IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

FLAMEL IRELAND, LTD., Plaintiff, v. MYLAN PHARMACEUTICALS INC., and MYLAN, INC., Defendants.	C.A. No. 1:15-CV-178 (Keeley) Electronically filed: 10/09/2015

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Flamel Ireland, Ltd. ("Flamel" or "Plaintiff") for its Complaint against Defendants Mylan Pharmaceuticals Inc. ("Mylan Pharma") and Mylan, Inc. (collectively "Mylan" or "Defendants") alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of Flamel's United States Patent No. 8,101,209 ("the '209 patent") under the patent laws of the United States, Title 35, United States Code, in response to Mylan's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Flamel's patented microparticulate system for the delayed and controlled release of active principles as claimed in the '209 patent.

THE PARTIES

2. Plaintiff Flamel is a corporation organized and existing under the laws of Ireland with its principal place of business at Block 10-1 Blanchardstown, Corporate Park, Ballycoolin Dublin 15, Ireland.

3. Defendant Mylan Pharma is a corporation organized and existing under the laws of West Virginia, having a principal place of business at 871 Chestnut Ridge, Morgantown, West Virginia 26505. Mylan Pharma is registered with the West Virginia Board of Pharmacy as a Manufacturer under License No. MR0000064 and as a Wholesale Distributor under License Nos. WD0559319, WD0557235, and WD0557236. Mylan Pharma is registered with the West Virginia Secretary of State, Business and Licensing, as a business operating in West Virginia under Organization ID No. 20402, and has appointed Corporation Service Company, 209 West Washington Street, Charleston, WV 25302, as its registered agent for service of process in West Virginia.

4. Mylan Pharma is a wholly-owned subsidiary of Mylan Inc.

5. Defendant Mylan, Inc. is a corporation organized and existing under the laws of Pennsylvania, with a principal place of business at 1000 Mylan Boulevard, Robert J. Coury Global Center, Canonsburg, PA, 15317, and has appointed Corporation Service Company, 209 West Washington Street, Charleston, WV 25302, as its registered agent for service of process in West Virginia. Mylan, Inc. is registered with the West Virginia Secretary of State, Business and Licensing, as a business operating in West Virginia under Organization ID No. 230499.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq*. generally and 35 U.S.C. § 271(e)(2) specifically, 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, 1338(a), 2201 and 2202.

7. This Court has personal jurisdiction over Mylan Pharma because Mylan Pharma has purposely availed itself of the benefits and protection of West Virginia laws such that it should reasonably anticipate being sued in this Court.

8. Mylan Pharma is a registered manufacturer and wholesale distributor of drugs in West Virginia, further demonstrating substantial, continuous and systematic contacts with this judicial district, including developing, marketing and/or selling generic pharmaceutical products in this judicial district.

9. Mylan Pharma derives substantial revenue from selling generic pharmaceutical products in this judicial district and throughout the United States. Mylan Inc. has authorized distribution of Mylan Pharma's generic pharmaceutical products throughout West Virginia.

10. Mylan Inc. markets, distributes and/or sells, throughout the United States and this judicial district, generic pharmaceutical products through Mylan Pharma. Mylan Inc. derives substantial revenue from selling generic pharmaceutical products throughout the United States and in this judicial district and is registered to do business in West Virginia, and therefore has consented to suit in West Virginia.

11. Mylan Pharma serves as an agent of Mylan Inc., and has submitted regulatory filings for generic pharmaceutical products to the FDA on Mylan Inc.'s behalf.

12. The Defendants operate and act in concert as an integrated, unitary business.

13. Mylan Pharma and Mylan Inc. have previously invoked this Court's jurisdiction, or have stipulated and/or consented to personal jurisdiction in this district in prior cases under the Hatch-Waxman Act. *See e.g. Novartis Pharms. Co. et al. v. Mylan Pharms. Inc. et al.*, No. 1:11-cv-00015-IMK (N.D. W. Va.); *Shire LLC et al. v. Mylan Pharms. Inc. et al.*, No. 1:11-cv-0055-IMK-JSK (N.D. W. Va.); *Alza Corp. et al. v. Mylan Pharms. Inc. et al.*, No. 1:14-cv-00086-

IMK-JSK (N.D. W. Va.); *Acorda Therapeutics, Inc. et al. v. Mylan Pharms. Inc. et al.*, No. 1:14-cv-00139-IMK (N.D. W. Va.); *Teva Pharms. USA, Inc. et al. v. Mylan Pharms. Inc. et al.*, No. 1:14-cv-00167-IMK (N.D. W. Va.); *Pfizer Inc. et al. v. Mylan Inc. et al.*, No. 1:15-cv-00004-IMK (N.D. W. Va.); *Noven Pharms., Inc. et al. v. Mylan Techs., Inc. et al*, No. 1:15-cv-00069-IMK-JSK (N.D. W. Va.); and *Janssen Pharmaceutica, N.V. et al. v. Mylan Pharms., Inc. and Mylan, Inc.*, No. 1:15-cv-00152-IMK (N.D. W. Va.).

14. Venue is proper in the Norther District of West Virginia pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

The '209 Patent

15. On January 24, 2012, the '209 patent, entitled "Microparticulate Oral Galenical Form For The Delayed And Controlled Release Of Pharmaceutical Active Principles," was duly and legally issued by the U.S. Patent and Trademark Office ("PTO"), listing as inventors Valerie Legrand, Catherine Castan, Remi Meyrueix, and Gerard Soula. A copy of the '209 patent is attached hereto as Exhibit A and incorporated by reference.

16. Flamel lawfully owns all right, title and interest, including the right to sue and recover past damages, in the '209 patent.

17. 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.

Orange Book Listing for Coreg CR®

18. The 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 '209 patent.

19. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations promulgated by the FDA pursuant thereto, the Coreg CR® related patents are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book") for indications of left ventricular dysfunction including myocardial infarction and hypertension.

20. The Orange Book lists the expiration date of the '209 patent as September 11, 2025.

Mylan's ANDA

21. On August 28, 2015, Flamel received a letter from Mylan Pharma dated August 26, 2015 ("Notification Letter"), stating that Mylan Pharma submitted Abbreviated New Drug Application ("ANDA") No. 207668 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 with stamped receipt date is attached hereto as Exhibit B and incorporated by reference.

22. According to the Notification Letter, Mylan Pharma ANDA No. 207668 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 carvedilol phosphate extended release capsules ("Mylan Product"), prior to the expiration of the '209 patent.

23. According to the Notification Letter, ANDA No. 207668 contains an allegation under § 505(j)(2)(A)(vii)(IV) that the claims of the '209 patent are invalid, unenforceable and/or not infringed by the Mylan Product.

24. Mylan Pharma's submission to the FDA of ANDA No. 207668 with its § 505(j)(2)(A)(vii)(IV) allegations constitutes infringement of the '209 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan commercially makes, uses, offers to sell or sells the Mylan Product in the United States or imports the Mylan Product into the United States, or induces or contributes to any such conduct during the term of the '209 patent, it would further infringe that patent under 35 U.S.C. § 271(a), (b) and/or (c).

25. Mylan had actual and constructive notice of the '209 patent prior to filing ANDA No. 207668 and, on information and belief, was aware that the filing of ANDA No. 207668 would infringe the '209 patent under 35 U.S.C. § 271(e)(2)(A).

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

27. This action is 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 – Mylan Pharma)

28. The foregoing allegations of this Complaint are incorporated by reference.

29. Mylan Pharma submitted ANDA No. 207668 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use or sale of the Mylan Product throughout the United States. By submitting ANDA No. 207668, Mylan Pharma committed a willful act of infringement with respect to one or more claims of the '209 patent under 35 U.S.C. § 271(e)(2)(A), entitling Plaintiff to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 207668 be a date, if any, which is not earlier than the expiration date of the '209 patent.

30. Any commercial manufacture, use, offer for sale and/or importation of the Mylan Product prior to the '209 patent expiration date will constitute infringement of the '209 patent, either literally or under the doctrine of equivalents, contributory infringement of the '209 patent and/or active inducement of infringement of the '209 patent.

31. Mylan Pharma had actual and constructive notice of the '209 patent prior to submitting ANDA No. 207668 to the FDA.

32. Flamel will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '209 patent. Flamel has no adequate remedy at law to redress the infringement by Mylan Pharma.

COUNT II
(Patent Infringement – Mylan Inc.)

33. The foregoing allegations of this Complaint are incorporated by reference.

34. Upon information and belief, Mylan Inc. actively and knowingly caused to be submitted and/or assisted, directly or indirectly, with, participated in, contributed to, and/or directed the submission of ANDA No. 207668 to the FDA, knowing of the '209 patent in relation to Coreg CR®.

35. By submitting ANDA No. 207668 through Mylan Pharma, Mylan Inc. committed a willful act of infringement with respect to one or more claims of the '209 patent under 35 U.S.C. § 271(e)(2)(A), entitling Plaintiff to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 207668 be a date, if any, which is not earlier than the expiration date of the '209 patent.

36. Any commercial manufacture, use, offer for sale and/or importation of the Mylan Product prior to the '209 patent expiration date will constitute infringement of the '209 patent,

either literally or under the doctrine of equivalents, contributory infringement of the '209 patent and/or active inducement of infringement of the '209 patent.

37. Mylan Inc. further induced infringement, under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), of the '209 patent by actively and knowingly causing and/or assisting with the submission of ANDA No. 207668 to the FDA knowing that the submission would constitute direct infringement of the '209 patent. Mylan Inc.'s knowing and purposeful activities of causing to be submitted and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 207668, constitute induced infringement of the '209 patent.

38. Mylan Inc. had actual and constructive notice of the '209 patent prior to the submission of ANDA No. 207668 to the FDA.

39. Flamel will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '209 patent. Flamel has no adequate remedy at law to redress the infringement by Mylan Inc.

COUNT III
(Declaratory Judgment)

40. The foregoing allegations of this Complaint are incorporated by reference.

41. The filing by Mylan with the FDA has raised the concern of Flamel that there is an imminent expectation that Mylan will begin making, using, selling and offering for sale materials that fall under one or more claims of the '209 patent.

42. Any commercial manufacture, use, offer for sale, sale and/or importation of the Mylan Product prior to the '209 patent expiration date will constitute infringement of the '209 patent, either literally or under the doctrine of equivalents, contributory infringement of the '209 patent and/or active inducement of infringement of the '209 patent, for which Flamel seeks declaratory judgment to this effect.

REQUEST FOR RELIEF

Flamel respectfully requests the following relief:

a. A judgment that Mylan Pharma and Mylan Inc. have infringed one or more claims of the '209 patent;

b. A judgment that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 207668 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 '209 patent, including any extension and additional periods of exclusivity;

c. A judgment granting preliminary and permanent injunctions, pursuant to 35 U.S.C. § 271(e)(4)(B) and otherwise, enjoining Mylan, 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 Mylan Product within the United States or importing the Mylan Product into the United States, prior to the expiration of the '209 patent, including any extension and additional periods of exclusivity;

d. A judgment declaring that any commercial manufacture, use, offer for sale, sale and/or importation of the Mylan Product prior to the patent expiration date will constitute infringement of the '209 patent, either literally or under the doctrine of equivalents, contributory infringement of the '209 patent and/or active inducement of infringement of the '209 patent;

e. A judgment for Flamel for damages if Mylan engages in the commercial manufacture, use, offer for sale, and/or importation of the Mylan Product prior to the '209 expiration date, and that relief be increased to treble the amount found or assessed, together with interest;

f. A judgment declaring that this is an exceptional case pursuant to 35 U.S.C. §§ 271(e)(4) and 285, entitling Flamel to its reasonable attorney's fees and the costs and expenses in this action;

g. Award of costs; and

h. Such other relief as the Court deems just and proper under the circumstances.

October 9, 2015

Respectfully submitted,

/s/*Chad L. Taylor*

Frank E. Simmerman, Jr. (WVSB# 3403)
fes@simmermanlaw.com
Chad L. Taylor (WVSB# 10564)
clt@simmermanlaw.com
Frank E. Simmerman, III (WVSB# 11589)
trey@simmermanlaw.com
SIMMERMAN LAW OFFICE, PLLC
254 East Main Street
Clarksburg, West Virginia 26301
(304) 623-4900 (Telephone)
(304) 623-4906 (Facsimile)

Attorneys for Flamel Ireland Ltd.

Of Counsel:
(pro hac vice applications forthcoming)

Scott Chambers, Ph.D.
Richard J. Oparil
Kevin M. Bell
William John McKeague, Ph.D.
B. Dell Chism
Caroline C. Maxwell
Porzio, Bromberg & Newman P.C.
1200 New Hampshire Ave., NW
Suite 710
Washington, DC 20036-6802