IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

SHIRE CANADA INC., SHIRE INTERNATIONAL LICENSING B.V., and SHIRE US INC.,

Plaintiffs,

- v -

MYLAN INC., MYLAN PHARMACEUTICALS INC., and MATRIX LABORATORIES LIMITED,

Defendants.

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Civ. Action No. 09-Civ-2555 (PGG) (KNF)

Plaintiffs Shire Canada Inc., Shire International Licensing B.V., and Shire US Inc. (collectively, "Shire"), by their attorneys, for their complaint against Mylan Inc., Mylan Pharmaceuticals Inc., and Matrix Laboratories Limited, allege as follows:

The Parties

1. Plaintiff Shire Canada Inc. is a corporation organized and existing under the laws of Canada and has a principal place of business at 2250, boul. Alfred-Nobel, bureau 500, Ville St-Laurent, QC H4S 2C9, Canada.

2. Plaintiff Shire International Licensing B.V. is a corporation organized and existing under the laws of the Netherlands and has a principal place of business at Strawinskylaan 847, 1077 XX Amsterdam, Noord-Holland, The Netherlands.

3. Plaintiff Shire US Inc., is a corporation organized and existing under the laws of New Jersey and has a principal place of business at 725 Chesterbrook Blvd., Wayne, PA 19087, United States.

4. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania and has a principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317.

5. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia and has a principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505.

6. Upon information and belief, Defendant Matrix Laboratories Limited ("Matrix") is a corporation organized and existing under the laws of India and has a principal place of business at 1-1-151/1, 4th Floor, Sai Ram Towers, Alexander Road, Secunderabad – 500 003, Andhra, Pradesh, India.

Jurisdiction and Venue

7. 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 No. 5,968,976 ("the '976 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Mylan Inc. is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, having conducted business in the State, having availed itself of the rights and benefits of New York law, and having engaged in substantial and continuing contacts with the State. In addition, upon information and belief, Mylan Inc. operates an office in New York, at the following address: 405 Lexington Ave, New York, NY 10174. Moreover, Mylan Inc. has made counterclaims in the United States District Court for the Southern District of New York in connection with other lawsuits.

9. Mylan Pharmaceuticals Inc. is subject to personal jurisdiction in this judicial district by virtue of having conducted business in the State. In addition, upon information and belief, Mylan Pharmaceuticals Inc. has made counterclaims in the United States District Court for the Southern District of New York in connection with other lawsuits.

10. Matrix is subject to personal jurisdiction in this judicial district by virtue of the fact that Mylan Inc. and Mylan Pharmaceuticals Inc. are designated U.S. agents of Matrix, and that Mylan Inc. is a corporate parent of Matrix. In addition, upon information and belief, Matrix has conducted business in the State.

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

Regulatory Requirements for Approval of New and Generic Drugs

12. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by the Food and Drug Administration ("FDA") – must first file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b). To secure approval of a NDA, the NDA applicant must, among other things, collect and submit to FDA extensive animal and human clinical trial data at a substantial cost of time and money.

13. A person wishing to market a generic copy of a pioneering drug that previously has been approved by FDA may follow a truncated approval process by filing an Abbreviated New Drug Application ("ANDA") for a generic version of the drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence

of the generic copy of the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv). To demonstrate bioequivalence, the ANDA applicant must show that the rate and extent of absorption of the therapeutic ingredient in the generic drug does not significantly differ from that in the pioneering drug, or, if the rate of absorption differs, that such difference is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug. 21 U.S.C. § 355(j)(8)(B).

14. However, unlike a NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. The ANDA applicant is not required, for example, to conduct well-controlled clinical trials concerning the safety and effectiveness of the proposed drug. Instead, the ANDA applicant is permitted to piggy-back on the safety and effectiveness data developed and submitted by the approved NDA holder. 21 U.S.C. § 355(j).

15. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

16. No person may market in the United States a new drug without an approved NDA or a generic version of a drug without an approved ANDA. 21 U.S.C. § 355(a).

Plaintiffs' Approved Drug Product

17. Shire is the holder of an approved new drug application, NDA No. 21-468, for lanthanum carbonate chewable tablets. That NDA was approved for tablets

of Eq. 500 mg base on October 26, 2004, and for tablets of Eq. 750 mg base and 1000 mg base on November 23, 2005.

18. Pursuant to FDA's approval, Shire currently markets lanthanum carbonate chewable tablets for reduction of serum phosphate in patients with end stage renal disease under the trademark FOSRENOL®.

19. FDA has listed the '976 patent in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 21-468.

20. The '976 patent qualifies for listing in the Orange Book in connection with NDA No. 21-468 because it claims an approved use of the drug product that is the subject of that NDA. Mylan Inc., Mylan Pharmaceuticals Inc., and Matrix Laboratories Limited (collectively, "Mylan") have never challenged the listing of this patent in the Orange Book.

Mylan's ANDA

21. Mylan has represented that on or before February 4, 2009, it submitted to FDA Matrix's ANDA (ANDA No. 90-976) and paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for lanthanum carbonate chewable tablets purportedly bioequivalent to Shire's FOSRENOL® lanthanum carbonate chewable tablets. The purpose of the ANDA and paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its proposed lanthanum carbonate chewable tablets before the expiration of the patents listed in the Orange Book for Shire's NDA No. 21-468. Hence, Mylan's purpose in

submitting ANDA No. 90-976 is to market in the United States the lanthanum carbonate products described therein before expiration of the '976 patent.

22. On or about February 4, 2009, Mylan sent a letter advising Shire of Mylan's paragraph IV certification relating to the '976 patent ("Mylan's Notice Letter"). Mylan's Notice Letter included an offer of confidential access that would permit Shire's outside counsel to review Mylan's ANDA, subject to conditions limiting its distribution and use. Mylan's Notice Letter is attached hereto as Exhibit A. Shire has received two additional letters from other entities advising Shire of paragraph IV certifications relating to the '976 patent. Those letters are attached hereto as Exhibits B and C. Shire has filed suit against those other entities in the Southern District of New York. *See* 09-Civ-2380; 09-Civ-3165. The complaints filed in those cases are attached hereto as Exhibits D and E.

23. Upon information and belief, the sole condition of use for which Mylan seeks approval in its ANDA No. 90-976 for its proposed lanthanum carbonate chewable tablets is the reduction of serum phosphate in patients with end stage renal disease, the same condition of use as that approved in Shire's NDA No. 21-468.

24. Upon information and belief, the sole indication set forth in the proposed labeling submitted by Mylan in its ANDA No. 90-976 for its proposed lanthanum carbonate chewable tablets is the reduction of serum phosphate in patients with end stage renal disease, the same indication as that set forth in the approved labeling for Mylan's FOSRENOL® lanthanum carbonate chewable tablet products.

Count 1: Patent Infringement – '976 patent

25. Shire realleges paragraphs 1 through 24 above as if fully set forth herein.

26. On October 19, 1999, the United States Patent and Trademark Office duly and legally issued the '976 patent, entitled "Pharmaceutical Composition Containing Selected Lanthanum Carbonate Hydrates." The term of the '976 patent runs through October 26, 2018. A true and correct copy of the '976 patent is attached hereto as Exhibit F.

27. Shire is the owner of the '976 patent.

28. Shire currently markets lanthanum carbonate chewable tablets in the United States under the trademark FOSRENOL®. The product FOSRENOL® and the conditions of use for which FOSRENOL® is approved fall within one or more of the claims of the '976 patent.

29. Mylan is liable for infringement of the '976 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing ANDA No. 90-976 with a paragraph IV certification seeking FDA approval of ANDA No. 90-976 prior to expiration of the '976 patent.

30. The product for which Mylan seeks approval in its ANDA No. 90-976 falls within one or more of the claims of the '976 patent. If approved, the manufacture, use, offer for sale, and sale in the United States, and importation into the United States of Mylan's proposed lanthanum carbonate product would infringe one or more of the claims of the '976 patent.

31. Upon information and belief, if ANDA No. 90-976 is approved, Mylan intends to manufacture, use, offer for sale, and sell in the United States, and import into the United States, the lanthanum carbonate product for which approval is sought in Mylan's ANDA No. 90-976.

32. The manufacture, use, offer for sale and sale in the United States, and importation into the United States of Mylan's proposed lanthanum carbonate product would infringe one or more claims of the '976 patent, and Mylan would be liable for direct infringement under 35 U.S.C. § 271(a).

33. Mylan's manufacture, use, offer for sale or sale in the United States, or importation into the United States, prior to expiration of the '976 patent, of the lanthanum carbonate products for which approval is sought in ANDA No. 90-976, would actively induce and contribute to infringement of the '976 patent, and Mylan would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

34. Upon information and belief, the conditions of use for which Mylan seeks approval in its ANDA No. 90-976 fall within one or more of the claims of the '976 patent. Upon information and belief, if approved, use of Mylan's proposed lanthanum carbonate product in accordance with the proposed labeling submitted in ANDA No. 90-976 would infringe one or more of the claims of the '976 patent.

35. Upon information and belief, if approved, Mylan's proposed lanthanum carbonate products for which approval is sought in Mylan ANDA No. 90-976 will be administered to human patients in a therapeutically effective amount for reduction of serum phosphate in patients with end stage renal disease, which administration would constitute direct infringement of one or more claims of the '976 patent. Upon

information and belief, this infringement will occur at Mylan's behest, with its intent, knowledge, and encouragement, and Mylan will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Shire's rights under the '976 patent.

36. Shire will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '976 patent. Shire does not have an adequate remedy at law.

Prayer For Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Mylan has infringed the '976 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment and order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of ANDA No. 90-976 for lanthanum carbonate chewable tablets be not earlier than the expiration date of the '976 patent;

C. A judgment declaring that Mylan's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the lanthanum carbonate products for which approval is sought in ANDA No. 90-976 would constitute infringement of the '976 patent, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

D. A permanent injunction 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, or offering to sell in the United States, or importing into the United States, the lanthanum carbonate chewable tablets for which approval is sought in ANDA No. 90-976, or any lanthanum carbonate product that infringes or induces or contributes to the infringement of the '976 patent, until expiration of that patent;

E. A finding that Mylan's paragraph IV certification is frivolous, 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. An award of costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

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