UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NYCOMED US INC.,

Plaintiff,

v.

PERRIGO ISRAEL PHARMACEUTICALS, LTD., AND PERRIGO COMPANY

Defendants.

Civil Action No. CV09- 5123

BLOOM, M.J. GLEESON, J.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Nycomed US Inc. ("Nycomed" or "Plaintiff"), by its attorneys Kramer Levin Naftalis & Frankel LLP, for its Complaint against Perrigo Israel Pharmaceuticals, Ltd. and Perrigo Company (collectively "Perrigo") for patent infringement alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent No. 7,300,669 (the " '669 Patent"), arising under the food and drug and patent laws of the United States, Titles 21 and 35, respectively. This action relates to the Abbreviated New Drug Application No. 91-553 ("Perrigo's ANDA" or "ANDA") filed by Perrigo with the United States Food and Drug Administration ("FDA") for approval to market a generic copy of Nycomed's Cutivate® Fluticasone Lotion 0.05% drug product ("Cutivate® Lotion") covered by the '669 Patent.

THE PARTIES, JURISDICTION AND VENUE

2. Nycomed is a company organized and existing under the laws of the State of New York with its principal place of business at 60 Baylis Road, Melville, NY 11747-0103.

3. On information and belief, Defendant Perrigo Israel Pharmaceuticals, Ltd. is a company organized and existing under the laws of Israel, having a principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel.

4. On information and belief, Defendant Perrigo Company is a company organized and existing under the laws of the State of Michigan, having a principal place of business at 515 Eastern Avenue, Allegan, Michigan, 49010.

5. On information and belief, Perrigo Israel Pharmaceuticals, Ltd. was formerly known as Agis Industries Limited. On information and belief, Perrigo Company purchased Agis Industries Limited in or around March 2005.

6. On information and belief, Perrigo Israel Pharmaceuticals, Ltd. is a wholly owned subsidiary of Perrigo Company.

7. On information and belief, Perrigo Israel Pharmaceuticals, Ltd. is an agent and/or alter ego of Perrigo Company.

8. On information and belief, Perrigo Israel Pharmaceuticals, Ltd. is under the direction, control and/or influence of Perrigo Company, both generally and with respect to the particular acts and conduct alleged in this Complaint.

9. On information and belief, Perrigo Company conducts operations through Perrigo Israel Pharmaceuticals, Ltd.

10. On information and belief, Perrigo is in the business of developing and manufacturing drug products for use and sale in the United States including in the State of New York and in this judicial district.

11. On information and belief, Perrigo conducts business and sells various drug products in the United States including in the State of New York and in this judicial district.

12. On information and belief, Perrigo has maintained continuous and systematic contacts with the State of New York and in this judicial district.

13. This Court has personal jurisdiction over Perrigo.

14. Perrigo has filed ANDA No. 91-553 with the purpose of obtaining the FDA's approval to market a proposed product that is a generic copy of Nycomed's Cutivate® Lotion before the expiration of Nycomed's '669 Patent. This ANDA creates a justiciable controversy between Nycomed and Perrigo with respect to the subject matter of Perrigo's ANDA, Perrigo's proposed product and the '669 Patent.

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

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

FACTUAL BACKGROUND

The ANDA Process

17. The Federal Food, Drug, and Cosmetic Act ("FFDCA") requires that before a drug manufacturer can market a new drug, it must submit a New Drug Application ("NDA") to the FDA for approval pursuant to section 505(b) of the Federal Food, Drug, and Cosmetics Act ("FFDCA"), 21 U.S.C. § 355(b). In addition to extensive testing and safety information concerning the drug, the manufacturer must also submit the patent number and expiration date of any patent that claims the drug or a method of using the drug with respect to which a claim of patent infringement could reasonably be asserted. 21 U.S.C. § 355(b)(1)(G).

18. Once the NDA is approved, the FDA lists this patent information with the approved drug in its *Approved Drug Products with Therapeutic Equivalence Evaluations*

publication, commonly known as the "Orange Book." *See* 21 U.S.C. §§ 355(b)(1). The FDA also maintains an electronic version of the Orange Book at www.fda.gov/cder/ob/.

19. In 1984 Congress adopted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act." This statute amended the FFDCA to provide for an ANDA, allowing manufacturers to obtain FDA approval for generic versions of previously approved drugs without having to repeat the extensive testing required for a new drug application, as long as certain requirements were met. *See* 21 U.S.C. § 355(j).

20. When submitting an ANDA to the FDA, the generic manufacturer must make one of the following four certifications with respect to each of the patents listed in the Orange Book for the drug for which the applicant seeks approval: (1) that no patent information has been filed (a "Paragraph I" certification), (2) that the patent has expired (a "Paragraph II" certification), (3) that the patent will expire on a specific date (a "Paragraph III" certification), or (4) that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" (a "Paragraph IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

21. If a generic drug applicant makes a Paragraph IV certification in its ANDA, the Hatch-Waxman Act requires that the applicant give notice to the patent owner ("Notice Letter"). In addition, in that Notice Letter, the ANDA applicant is required to provide the patent owner with a "detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II).

22. The intended purpose of a Notice Letter is to inform a patentee of the basis for a Paragraph IV certification so that a patentee may determine, as permitted under the patent act, whether to commence an action for infringement of an Orange Brook listed patent or to understand that such an action would not be justified under the patent act.

Nycomed's Cutivate® Lotion And '669 Patent

23. Nycomed is the owner of the '669 Patent.

24. The '669 Patent, entitled "Fluticasone Lotion Having Improved Vasoconstrictor Activity," was duly and legally issued on November 27, 2007 to inventors Gordon Dow et al., by the United States Patent and Trademark Office. A copy of the '669 Patent is attached hereto as **Exhibit A**. The claims of the '669 Patent are directed to, *inter alia*, topical lotions containing fluticasone.

25. Nycomed is the owner of NDA No. 21-152, which the FDA approved pursuant to section 505(b) of the FFDCA, 21 U.S.C. § 355(b). This NDA is directed to Cutivate® Lotion, a topical prescription medication sold on the market and used to treat a variety of dermatological conditions such as eczema.

26. Nycomed is also the owner, marketer and seller of Cutivate® Lotion.

27. Nycomed's '669 Patent claims cover Nycomed's Cutivate® Lotion.

28. The FDA lists the '669 Patent with Nycomed's Cutivate® Lotion in the Orange Book.

Perrigo's ANDA And Notice Letter

29. On or about October 9, 2009, Perrigo sent Nycomed a Notice Letter stating, among other things, that Perrigo had submitted ANDA No. 91-553 to the FDA pursuant to 21 U.S.C. § 355 (j) seeking approval of Perrigo's proposed drug product Fluticasone Propionate Lotion 0.05% ("Perrigo's Lotion") as a copy of Nycomed's Cutivate® Lotion.

30. Perrigo's Notice Letter demonstrates that Perrigo seeks approval to "engage in the commercial manufacture, use, sale or importation of" a copy of Nycomed's Cutivate® Lotion prior to the expiration date of the '669 Patent.

31. Perrigo's Notice Letter states that Perrigo's ANDA contains a Paragraph IV certification with respect to the '669 Patent.

32. Perrigo's Notice Letter does not assert any cognizable or prima facie grounds of noninfringement, invalidity or unenforceability.

COUNT ONE: DIRECT INFRINGEMENT

33. Plaintiff alleges the paragraphs set forth above as if fully set forth herein.

34. Pursuant to 35 U.S.C. § 271(e)(2)(A), Perrigo has committed an act of infringement of the '669 Patent by filing an ANDA with a Paragraph IV certification that seeks FDA marketing approval for Perrigo's generic copy of Nycomed's Cutivate® Lotion prior to expiration of Nycomed's '669 Patent. This Court has subject matter jurisdiction with respect to this action to declare Nycomed's rights under the '669 Patent.

35. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for Perrigo's ANDA be a date that is not earlier than the expiration date for the last to expire of the '669 Patent or any other Patent listed in the Orange Book for Cutivate® Lotion.

36. Plaintiff is further entitled to a declaration that, if Perrigo commercially manufactures, uses, offers for sale or sells Perrigo's generic copy of Cutivate® Lotion within the United States, imports Perrigo's generic copy of Cutivate® Lotion into the United States, or induces or contributes to such conduct, Perrigo would further infringe the '669 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

37. Plaintiff will be irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. Plaintiff does not have an adequate remedy at law.

COUNT TWO: INDIRECT INFRINGEMENT

38. Plaintiff repeats and realleges the allegations of the paragraphs set forth above as if fully set forth herein.

39. Perrigo's actual commercial manufacture, importation, use, offer for sale or sale of Perrigo's Lotion prior to the expiration of the '699 Patent is contributory infringement and/or active inducement of infringement by others of the '699 Patent under 35 U.S.C. § 271.

40. Perrigo Company, is jointly and severally liable with Perrigo Israel Pharmaceuticals, Ltd. for this indirect infringement of the '669 Patent. This is so, because upon information and belief, Perrigo Company will direct, participate in, contribute to, aid and abet Perrigo Israel Pharmaceuticals, Ltd.'s acts of manufacturing, importing, using, offering for sale, and selling Perrigo's Lotion prior to the expiration of the '669 Patent.

RELIEF SOUGHT

WHEREFORE, Plaintiff requests:

A) A judgment declaring the '669 Patent is valid and enforceable;

B) A judgment declaring that Perrigo has infringed, and that Perrigo's making, using, selling, offering to sell or importing Perrigo's Lotion will infringe, the '669 Patent;

C) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Perrigo's ANDA No. 91-553 be a date that is not earlier than the expiration date of the '669 Patent, including any extensions of the patent term and/or exclusivities relating to Nycomed's Cutivate® Lotion;

D) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Perrigo and its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from commercial manufacture, use, offer to sell, or sale within

the United States or importation into the United States of Perrigo's Lotion or any other product that infringes, induces or contributes to the infringement of the '669 Patent prior to the expiration date of the '669 Patent, including any extensions of the patent term and/or exclusivities relating to Nycomed's Cutivate® Lotion;

E) A judgment of damages, should Perrigo engage in commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Perrigo's Lotion or any other product that infringes, induces or contributes to the infringement of the '669 Patent prior to the expiration date of the '669 Patent, including any extensions of the patent term and/or exclusivities relating to Nycomed's Cutivate® Lotion, resulting from such infringing activities, increased to treble the amount found or assessed together with interest;

F) A judgment declaring that this is an exceptional case entitling Nycomed to an award of its reasonable attorney's fees, together with interest, and costs of the action, pursuant to 35 U.S.C. § 285;

G) Costs and expenses in the action; and

H) Such other and further relief as the Court may deem just and proper.

Dated: November 20, 2009

Respectfully submitted,

By: 

Donald L. Rhoads, Esq.
Nicholas L. Coch, Esq.
Albert B. Chen, Esq.
KRAMER LEVIN NAFTALIS & FRANKEL, LLP
1177 Avenue of the Americas
New York, New York 10036
Telephone: (212) 715-9100
Facsimile: (212) 715-8000