, Cobalt has knowingly and willfully infringed the '802 patent.

32. Novartis will be irreparably harmed if Cobalt is not enjoined from infringing the '802 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Novartis Corporation and Novartis Pharmaceuticals Corporation pray for a judgment in their favor and against Defendants Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals Inc., as follows:

A. Entering judgment for Plaintiffs on their Count for Infringement of U.S. Patent No. 6,162,802.

B. Entering judgment permanently enjoining Cobalt from making, using, offering to sell, selling, or importing the Cobalt Lower Strength ANDA Products described in the Cobalt Lower Strength ANDA or active ingredients for use in a method that would infringe the '802 patent, until after the expiration of the '802 patent and until after the expiration of any additional exclusivity period provided under the Federal Food, Drug & Cosmetic Act.

C. Determining that this is an exceptional case under 35 U.S.C. § 285 and awarding Plaintiffs their reasonable attorneys' fees, costs and expenses.

D. Awarding Plaintiffs such other relief as the Court deems just and proper.

Dated: December 18, 2008
Newark, New Jersey

Respectfully submitted,

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