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. _____
BARR LABORATORIES, INC., and BARR PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca LP, Aktiebolaget Draco, KBI Inc. and KBI-E Inc. (collectively, "Plaintiffs"), by their attorneys, for their complaint against Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, "Barr"), 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 Barr Laboratories, Inc. ("Barr Laboratories") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 223 Quaker Road, Pomona, New York 10970. Barr Laboratories does business in the State of Delaware.

6. Upon information and belief, Defendant Barr Pharmaceuticals, Inc. ("Barr Pharmaceuticals") is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 223 Quaker Road, Pomona, New York 10970. Barr Pharmaceuticals does business in the State of Delaware. Barr Pharmaceuticals is the parent of Barr Laboratories, and Barr Laboratories is a wholly-owned subsidiary of Barr Pharmaceuticals.

7. Upon information and belief, Barr Laboratories and Barr Pharmaceuticals collaborated in the research and development of Barr's Abbreviated New Drug Application ("the Barr ANDA") No. 90-379 for budesonide enteric coated capsules, 3 mg, continue to collaborate in seeking approval of that application from the Food and Drug Administration ("FDA"), and intend to collaborate in the commercial manufacture, marketing, and sale of budesonide products ("the Barr ANDA product"), in the event the FDA approves the Barr ANDA.

Jurisdiction and Venue

8. 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).

9. Barr Laboratories is subject to personal jurisdiction in this judicial district by virtue of, *inter alia,* its incorporation in Delaware, its conduct of business in Delaware, and having availed itself of the rights and benefits of Delaware law.

10. Barr Pharmaceuticals is subject to personal jurisdiction in this judicial district by virtue of, *inter alia,* its incorporation in Delaware, its conduct of business in Delaware, and having availed itself of the rights and benefits of Delaware law.

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

Claim I for Patent Infringement

12. Plaintiffs reallege paragraphs 1 through 11 above as if fully set forth herein.

13. 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.

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

15. 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.

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

17. Upon information and belief, Barr Laboratories submitted the Barr 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.

18. On or about April 11, 2008, Plaintiffs AstraZeneca LP and Aktiebolaget Draco received a letter dated April 9, 2008, stating that Barr Laboratories had filed the Barr

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 Barr ANDA was submitted with a certification pursuant to Section 505(j)(2)(B)(i) of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that Barr's manufacture, use, or sale of the Barr 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.

19. Upon information and belief, Barr Pharmaceuticals and Barr Laboratories collaborated in the research and development of Barr Laboratories' ANDA seeking approval to manufacture, use, and sell a generic version of ENTOCORT® EC before the expiration of the '340 patent, continue to collaborate in seeking approval of that application from the FDA, and intend to collaborate in the commercial manufacture, marketing and sale of a generic version of ENTOCORT® EC in the event the FDA approves the Barr ANDA.

20. Upon information and belief, Barr Pharmaceuticals participated in, contributed to, aided, abetted, and/or induced the submission of the Barr ANDA and its Paragraph IV certification to the FDA.

21. Defendants have infringed the '340 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their filing the Barr ANDA with a Paragraph IV certification and seeking FDA approval of the Barr ANDA prior to expiration of the '340 patent.

22. The commercial manufacture, use, sale, offer to sell, or importation of the Barr ANDA product would infringe the '340 patent.

23. 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 Barr 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.

24. Plaintiffs will be irreparably harmed if Barr Laboratories and Barr Pharmaceuticals are 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

25. Plaintiffs reallege paragraphs 1 through 24 above as if fully set forth herein.

26. 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.

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

28. 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.

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

30. Upon information and belief, Barr Laboratories submitted the Barr 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.

31. On or about April 11, 2008, Plaintiffs AstraZeneca LP and Aktiebolaget Draco received a letter dated April 9, 2008, stating that Barr Laboratories had filed the Barr 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 Barr ANDA was submitted with a Paragraph IV certification that Barr's manufacture, use, or sale of the Barr 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.

32. Upon information and belief, Barr Pharmaceuticals and Barr Laboratories collaborated in the research and development of Barr Laboratories' ANDA seeking approval to manufacture, use and sell a generic version of ENTOCORT® EC before the expiration of the '602 patent, continue to collaborate in seeking approval of that application from the FDA, and intend to collaborate in the commercial manufacture, marketing and sale of a generic version of ENTOCORT® EC in the event the FDA approves the Barr ANDA.

33. Upon information and belief, Barr Pharmaceuticals participated in, contributed to, aided, abetted, and/or induced the submission of the Barr ANDA and its Paragraph IV certification to the FDA.

34. Defendants have infringed the '602 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of their filing the Barr ANDA with a Paragraph IV certification and seeking FDA approval of the Barr ANDA prior to expiration of the '602 patent.

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

36. 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 Barr 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 becomes entitled.

37. Plaintiffs will be irreparably harmed if Barr Laboratories and Barr Pharmaceuticals are 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 Barr Laboratories and Barr Pharmaceuticals have 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 Barr 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 Barr Laboratories and Barr Pharmaceuticals and their 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 Barr ANDA;

D. A judgment declaring that the manufacture, use, sale, offer to sell, or importation of the product described in the Barr ANDA would constitute infringement of the '340 and '602 patents, or inducing or contributing to such conduct, by Barr Laboratories and Barr Pharmaceuticals 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

Jack B. Blumenfeld (#1014)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
jparrett@mnat.com
Attorneys for Plaintiffs

Of Counsel:

George F. Pappas
Jeffrey B. Elikan
Edward H. Rippey
Andrea G. Reister
Sarah J. Chickos
Derek J. Fahnestock
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 662-6000

May 22, 2008