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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ELAN PHARMA INTERNATIONAL LTD. and FOURNIER LABORATORIES IRELAND LTD.,	)	
Plaintiffs,	)	**Civil Action No. _____**
v.	)	
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Elan Pharma International Ltd. ("Elan") and Fournier Laboratories Ireland Ltd. ("Fournier") for their Complaint against Impax Laboratories, Inc. ("Impax") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 5,145,684

("the '684 patent"), 7,276,249 ("the '249 patent"), and 7,320,802 ("the '802 patent"). This action arises out of Defendant's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic copies of the highly successful TRICOR® 48 mg and 145 mg products prior to the expiration of Plaintiffs' patents.

THE PARTIES

2. Plaintiff Elan Pharma International Ltd. is an Irish corporation having a principal place of business at Monksland, Athlone, Co. Westmeath, Ireland.

3. Plaintiff Fournier Laboratories Ireland Ltd. is an Irish corporation having a principal place of business at Anngrove, Carrigtwohill, Co. Cork, Ireland.

4. On information and belief, Impax is a Delaware corporation having its principal place of business at 30831 Huntwood Avenue, Hayward, California, 94544, and having a its primary commercial center at 3735 Castor Avenue, Philadelphia, PA 19124. On information and belief, Impax is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. On information and belief, this Court has personal jurisdiction over Impax because Impax has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Impax has had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products that are sold in this judicial district.

7. Impax previously consented to personal jurisdiction in this district in prior

patent cases. *E.g.*, Answer, Affirmative Defenses, and Counterclaims, *Warner Chilcott Laboratories et al. v. Impax Laboratories, Inc.*, Case No. 09-1233 (D.N.J. Apr. 3, 2009) (refusing to contest personal jurisdiction in that case and admitting that it had not contested personal jurisdiction in another case in this judicial district).

8. Three related lawsuits are currently pending in this Court. On February 29, 2008, Elan and Fournier filed suit in this Court against Teva Pharmaceuticals USA, Inc. ("Teva") seeking a judgment that each of the '684, '249, and '802 patents, in addition to one other patent, is infringed by Teva's filing of its ANDA No. 90-069. *See Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Teva Pharmaceuticals USA, Inc.*, Case No. 08-1085 (D.N.J.). On November 3, Elan and Fournier filed suit in this Court against Biovail Laboratories International SRL and Biovail Corporation (collectively "Biovail") seeking a judgment that each of the '684, '249, and '802 patents, in addition to one other patent, is infringed by Biovail's filing of its ANDA No. 90-715. *See Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Biovail Laboratories International SRL and Biovail Corp.*, Case No. 08-5412 (D.N.J.). On March 6, 2009, Elan and Fournier filed suit in this court against Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin") seeking a judgment that each of the '249 and '802 patents is infringed by Lupin's filing of its ANDA No. 90-856. *See Elan Pharma International Ltd. and Fournier Laboratories Ireland Ltd. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, Case No. 09-1008 (D.N.J.).

9. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

BACKGROUND

10. On September 8, 1992, the '684 patent, entitled "Surface Modified Drug

Nanoparticles," was duly and legally issued. A true and correct copy of the '684 patent is attached as Exhibit A. Elan is the current assignee of the '684 patent.

11. On October 2, 2007, the '249 patent, entitled "Nanoparticulate Fibrate Formulations," was duly and legally issued to Elan and Fournier as assignees. A true and correct copy of the '249 patent is attached as Exhibit B.

12. On January 22, 2008, the '802 patent, entitled "Methods of Treatment Using Nanoparticulate Fenofibrate Compositions," was duly and legally issued to Elan and Fournier as assignees. A true and correct copy of the '802 patent is attached as Exhibit C.

13. On November 5, 2004, the FDA approved New Drug Application ("NDA") No. 21-656 for TRICOR® tablets, which contain fenofibrate, under § 505(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a), as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia and to reduce elevated LDL-C, Total-C, Triglycerides and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia, or mixed dyslipidemia.

14. The '684, '249, and '802 patents are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for TRICOR® tablets.

15. On information and belief, Impax submitted ANDA No. 91-548 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of fenofibrate tablets in 48 mg and 145 mg dosages ("Impax's Tablets, 48 mg and 145 mg"), as generic versions of the TRICOR® 48 mg and 145 mg tablets. Upon information and belief, Impax will market and/or distribute Impax's Tablets, 48 mg and 145 mg if ANDA No. 91-548 is approved by the FDA.

16. By letter dated September 14, 2009, Impax advised Elan and Fournier that

it had submitted ANDA No. 91-548 seeking approval to manufacture, use, or sell fenofibrate tablets in 145 mg doses ("Impax's Tablets, 145 mg") prior to the expiration of the '684, '249, and '802 patents.

17. The September 14, 2009 letter also advised Elan and Fournier that Impax's ANDA included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Impax's opinion, the '684, '249, and '802 patents are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Impax's Tablets, 145 mg.

18. By letter dated September 30, 2009, Impax advised Elan and Fournier that it had submitted an amendment to its ANDA No. 91-548 seeking approval to manufacture, use, or sell fenofibrate tablets in 48 mg doses ("Impax's Tablets, 48 mgs") prior to the expiration of the '684, '249, and '802 patents.

19. The September 30, 2009 letter also advised Elan and Fournier that Impax's ANDA included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Impax's opinion, the '684, '249, and '802 patents are invalid and/or will not be infringed by the commercial manufacture, use, or sale of Impax's Tablets, 48 mg.

COUNT I

20. Plaintiffs incorporate each of the preceding paragraphs 1-19 as if fully set forth herein.

21. By filing ANDA No. 91-548 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Impax's Tablets, 48 mg and 145 mg prior to the expiration of the '684 patent, Defendant committed an act of infringement, and/or induced infringement, of the '684 patent under 35 U.S.C. § 271(e)(2).

22. The commercial manufacture, use, offer to sell, sale, or importation of

Impax's Tablets, 48 mg and 145 mg would infringe one or more of the claims of the '684 patent under 35 U.S.C. § 271.

23. On information and belief, Impax was aware of the existence of the '684 patent and was aware that the filing of its ANDA and certification with respect to the '684 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

24. Plaintiffs incorporate each of the preceding paragraphs 1-19 as if fully set forth herein.

25. By filing ANDA No. 91-548 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Impax's Tablets, 48 mg and 145 mg prior to the expiration of the '249 patent, Defendant committed an act of infringement, and/or induced infringement, of the '249 patent under 35 U.S.C. § 271(e)(2).

26. The commercial manufacture, use, offer to sell, sale, or importation of Impax's Tablets, 48 mg and 145 mg would infringe one or more of the claims of the '249 patent under 35 U.S.C. § 271.

27. On information and belief, Impax was aware of the existence of the '249 patent and was aware that the filing of its ANDA and certification with respect to the '249 patent constituted infringement of that patent. This is an exceptional case.

COUNT III

28. Plaintiffs incorporate each of the preceding paragraphs 1-19 as if fully set forth herein.

29. By filing ANDA No. 91-548 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Impax's Tablets, 48 mg and 145 mg prior

to the expiration of the '802 patent, Defendant committed an act of infringement, and/or induced infringement, of the '802 patent under 35 U.S.C. § 271(e)(2).

30. The commercial manufacture, use, offer to sell, sale, or importation of Impax's Tablets, 48 mg and 145 mg would infringe one or more of the claims of the '802 patent under 35 U.S.C. § 271.

31. On information and belief, Impax was aware of the existence of the '802 patent and was aware that the filing of its ANDA and certification with respect to the '802 patent constituted infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Impax has infringed the '684, '249, and '802 patents;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Impax's ANDA No. 91-548 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), be a date which is not earlier than the expiration date of the '684, '249, and '802 patents;

C. An injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Impax and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from infringement of the '684, '249, and '802 patents for the full terms thereof;

D. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

E. Costs and expenses in this action; and

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

Respectfully submitted,

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Dated: October 29, 2009

CERTIFICATION PURSUANT TO L. CIV.R. 11.2

Plaintiffs, by their undersigned counsel, hereby certify pursuant to L.CIV.R. 11.2 that the matters in controversy are not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding, with the exception of the related lawsuits identified in Paragraph 8 of this Complaint involving different defendants but the same Patents-in-Suit.

Respectfully submitted,

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Dated: October 29, 2009