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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NYCOMED US INC. and JAGOTEC AG, Plaintiffs, v. TOLMAR, INC., Defendant.	§	Civil Action No. 10-02635 (KSH)(PS) **AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Nycomed US Inc. (“Nycomed” or “Plaintiff”) and Jagotec AG (“Jagotec”) (collectively, “Plaintiffs”) for their Complaint against TOLMAR, Inc. (“TOLMAR” or “Defendant”) for patent infringement, upon information and belief allege as follows:

Nature Of The Action

1. This is an action for patent infringement 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. 20-936 ("Tolmar's ANDA" or "ANDA") filed by Tolmar with the United States Food and Drug Administration ("FDA") for approval to market a generic copy of Nycomed's SOLARAZE® drug product.

The Parties

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

3. PharmaDerm® is a wholly owned subsidiary of Nycomed US Inc. based at 210 Park Avenue, Florham Park, NJ 07932. PharmaDerm® markets and sells SOLARAZE® Gel in New Jersey and other states.

4. Plaintiff Jagotec AG is a company organized and existing under Swiss law, having a principal place of business at Eptingerstrasse 51, CH-4132 Muttenz, Switerland.

5. Upon information and belief, Defendant TOLMAR, Inc. is a corporation incorporated under the laws of State of Delaware, having its principal place of business at 701 Centre Avenue, Fort Collins, Colorado 80526.

Jurisdiction And Venue

6. This action arises under the Patent laws of the United States, and the Food and Drug laws of the United States, Titles 28, 35, and 21, respectively, of the United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271.

7. Venue is proper in this Court under 28 U.S.C. § 1391(c) and § 1391(b).

The Approved SOLARAZE® Gel And Related Patents

8. Nycomed is the holder of NDA No. 21-005, which is approved by the FDA pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b). This NDA is directed to a pharmaceutical product that is 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. United States Patent Nos. 5,639,738 (the "'738 Patent"), 5,792,753 (the "'753 Patent"), 5,852,002 (the "'002 Patent"), 5,914,322 (the "'322 Patent"), 5,929,048 (the "'048 Patent"), and 5,985,850 (the "'850 Patent") (collectively "the Patents-in-Suit") are owned by Jagotec. The Patents-in-Suit are exclusively licensed to Nycomed.

11. The Patents-in-Suit are valid, enforceable, and have not expired.

12. The FDA has listed the '738 Patent, the '753 Patent, the '002 Patent, the '322 Patent, the '048 Patent, and the '850 Patent in its *Approved Drug Products with Therapeutic Equivalence Evaluations* publication, commonly known as the "Orange Book," in connection with NDA No. 21-005 and SOLARAZE® Gel. The FDA also maintains an electronic version of the Orange Book at www.fda.gov/cder/ob/.

13. United States Patent No. 5,639,738, entitled "Treatment of basal cell carcinoma and actinic keratosis employing hyaluronic acid and NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on June 17, 1997 to inventors Falk et al.

14. A copy of the '738 Patent is attached hereto as **Exhibit A**.

15. United States Patent No. 5,792,753, entitled "Compositions comprising hyaluronic acid and prostaglandin-synthesis-inhibiting drugs," was duly and legally issued by the United States Patent and Trademark Office on August 11, 1998 to inventors Falk et al.

16. A copy of the '753 Patent is attached hereto as **Exhibit B**.

17. United States Patent No. 5,852,002, entitled "Treatment of conditions and disease," was duly and legally issued by the United States Patent and Trademark Office on December 22, 1998 to inventors Falk et al.

18. A copy of the '002 Patent is attached hereto as **Exhibit C**.

19. United States Patent No. 5,914,322, entitled "Treatment of disease and conditions," was duly and legally issued by the United States Patent and Trademark Office on June 22, 1999 to inventors Falk et al.

20. A copy of the '322 Patent is attached hereto as **Exhibit D**.

21. United States Patent No. 5,929,048, entitled "Treatment of conditions and disease," was duly and legally issued by the United States Patent and Trademark Office on July 27, 1999 to inventors Falk et al.

22. A copy of the '048 Patent is attached hereto as **Exhibit E**.

23. United States Patent No. 5,985,850, entitled "Compositions comprising hyaluronic acid and drugs," was duly and legally issued by the United States Patent and Trademark Office on November 16, 1999 to inventors Falk et al.

24. A copy of the '850 Patent is attached hereto as **Exhibit F**.

The TOLMAR ANDA And Notice Letter

25. Upon information and belief, TOLMAR submitted ANDA No. 20-936, the TOLMAR ANDA, to the FDA, seeking approval to engage in the commercial manufacture, use, and/or sale of TOLMAR Gel.

26. TOLMAR sent a patent certification notice letter, TOLMAR's Paragraph IV Notice, dated April 8, 2010, addressed to Plaintiffs. The Paragraph IV Notice represented that TOLMAR had submitted to the FDA the TOLMAR ANDA and purported certifications under

21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV certifications"). The purpose of the TOLMAR ANDA and purported Paragraph IV certifications was to obtain FDA approval to engage in the commercial manufacture, use, and/or sale of TOLMAR Gel, before the expiration of the '738, '753, '002, '322, '048 and '850 Patents listed in the Orange Book for NDA No. 21-005.

27. Upon information and belief, if the TOLMAR ANDA is approved by the FDA, TOLMAR will manufacture, use, offer for sale, and/or sell within the United States, and/or import into the United States, the product for which approval is sought in ANDA No. 20-936.

COUNT I
(Patent Infringement of the '738 Patent)

28. Plaintiffs reallege paragraphs 1 through 27 above as fully set forth therein.

29. Jagotec is the owner and Nycomed is the exclusive licensee of the '738 Patent.

30. The submission of the TOLMAR ANDA to the FDA with a Paragraph IV certification for the '738 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 '738 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

31. 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 TOLMAR ANDA by TOLMAR would infringe one or more claims of the '738 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. § 271(a).

32. 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 TOLMAR ANDA by TOLMAR would actively induce and contribute to infringement of the '738 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

COUNT II
(Patent Infringement of the '753 Patent)

33. Plaintiffs reallege paragraphs 1 through 32 above as fully set forth therein.

34. Jagotec is the owner and Nycomed is the exclusive licensee of the '753 Patent.

35. The submission of the TOLMAR ANDA to the FDA with a Paragraph IV certification for the '753 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 '753 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(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 TOLMAR ANDA by TOLMAR would infringe one or more claims of the '753 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. § 271(a).

37. 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 TOLMAR ANDA by TOLMAR would actively induce and contribute to infringement of the '753 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

COUNT III
(Patent Infringement of the '002 Patent)

38. Plaintiffs reallege paragraphs 1 through 37 above as fully set forth therein.

39. Jagotec is the owner and Nycomed is the exclusive licensee of the '002 Patent.

40. The submission of the TOLMAR ANDA to the 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).

41. 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 TOLMAR ANDA by TOLMAR would infringe one or more claims of the '002 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. § 271(a).

42. 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 TOLMAR ANDA by TOLMAR would actively induce and contribute to infringement of the '002 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

COUNT IV
(Patent Infringement of the '322 Patent)

43. Plaintiffs reallege paragraphs 1 through 42 above as fully set forth therein.

44. Jagotec is the owner and Nycomed is the exclusive licensee of the '322 Patent.

45. The submission of the TOLMAR ANDA to the FDA with a Paragraph IV certification for the '322 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 '322 Patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

46. 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 TOLMAR ANDA by TOLMAR would infringe one or more claims of the '322 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. § 271(a).

47. 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 TOLMAR ANDA by TOLMAR would actively induce and contribute to infringement of the '322 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

COUNT V
(Patent Infringement of the '048 Patent)

48. Plaintiffs reallege paragraphs 1 through 47 above as fully set forth therein.

49. Jagotec is the owner and Nycomed is the exclusive licensee of the '048 Patent.

50. The submission of the TOLMAR ANDA to the 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).

51. 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 TOLMAR ANDA by TOLMAR would infringe one or more claims of the '048 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. § 271(a).

52. 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 TOLMAR ANDA by TOLMAR would actively induce and contribute to infringement of the '048 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

COUNT VI
(Patent Infringement of the '850 Patent)

53. Plaintiffs reallege paragraphs 1 through 52 above as fully set forth therein.

54. Jagotec is the owner and Nycomed is the exclusive licensee of the '850 Patent.

55. The submission of the TOLMAR ANDA to the 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).

56. 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 TOLMAR ANDA by TOLMAR would infringe one or more claims of the '850 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. § 271(a).

57. 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 TOLMAR ANDA by TOLMAR would actively induce and contribute to infringement of the '850 Patent, and TOLMAR would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

INJUNCTIVE RELIEF

58. Plaintiffs will be irreparably harmed by the Defendant TOLMAR's activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

EXCEPTIONAL CASE

59. This case is an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorneys' fees, costs and expenses, under 35 U.S.C. § 285 and any other available statute or law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests the following relief:

A. A judgment that TOLMAR has infringed the '738, '753, '002, '322, '048, and '850 Patents under 35 U.S.C. § 271(e)(2)(A);

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the TOLMAR ANDA be no earlier than the expiration of the '738, '753, '002, '322, '048 and '850 Patents, including any extensions or regulatory exclusivities appended thereto;

C. A judgment declaring that the making, using, offering to sell, selling within the United States, or importing into the United States, of the product for which approval is sought in the TOLMAR ANDA would constitute infringement of the

'738, '753, '002, '322, '048, and '850 Patents, or inducing or contributing to such conduct, by TOLMAR pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

D. A judgment permanently enjoining TOLMAR 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 TOLMAR ANDA, or any product that infringes or induces or contributes to the infringement of the '738, '753, '002, '322, '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.

Dated: May 16, 2011

Respectfully submitted,

By: /s/ Leda Dunn Wettre

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