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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BIOGLAN PHARMACEUTICALS CORP. and JAGOTEC AG Plaintiffs, v. NOVARTIS CONSUMER HEALTH, INC., Defendant.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY RELIEF

Plaintiffs Bioglan Pharmaceuticals Corp. (Bioglan") and Jagotec AG ("Jagotec"), by their attorneys, for their Complaint, allege as follows:

Nature of the Action

1. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Plaintiffs seek

declaratory relief, i.e., declarations that the patents in suit are infringed, injunctive relief precluding infringement, and attorneys' fees.

The Parties

2. Bioglan is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 383 Route 46 West, Fairfield, New Jersey 07004. Bioglan is a wholly owned subsidiary of Bradley Pharmaceuticals, Inc.

3. Jagotec is a corporation organized and existing under the laws of Switzerland and has its principal place of business at Eptingerstrasse 51 Ch-4132, Muttenz, Switzerland.

4. Upon information and belief, defendant Novartis Consumer Health, Inc. ("NCH") is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 200 Kimball Drive, Parsippany, New Jersey 07054. Upon information and belief, NCH operates, conducts, and transacts business in New Jersey and contracts to supply goods and services in New Jersey.

Jurisdiction and Venue

5. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent Nos. 5,852,002 ("the '002 Patent"), 5,929,048 ("the '048 Patent") and 5,985,850 ("the '850 Patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

The Approved SOLARAZE® Drug

7. Any person wishing to market a pioneering drug -- that is, a new drug that has not previously been approved by the Food and Drug Administration ("FDA") -- must first file a new drug application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b)(1). To secure approval of an NDA, the NDA applicant must, among other things, collect and submit to FDA extensive animal and human clinical trial data at a substantial cost of time and money.

8. Bioglan is the holder of New Drug Application No. 21-005 ("NDA 21-005"), which was approved by FDA for treatment of actinic keratoses. This drug is marketed and sold in the United States under the trade name SOLARAZE®.

9. The active ingredient in SOLARAZE® is diclofenac sodium. The dosage form of SOLARAZE® is a gel, and the route of administration is topical.

10. FDA has listed the '002 Patent, the '048 Patent and the '850 Patent in the Orange Book -- formally known as Approved Drug Products With Therapeutic Equivalence Evaluations -- in connection with NDA 21-005. The '002 Patent, the '048 Patent and the '850 Patent are owned by Jagotec and exclusively licensed to Bioglan.

11. The '002 Patent qualifies for listing in the Orange Book in connection with NDA No. 21-005 because it claims a method of treatment that is the subject of the approved NDA.

12. The '048 Patent qualifies for listing in the Orange Book in connection with NDA No. 21-005 because it claims a method of treatment that is the subject of the approved NDA.

13. The '850 Patent qualifies for listing in the Orange Book in connection with NDA No. 21-005 because it claims a dosage amount of a pharmaceutical composition that is the subject of the approved NDA.

The NCH Section 505(b)(2) Application

14. A person seeking approval for a new drug who wishes to rely on safety or efficacy investigations conducted by or on behalf of the applicant for a pioneering drug previously approved by FDA, under certain circumstances, may follow a truncated approval process, pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b)(2).

15. Upon information and belief, NCH submitted New Drug Application No. 22-122 (the "NCH § 505(b)(2) Application") to FDA under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2), seeking approval to engage in commercial manufacture and sale of a diclofenac sodium topical gel.

16. Upon information and belief, the NCH § 505(b)(2) Application relies on reports of investigations into safety or efficacy submitted to the FDA in connection with NDA 21-005, held by Bioglan.

17. NCH sent a Patent Certification Notice letter dated March 20, 2007 addressed to Bioglan Pharmaceuticals Corp. c/o Bradley Pharmacueticals, Inc. and to Hyal Pharmaceutical Corporation c/o Skyepharma PLC ("the Notice Letter"). The Notice Letter represented that NCH had submitted to FDA the NCH § 505(b)(2) Application and purported certifications under section 505(b)(2)(A)(iv) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b)(2)(A)(iv) ("Paragraph IV certifications"). The purpose of the NCH § 505(b)(2) Application and purported Paragraph IV certifications was to obtain FDA approval under Section 505(b) of the FDCA to engage in the commercial manufacture and sale

of the diclofenac sodium topical gel product before the expiration of the '002, '048 and '850 Patents listed in the Orange Book for NDA No. 21-005.

18. Upon information and belief, if the NCH § 505(b)(2) Application is approved by FDA, NCH will manufacture, offer for sale, or sell the product for which approval is sought in NDA No. 22-122.

19. Upon information and belief, if the NCH § 505(b)(2) Application is approved by FDA, NCH will induce or contribute to the manufacture, offer for sale, or sale of the product for which approval is sought in NDA No. 22-122.

COUNT I

(Patent Infringement of the '002 Patent)

20. Plaintiffs re-allege paragraphs 1 through 19 above as fully set forth therein.

21. On December 22, 1998, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '002 Patent. A true and correct copy of the '002 Patent is attached hereto as Exhibit A. Jagotec is the owner and Bioglan is the exclusive licensee of the '002 Patent.

22. The submission of the NCH § 505(b)(2) Application to FDA with a Paragraph IV certification for the '002 Patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '002 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

23. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the NCH § 505(b)(2) Application by NCH would infringe one or more claims of the '002 Patent, and NCH would be liable as an infringer under 35 U.S.C. § 271(a).

24. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the NCH § 505(b)(2) Application by NCH would actively induce and contribute to infringement of the '002 Patent, and NCH would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

25. NCH had actual and constructive notice of the '002 Patent prior to the filing of the NCH § 505(b)(2) Application and filed the NCH § 505(b)(2) Application with a Paragraph IV certification without adequate justification for claiming the patent will not be infringed. The conduct of NCH in connection with the filing of the NCH § 505(b)(2) Application and certification of non-infringement has been, and continues to be, willful.

COUNT II

(Patent Infringement of the '048 Patent)

26. Plaintiffs re-allege paragraphs 1 through 25 above as fully set forth therein.

27. On July 27, 1999, the USPTO duly and legally issued the '048 Patent. A true and correct copy of the '048 Patent is attached hereto as Exhibit B. Jagotec is the owner and Bioglan is the exclusive licensee of the '048 Patent.

28. The submission of the NCH § 505(b)(2) Application to FDA with a Paragraph IV certification for the '048 Patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '048 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

29. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the NCH § 505(b)(2) Application by NCH would infringe one or more claims of the '048 Patent, and NCH would be liable as an infringer under 35 U.S.C. § 271(a).

30. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the NCH § 505(b)(2) Application by NCH would actively induce and contribute to infringement of the '048 Patent, and NCH would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

31. NCH had actual and constructive notice of the '048 Patent prior to the filing of the NCH § 505(b)(2) Application and filed the NCH § 505(b)(2) Application with a Paragraph IV certification without adequate justification for claiming the patent will not be infringed. The conduct of NCH in connection with the filing of the NCH § 505(b)(2) Application and certification of non-infringement has been, and continues to be, willful.

COUNT III

(Patent Infringement of the '850 Patent)

32. Plaintiffs re-allege paragraphs 1 through 31 above as fully set forth therein.

33. On November 16, 1999, the USPTO duly and legally issued the '850 Patent. A true and correct copy of the '850 Patent is attached hereto as Exhibit C. Jagotec is the owner and Bioglan is the exclusive licensee of the '850 Patent.

34. The submission of the NCH § 505(b)(2) Application to FDA with a Paragraph IV certification for the '850 Patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '850 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

35. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the NCH § 505(b)(2) Application by NCH would infringe one or more claims of the '850 Patent, and NCH would be liable as an infringer under 35 U.S.C. § 271(a).

36. The commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed drug product that is the subject of the NCH § 505(b)(2) Application by NCH would actively induce and contribute to infringement of the '850 Patent, and NCH would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

37. NCH had actual and constructive notice of the '850 Patent prior to the filing of the NCH § 505(b)(2) Application and filed the NCH § 505(b)(2) Application with a Paragraph IV certification without adequate justification for claiming the patent will not be infringed. The conduct of NCH in connection with the filing of the NCH § 505(b)(2) Application and certification of non-infringement has been, and continues to be, willful.

Prayer for Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that NCH has infringed the '002, '048 and '850 Patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment providing that the effective date of any FDA approval of the NCH § 505(b)(2) Application be no earlier than the expiration of the '002, '048 and '850 Patents, including any extensions or regulatory exclusivities appended thereto;

C. A judgment declaring that the making, using, selling, offering to sell, or importing of the product for which approval is sought in the NCH § 505(b)(2) Application would constitute infringement of the '002, '048 and '850 Patents, or inducing or contributing to such conduct, by NCH pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

D. A judgment permanently enjoining NCH and its officers, agents, servants and employees, and those persons in active concert or participation with

any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the product for which approval is sought in the NCH § 505(b)(2) Application, or any product that infringes or induces or contributes to the infringement of the '002, '048 and '850 Patents, until the expiration of those patents, including any extensions or regulatory exclusivities appended thereto;

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

Respectfully submitted,

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