

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA LP, AKTIEBOLAGET)
DRACO, KBI INC. and KBI-E INC.,)
)
Plaintiffs,)
)
v.) C.A. No. _____
)
MYLAN PHARMACEUTICALS, INC.,)
)
Defendant.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca LP, Aktiebolaget Draco, KBI Inc. and KBI-E Inc. (collectively, “Plaintiffs”), by their attorneys, for their complaint against Mylan Pharmaceuticals, Inc. (“Mylan”), allege as follows:

THE PARTIES

1. Plaintiff AstraZeneca LP is a limited partnership organized and existing under the laws of the State of Delaware, and has its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850-5437.
2. Plaintiff Aktiebolaget Draco is a corporation organized and existing under the laws of Sweden and has its principal place of business at Lund, S-221 00, Sweden.
3. Plaintiff KBI Inc. (“KBI”) is a Delaware corporation having its principal place of business at Whitehouse Station, New Jersey.
4. Plaintiff KBI-E Inc. (“KBI-E”) is a Delaware corporation having its principal place of business at Wilmington, Delaware.
5. Upon information and belief, Defendant Mylan Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of West Virginia and has a

principal place of business at 781 Chesnut Ridge Road, Morgantown, West Virginia, 26505. Mylan does business in the State of Delaware.

JURISDICTION AND VENUE

6. 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. 6,423,340 (“the ’340 patent”) and 5,643,602 (“the ’602 patent”). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Mylan is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its having conducted business in Delaware, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State. Upon information and belief, Mylan has previously availed itself of this forum for purposes of litigating its patent disputes. For example, in 2002, Mylan filed a patent infringement lawsuit in *Mylan Pharmaceuticals Inc. v. Kremers Development Company et al.*, C.A. No. 02-1628 (D. Del.). Mylan has also submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Mylan admitted jurisdiction (for the purpose of the litigation) and filed counterclaims in *Forest Laboratories, Inc., et al. v. Dr. Reddy’s Laboratories, Inc., et al.*, C.A. No. 08-52 (D. Del.); *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals, Inc.*, C.A. No. 07-805 (D. Del.); *Sciele Pharmaceuticals v. Mylan Pharmaceuticals Inc.*, C.A. No. 07-664 (D. Del.); *sanofi-aventis, et al. v. Actavis, et al.*, C.A. No. 07-572 (D. Del.); *Boehringer Ingelheim International GMBH, et al. v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 05-854 (D. Del.); and *Janssen Pharmaceutica N.V., et al. v. Mylan Pharmaceuticals Inc., et al.*, C.A. No. 05-371 (D. Del.)

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

CLAIM I FOR PATENT INFRINGEMENT

9. Plaintiffs reallege paragraphs 1 through 8 above as if fully set forth herein.

10. On July 23, 2002, the United States Patent and Trademark Office duly and legally issued the '340 patent, entitled "Method For The Treatment Of Inflammatory Bowel Diseases." A true and correct copy of the '340 patent is attached hereto as Exhibit A.

11. Aktiebolaget Draco is the owner of the '340 patent, which discloses and claims, *inter alia*, methods for treating inflammatory bowel diseases.

12. KBI and KBI-E have rights in the United States under the '340 patent. AstraZeneca LP is the holder of approved New Drug Application ("NDA") 21-324 under Section 505(a) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for an oral budesonide product marketed under the trademark ENTOCORT[®] EC.

13. The use of ENTOCORT[®] EC is covered by the claims of the '340 patent, and Plaintiffs have the right to enforce the '340 patent.

14. Upon information and belief, Mylan submitted Abbreviated New Drug Application No. 90-410 ("Mylan ANDA") to the FDA under § 505(j) of the FFDCA, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale and sale of a generic version of ENTOCORT[®] EC before the expiration of the '340 patent.

15. On or about June 10, 2008, AstraZeneca received a letter dated June 9, 2008 stating that Mylan had filed the Mylan ANDA seeking approval to manufacture, use and sell a generic version of ENTOCORT[®] EC before the expiration of the '340 patent. The letter purports to notify AstraZeneca LP and Aktiebolaget Draco that the Mylan ANDA was submitted

with a certification pursuant to Section 505(j)(2)(B)(i) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV certification”) that Mylan’s manufacture, use, or sale of the Mylan ANDA product will not infringe any claims of the ’340 patent, that the ’340 patent is invalid, and/or that the ’340 patent is unenforceable.

16. Defendant has infringed the ’340 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to expiration of the ’340 patent.

17. The commercial manufacture, use, sale, offer to sell, or importation of the Mylan ANDA product would infringe the ’340 patent.

18. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Mylan ANDA be a date that is not earlier than the expiration of the ’340 patent, or any later expiration of exclusivity for the ’340 patent to which Plaintiffs become entitled.

19. Plaintiffs will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the ’340 patent. Plaintiffs do not have an adequate remedy at law.

CLAIM II FOR PATENT INFRINGEMENT

20. Plaintiffs reallege paragraphs 1 through 19 above as if fully set forth herein.

21. On July 1, 1997, the United States Patent and Trademark Office duly and legally issued the ’602 patent, entitled “Oral Composition For The Treatment Of Inflammatory Bowel Diseases.” A true and correct copy of the ’602 patent is attached hereto as Exhibit B.

22. Aktiebolaget Draco is the owner of the '602 patent, which discloses and claims, *inter alia*, oral compositions for treating inflammatory bowel diseases.

23. KBI and KBI-E have rights in the United States under the '602 patent. AstraZeneca LP is the holder of approved NDA 21-324 under Section 505(a) of the FFDCA, 21 U.S.C. § 355(a), for an oral budesonide product marketed under the trademark ENTOCORT® EC.

24. ENTOCORT® EC is covered by the claims of the '602 patent. Plaintiffs have the right to enforce the '602 patent.

25. Upon information and belief, Mylan submitted the Mylan ANDA to the FDA under § 505(j) of the FFDCA, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of ENTOCORT® EC before the expiration of the '602 patent.

26. On or about June 10, 2008, AstraZeneca received a letter dated June 9, 2008, stating that Mylan had filed the Mylan ANDA seeking approval to manufacture, use, and sell a generic version of ENTOCORT® EC before the expiration of the '602 patent. The letter purports to notify AstraZeneca LP and Aktiebolaget Draco that the Mylan ANDA was submitted with a Paragraph IV certification that Mylan's manufacture, use, or sale of the Mylan ANDA product will not infringe any claims of the '602 patent, that the '602 patent is invalid, and/or that the '602 patent is unenforceable.

27. Defendant has infringed the '602 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to expiration of the '602 patent.

28. The commercial manufacture, use, sale, offer to sell, or importation of the Mylan ANDA product would infringe the '602 patent.

29. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4) including an order of this Court that the effective date of the approval of the Mylan ANDA be a date that is not earlier than the expiration of the '602 patent, or any later expiration of exclusivity for the '602 patent to which Plaintiffs become entitled.

30. Plaintiffs will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '602 patent. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Mylan has infringed the '340 and '602 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 Mylan ANDA be not earlier than the expiration date of the '340 and '602 patents or any later expiration of exclusivity for these patents to which Plaintiffs are or become entitled;

C. A permanent injunction restraining and enjoining Mylan and its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing the product described in the Mylan ANDA;

D. A judgment declaring that the manufacture, use, sale, offer to sell, or importation of the product described in the Mylan ANDA would constitute infringement of the

'340 and '602 patents, or inducing or contributing to such conduct, by Mylan pursuant to 35 U.S.C. § 271 (a), (b) and/or (c);

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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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