

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FILED
MAY - 4 2011
Clerk, U.S. District & Bankruptcy
Courts for the District of Columbia

FLAMEL TECHNOLOGIES S.A.,
Parc Club du Moulin à Vent
33 avenue du Docteur Georges Lévy
69693 Venissieux Cedex, France

Plaintiff,

v.

LUPIN LIMITED,
Laxmi Towers, B Wing
Bandra Kurla Complex
Bandra (East)
Mumbai, 400 051 India, and

LUPIN PHARMACEUTICALS, INC.,
Harborplace Tower, 111 South Calvert Street
Baltimore, Maryland 21202,

Defendants.

Case: 1:11-cv-00826
Assigned To : Sullivan, Emmet G
Assign. Date : 5/4/2011
Description: General Civil

COMPLAINT

Plaintiff, Flamel Technologies S.A., by counsel, files this complaint against defendants, Lupin Limited and Lupin Pharmaceuticals, Inc., and hereby alleges as follows:

THE PARTIES

1. Plaintiff Flamel Technologies S.A. ("Flamel") is a corporation organized and existing under the laws of France with its principal place of business in Venissieux Cedex, France.

2. Defendant Lupin Limited is a corporation organized and existing under the laws of India with its principal place of business in Mumbai, India.

3. Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Virginia with its principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland.

NATURE OF THE ACTION

4. This is a civil action for infringement of U.S. Patent No. 6,022,562 (“the ‘562 patent”).

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.* and the declaratory judgment laws of the United States, 28 U.S.C. §§ 2201 *et seq.* This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Personal jurisdiction over Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively referred to as “Lupin”) is proper in this District. On information and belief, Lupin has engaged and are engaged in continuous and systemic contacts with the District of Columbia and has purposefully availed itself of the benefits and protections of the laws of the District of Columbia. Lupin offers for sale and sells generic drug products in this District. Personal jurisdiction also exists pursuant to D.C. Code § 13-423.

7. Venue is proper in this district under 28 U.S.C. § 1391(b)-(d).

CASE OR CONTROVERSY

8. An immediate, real, and justiciable controversy exists between the parties to this action.

FACTS

9. On February 8, 2000, the ‘562 patent, titled “Medicinal and/or Nutritional Microcapsules for Oral Administration,” was duly and legally issued by the U.S. Patent and Trademark Office (“PTO”). Flamel is the lawful owner by assignment of right, title and interest

to the '562 patent, including the right to sue and recover for infringement thereof. A copy of the '562 patent is attached hereto as Exhibit 1 and incorporated by reference.

10. Flamel is a leading drug delivery company focused on developing safer, more efficacious drug formulations. Flamel's product development pipeline includes biological and chemical drugs formulated with platforms or drug carriers developed by Flamel.

11. The Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 022012 for 10mg, 20mg, 40mg and 80mg carvedilol phosphate extended release capsules for indications of left ventricular dysfunction including myocardial infarction and hypertension. The capsules approved under the NDA are prescribed and sold in the United States under the trade name Coreg CR®. This commercial product or its use is covered by one or more claims of the '562 patent.

12. Lupin manufactures numerous generic drugs, including, *inter alia*, cefprozil, lisinopril, and meloxicam, for sale and use throughout the United States.

13. On March 23, 2011, Flamel received a letter from Lupin dated March 21, 2011 (the "Notification Letter"), stating that Lupin submitted an Abbreviated New Drug Application ("ANDA") No. 201274 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). A copy of the Notification Letter is attached hereto as Exhibit 2 and incorporated by reference.

14. According to the Notification Letter, Lupin ANDA No. 201274 seeks FDA approval to engage in the commercial manufacture, use, offer for sale or sale of a generic version of 10mg, 20mg, 40mg and 80mg of carvedilol phosphate extended release capsules ("Lupin Product"), prior to the expiration of the '562 patent.

15. According to the Notification Letter, ANDA No. 201274 contains an allegation under § 505(j)(2)(A)(vii)(IV) that the claims of the '562 patent are invalid, unenforceable and/or not infringed by the Lupin Product.

16. Lupin's submission to the FDA of ANDA No. 201274 with its § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '562 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin commercially makes, uses, offers to sell or sells the Lupin Product in the United States or imports the Lupin Product into the United States, or induces or contributes to any such conduct during the term of the '562 patent, it would further infringe that patent under 35 U.S.C. § 271(a), (b) and/or (c).

17. Lupin had actual and constructive notice of the '562 patent prior to filing ANDA No. 201274 and, on information and belief, was aware that the filing of ANDA No. 201274 would infringe under 35 U.S.C. § 271(e)(2)(A).

18. Flamel will be irreparably harmed by Lupin's infringing activities unless these activities are enjoined by this Court. Flamel does not have an adequate remedy at law.

19. This action has been brought, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), before the expiration of forty-five (45) days from the date of receipt by Flamel of the Notification Letter.

COUNT I
(Patent Infringement)

20. The foregoing allegations of the complaint are incorporated by reference.

21. Lupin submitted ANDA No. 201274 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or sale of the Lupin Product throughout the United States. By submitting ANDA No. 201274, Lupin committed an act of infringement with respect to one or more claims of the '562 patent under 35 U.S.C. § 271(e)(2)(A).

22. Any commercial manufacture, use, offer for sale, sale and/or importation of the Lupin Product prior to the '562 patent expiration date will constitute direct and/or contributory infringement of the '562 patent and/or active inducement of infringement of the '562 patent.

COUNT II
(Declaratory Judgment)

23. The foregoing allegations of the complaint are incorporated by reference.

24. The filing of Lupin with the FDA has raised the concern of Flamel that there is an imminent expectation that Lupin will begin making, using, selling and offering for sale materials that fall under one or more claims of the '562 patent.

25. Any commercial manufacture, use, offer for sale, sale and/or importation of the Lupin Product prior to the '562 patent expiration date will constitute direct and/or contributory infringement of the '562 patent and/or active inducement of infringement of the '562 patent, and Flamel seeks a declaratory judgment to this effect.

REQUEST FOR RELIEF

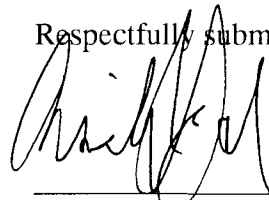
Flamel respectfully requests the following relief:

- a. judgment that Lupin has infringed one or more claims of the '562 patent;
- b. judgment that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 201274 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration of the '562 patent, including any extension and additional periods of exclusivity;
- c. granting preliminary and permanent injunctions, pursuant to 35 U.S.C. § 271(e)(4)(B) and otherwise, enjoining Lupin, its officers, agents, servants and employees, and those persons in active concert with any of them, from making, using, offering to sell or selling the Lupin Product within the United States or

- importing the Lupin Product into the United States, prior to the expiration of the '562 patent, including any extension and additional periods of exclusivity;
- d. judgment declaring that any commercial manufacture, use, offer for sale, sale and/or importation of the Lupin Product prior to the patent expiration date will constitute direct and/or contributory infringement of the '562 patent and/or active inducement of infringement of the '562 patent;
- d. judgment for Flamel for damages if Lupin engages in the commercial manufacture, use, offer for sale, and/or importation of the Lupin Product prior to the '562 patent expiration date, and that relief be increased to treble the amount found or assessed, together with interest;
- e. declaration that this is an exceptional case pursuant to 35 U.S.C. §§ 271(e)(4) and 285, entitling Flamel to its reasonable attorneys' fees and the costs and expenses in this action;
- f. award of costs; and
- g. such other relief as the Court deems just and appropriate under the circumstances.

Dated: May 4, 2011

Respectfully submitted,



Richard J. Oparil (D.C. Bar No. 409723) ✓

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