IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

SHIRE DEVELOPMENT LLC, SHIRE PHARMACEUTICAL DEVELOPMENT INC., COSMO TECHNOLOGIES LIMITED, and GIULIANI INTERNATIONAL LIMITED,	)	C.A. No. _____
Plaintiffs,	)	
v.	)	
MYLAN PHARMACEUTICALS INC., and MYLAN INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Shire Development LLC, Shire Pharmaceutical Development Inc. (collectively, "Shire"), Cosmo Technologies Limited ("Cosmo"), and Giuliani International Limited ("Giuliani") (collectively, "Plaintiffs") by their undersigned attorneys, for their Complaint against defendants Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") and Mylan Inc. ("Mylan Inc.") (collectively, "Defendants") herein, allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 6,773,720 ("the '720 patent" or "the patent-in-suit") (attached as Exhibit A).

THE PARTIES

2. Plaintiff Shire Development LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 725 Chesterbrook Boulevard, Wayne, Pennsylvania 19087.

3. Plaintiff Shire Pharmaceutical Development Inc. is a corporation organized and existing under the laws of the State of Maryland, having its principal place of business at 1801 Research Boulevard, Rockville, Maryland 20850.

4. Plaintiff Cosmo is a company organized and existing under the laws of Ireland, having its principal place of business at 2, Duncairn Terrace, Bray Co., Wicklow, Ireland.

5. Plaintiff Giuliani is a company organized and existing under the laws of Ireland, having its principal place of business at 33 Sir John Rogerson's Quay, Dublin 2, Ireland.

6. Upon information and belief, Mylan Pharmaceuticals is a company organized under the laws of the State of West Virginia and operating at its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals is registered to transact business in the State of Florida and maintains an office located at 450 Westshore Plaza, Tampa, Florida 33609.

7. Upon information and belief, Mylan Inc. is a company organized and existing under the laws of the State of Pennsylvania and operating at its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

8. Upon information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc. Upon information and belief, Mylan Pharmaceuticals acts at the direction of, under the control of, and for the direct benefit of Mylan Inc. and is controlled and/or dominated by Mylan Inc.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c), 1391(d) and 1400(b).

10. This Court has personal jurisdiction over Mylan Pharmaceuticals. Mylan Pharmaceuticals has submitted to personal jurisdiction in this Court because, *inter alia*, it resides and is transacting business in this judicial district.

11. Upon information and belief, Mylan Inc. is in the business of, *inter alia*, the development, manufacturing, marketing, sale and distribution of generic pharmaceutical products for the United States market through its various subsidiaries, including Mylan Pharmaceuticals. Mylan Inc.'s Form 10-K, filed with the U.S. Securities and Exchange Commission on February 21, 2012, identifies Mylan Pharmaceuticals as its "primary U.S. pharmaceutical research, development, manufacturing and distribution subsidiary" and further states that "sales [of generic prescriptions] in the U.S. are derived principally through" Mylan Pharmaceuticals.

12. Upon information and belief, Mylan Pharmaceuticals and Mylan Inc. are agents of each other and/or work in concert with each other and/or other subsidiaries of Mylan Inc. with respect to the development, regulatory approval, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

13. Upon information and belief, Defendants derive substantial revenue from articles used and consumed in this judicial district. Upon information and belief, Walgreen Co. sells at least Defendants' Bupropion Tablets (75 mg and 100 mg), Bupropion XL Tablets (150 mg and 300 mg), and Diazepam Tablets (2 mg, 5 mg and 10 mg) through a broad distribution network in this judicial district, with at least thirty locations in Tampa, Florida and at least forty-seven locations in Orlando, Florida. Upon information and belief, CVS/pharmacy sells at least

Defendants' Levothyroxine Tablets (0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.1 mg, 0.112 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg and 0.3 mg), Lorazepam Tablets (1 mg and 2 mg), and Paroxetine Extended-Release Tablets (12.5 mg and 25 mg) through a broad distribution network in this judicial district, with at least nineteen locations in Tampa, Florida and at least twenty-one locations in Orlando, Florida.

14. This Court has personal jurisdiction over Mylan Pharmaceuticals and Mylan Inc. because, *inter alia*, they directly or indirectly through agents, including each other, regularly transact or solicit business in this judicial district and/or derive substantial revenue from services or things used or consumed in this judicial district. These activities demonstrate that Mylan Pharmaceuticals and Mylan Inc. have continuous and systematic contacts with this judicial district.

FACTS AS TO ALL COUNTS

15. Shire Development LLC is the owner of New Drug Application ("NDA") No. 22-000, approved by the U.S. Food and Drug Administration ("FDA") for the manufacture and sale of mesalamine delayed release tablets, containing 1.2g mesalamine, which are commercialized under the name of Lialda®. Lialda® is indicated for the induction of remission in adults with active, mild to moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis.

16. Pursuant to 21 U.S.C. § 355(b)(1), the patent-in-suit is listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange *Book*") as covering Lialda®.

17. Upon information and belief, Defendants worked in concert to prepare, submit, and file ANDA No. 20-3574 ("the Mylan ANDA") to FDA under § 505(j) of the Federal Food,

Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic mesalamine delayed-release tablets, containing 1.2g of mesalamine as the active ingredient ("the Mylan Product") and included a "paragraph IV" certification seeking approval before patent expiration.

18. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

19. Mylan Pharmaceuticals sent letters addressed to Shire Pharmaceuticals and Cosmo Technologies Ltd., dated April 12, 2012, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(i)-(iv) of the Federal Food, Drug, and Cosmetic Act ("FDCA") and 21 C.F.R. § 314.95 regarding the Mylan Product (the "Mylan Notice Letter").

20. The Mylan Notice Letter provides insufficient basis for the determination of any alleged non-infringement and/or invalidity of the '720 patent. Specifically, it does not provide "a detailed statement of the factual and legal basis" of the opinion that the '720 patent is invalid or

will not be infringed, under the requirements of 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F. R. § 314.95(c)(6).

21. The Mylan Notice Letter included an "Offer of Confidential Access" purportedly pursuant to 21 U.S.C. § 355(j)(5)(C). Plaintiffs' counsel have contacted Defendants through their counsel, objecting to certain provisions of the Offer of Confidential Access as unreasonable and requesting, *inter alia*, confidential access to the Mylan ANDA in its entirety. As of the date of this Complaint, Plaintiffs have not received a response and have not been granted such access to the Mylan ANDA.

22. Plaintiffs believe that infringement of valid patent claims exists, but must resort to the judicial process to fully assess Defendants' potential defenses to Plaintiffs' claims, in light of Defendants' denial of confidential access to the Mylan ANDA in its entirety and the limited information provided in the Mylan Notice Letter. *See, e.g.*, 21 U.S.C. § 355(j)(2)(B)(iv)(II); 21 C.F.R. § 314.95(c)(6).

FIRST COUNT
(Infringement of the '720 Patent by Defendants)

23. Plaintiffs repeat and re-allege each of foregoing paragraphs as if fully set forth herein.

24. The '720 patent, titled "Mesalazine Controlled Release Oral Pharmaceutical Compositions," was duly and legally issued by the United States Patent and Trademark Office on August 10, 2004 to Roberto Villa, Massimo Pedrani, Mauro Ajani, and Lorenzo Fossati, who assigned the '720 patent to Cosmo S.p.A. Cosmo S.p.A. granted Giuliani S.p.A. an exclusive license for the '720 patent. Giuliani S.p.A., in turn, granted Shire Pharmaceutical Development Inc. an exclusive sublicense for the '720 patent. Subsequently, Giuliani S.p.A. assigned the

license agreement with Shire Pharmaceutical Development Inc. to Giuliani, and Cosmo became the owner of the '720 patent on assignment from Cosmo S.p.A.

25. Upon information and belief, Defendants seek FDA approval for the manufacture and/or distribution of the Mylan Product.

26. Upon information and belief, the Mylan ANDA includes a paragraph IV certification to the '720 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Product before the expiration of the '720 patent.

27. Upon information and belief, Mylan Pharmaceuticals and/or Mylan Inc. will commercially manufacture, sell, offer for sale, and/or import the Mylan Product immediately upon FDA approval.

28. Upon information and belief, as of the date of the Mylan Notice Letter, Defendants were aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

29. The submission and filing of ANDA No. 20-3574 with a paragraph IV certification to the '720 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Mylan Product before the expiration of the '720 patent is an act of infringement by Mylan Pharmaceuticals and/or Mylan Inc. of one or more claims of the '720 patent under 35 U.S.C. § 271(e)(2)(A).

30. Upon information and belief, the commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Mylan Product that is the subject of ANDA No. 20-3574 will infringe one or more claims of the '720 patent under 35 U.S.C. § 271.

31. Upon information and belief, the sale or offer for sale of the Mylan Product by Mylan Pharmaceuticals and/or Mylan Inc. would induce and/or contribute to third party infringement of one or more claims of the '720 patent under 35 U.S.C. § 271.

32. Upon information and belief, as of the date of the Mylan Notice Letter, Mylan Pharmaceuticals and/or Mylan Inc. were aware of the existence of the '720 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '720 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

33. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which none has an adequate remedy at law, unless Mylan Pharmaceuticals and/or Mylan Inc. are preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Induced and/or Contributory Infringement of the '720 Patent by Mylan Inc.)

34. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

35. Mylan Inc. is jointly and severally liable for Mylan Pharmaceuticals' infringement of one or more claims of the '720 patent.

36. Upon information and belief, Mylan Inc. knowingly induced Mylan Pharmaceuticals to infringe and/or contributed to Mylan Pharmaceuticals' infringement of one or more claims of the '720 patent.

37. Upon information and belief, Mylan Inc. actively induced, encouraged, aided, or abetted Mylan Pharmaceuticals' preparation, submission and filing of ANDA No. 20-3574 with a paragraph IV certification to the '720 patent.

38. Mylan Inc.'s inducement, encouragement, aiding, or abetting of Mylan Pharmaceuticals' preparation, submission, and filing of ANDA No. 20-3574 with a paragraph IV

certification constitutes infringement of the '720 patent under 35 U.S.C. § 271(e)(2)(A). Further, Mylan Inc.'s commercial use, sale, offer for sale and/or importation of the Mylan Product would induce and/or contribute to Mylan Pharmaceuticals' infringement of the '720 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

39. Upon information and belief, Mylan Inc.'s inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of the Mylan Product by Mylan Pharmaceuticals would induce and/or contribute to third party infringement of one or more claims of the '720 patent under 35 U.S.C. § 271.

40. Upon information and belief, Mylan Inc. has, continues to, and will actively induce, encourage, aid, or abet Mylan Pharmaceuticals' infringement of the '720 patent with knowledge that it is in contravention of the rights of Plaintiffs.

41. Upon information and belief, as of the date of the Mylan Notice Letter, Mylan Inc. was aware of the existence of the '720 patent and acted without a reasonable basis for believing that it would not be liable for inducing and/or contributing to Mylan Pharmaceuticals' infringement of the '720 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

42. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which none has an adequate remedy at law, unless Mylan Inc. is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the '720 patent is valid and enforceable;

(b) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission and filing of ANDA No. 20-3574 with a paragraph IV certification to the FDA to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in

the United States of the products that are the subject of ANDA No. 20-3574 prior to the expiration of the '720 patent was an act of infringement of the '720 patent by Defendants;

(c) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A) and/or 35 U.S.C. § 271(a), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 20-3574 prior to the expiration of the '720 patent will constitute an act of infringement of the '720 patent by Defendants;

(d) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Mylan Inc. has and continues to induce and/or contribute to Mylan Pharmaceuticals' infringement of the '720 patent based on the submission to the FDA of ANDA No. 20-3574 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 20-3574 prior to the expiration of the '720 patent;

(e) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 20-3574 by Mylan Pharmaceuticals and/or Mylan Inc. would induce and/or contribute to third party infringement of the '720 patent;

(f) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Mylan Inc. would induce and/or contribute to Mylan Pharmaceuticals' infringement of the '720 patent based on the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 20-3574 prior to the expiration of the '720 patent;

(g) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Mylan Inc.'s inducement, encouragement, aiding, or abetting of Mylan Pharmaceuticals' commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 20-3574 would induce and/or contribute to third party infringement of the '720 patent;

(h) An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 20-3574 shall be no earlier than the date on which the '720 patent expires;

(i) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the products that are the subject of ANDA No. 20-3574 until the expiration of the '720 patent;

(j) A judgment awarding Plaintiffs damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell and/or import into the United States any products that are the subject of ANDA No. 20-3574 prior to the expiration of the '720 patent;

(k) A judgment declaring that Defendants' infringement of the '720 patent based on ANDA No. 20-3574 is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 20-3574 prior to the expiration of the '720 patent;

(l) A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Plaintiffs its attorneys' fees and costs;

(m) Such other and further relief as this Court may deem just and proper.

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