IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
FORT LAUDERDALE DIVISION

CASE NO.: _____

SHIRE DEVELOPMENT LLC,
SHIRE PHARMACEUTICAL
DEVELOPMENT INC.,
COSMO TECHNOLOGIES LIMITED and
GIULIANI INTERNATIONAL LIMITED,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC. and
WATSON LABORATORIES, INC. –
FLORIDA ,

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 Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") and Watson Laboratories, Inc. – Florida ("Watson Florida") (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 hereto as Ex. "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, Watson Pharmaceuticals is a company organized under the laws of the State of Nevada and operating at its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. Watson Pharmaceuticals 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 Watson Florida.

8. Upon information and belief, Watson Florida is a company organized and existing under the laws of the State of Florida and operating at its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Watson has a registered agent for service of process in the State of Florida located at 1200 South Pine Island Road, Plantation, Florida 33324.

9. Watson Florida was formerly known as Andrx Pharmaceuticals, Inc. and is a wholly-owned subsidiary of defendant Watson Pharmaceuticals. Upon information and belief,

Watson Florida acts at the direction of, under the control of, and for the direct benefit of Watson Pharmaceuticals and is controlled and/or dominated by Watson Pharmaceuticals.

JURISDICTION AND VENUE

10. 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) and 1400(b).

11. This Court has personal jurisdiction over Watson Florida. Watson Florida has submitted to personal jurisdiction in this Court because, *inter alia*, it resides and is doing business in this judicial district.

12. This Court has personal jurisdiction over Watson Pharmaceuticals and Watson Florida because, *inter alia*, they directly or indirectly through agents, including each other regularly do 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 Watson Pharmaceuticals and Watson Florida have continuous and systematic contacts with this judicial district.

13. Watson Pharmaceuticals and Watson Florida are agents of each other and/or work in concert with each other and/or other subsidiaries of Watson Pharmaceuticals with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products throughout the United States, including in this judicial district.

14. Watson Pharmaceuticals' website states that its Global Generics segment has a portfolio of over 190 pharmaceutical product families, and that the Generic Division filed thirty (30) new Abbreviated New Drug Applications ("ANDAs") in 2011. Watson Pharmaceuticals' website further states that net revenues from the Global Generics segment accounted for $3.4 billion, roughly 73% of total net revenues in 2011, and that their "global generics business in the

U.S. remains the dominant source of revenue for the Company with approximately 84% of total generic net revenues coming from our U.S. businesses."

15. Watson Pharmaceuticals' Form 10-K, filed with the U.S. Securities and Exchange Commission on February 16, 2012, states that their research and development efforts relating to, *inter alia*, generic products were being conducted in Davie and Weston, Florida. Upon information and belief, Watson Pharmaceuticals presently distributes generic products from its Weston, Florida facility. Upon information and belief, Watson Pharmaceuticals also maintains distribution (including warehousing and storage) facilities in Sunrise, Florida and maintains administration, sales and marketing facilities in Weston, Florida.

16. Upon information and belief, G. Michael Bryner, to whom correspondence is directed in the March 26, 2012 "Notification of Certifications of Invalidity and/or Noninfringement for U.S. Patent No. 6,773,720 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" (the "Watson Notice Letter") is registered with the United States Patent and Trademark Office as a patent attorney for Watson Pharmaceuticals.

FACTS AS TO ALL COUNTS

17. 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.

18. 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®.

19. Upon information and belief, Defendants worked in concert to prepare, submit, and file ANDA No. 203817 ("the Watson 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 Watson Product") and included a "paragraph IV" certification seeking approval before patent expiration.

20. 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).

21. The Watson Notice Letter, dated March 26, 2012, was sent purportedly pursuant to § 505(j)(2)(B)(iv) of the FDCA and 21 C.F.R. § 314.95 regarding the Watson Product.

22. The Watson 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).

23. The Watson 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 Watson ANDA in its entirety. As of the date of this Complaint, Defendants have not granted such access.

24. 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 Watson ANDA in its entirety and the extremely limited information provided in the Watson 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)

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

26. 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.

27. Upon information and belief, Defendants seek FDA approval for the manufacture

and/or distribution of the Watson Product.

28. Upon information and belief, the Watson 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 Watson Product before the expiration of the '720 patent.

29. Upon information and belief, Watson Pharmaceuticals and/or Watson Florida will commercially manufacture, sell, offer for sale, and/or import the Watson Product immediately upon FDA approval.

30. Upon information and belief, as of the date of the Watson 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).

31. The submission and filing of ANDA No. 203817 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 Watson Product before the expiration of the '720 patent is an act of infringement by Watson Pharmaceuticals and/or Watson Florida of one or more claims of the '720 patent under 35 U.S.C. § 271(e)(2)(A).

32. Upon information and belief, the commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Watson Product that is the subject of ANDA No. 203817 will infringe one or more claims of the '720 patent under 35 U.S.C. § 271.

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

34. Upon information and belief, as of the date of the Watson Notice Letter, Watson

Pharmaceuticals and Watson Florida were aware of the existence of the '720 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '720 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

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

SECOND COUNT
(Induced and/or Contributory Infringement of '720 Patent by Watson Pharmaceuticals)

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

37. Watson Pharmaceuticals is jointly and severally liable for Watson Florida's infringement of one or more claims of the '720 patent.

38. Upon information and belief, Watson Pharmaceuticals knowingly induced Watson Florida to infringe and/or contributed to Watson Florida's infringement of one or more claims of the '720 patent.

39. Upon information and belief, Watson Pharmaceuticals actively induced, encouraged, aided, or abetted Watson Florida's preparation, submission and filing of ANDA No. 203817 with a paragraph IV certification to the '720 patent.

40. Watson Pharmaceuticals' inducement, encouragement, aiding, or abetting of Watson Florida's preparation, submission, and filing of ANDA No. 203817 with a paragraph IV certification constitutes infringement of the '720 patent under 35 U.S.C. § 271(e)(2)(A). Further, Watson Pharmaceuticals' commercial use, sale, offer for sale and/or importation of the Watson Product would induce and/or contribute to Watson Florida's infringement of the '720 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

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

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

43. Upon information and belief, as of the date of the Watson Notice Letter, Watson Pharmaceuticals 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 Watson Florida's infringement of the '720 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

44. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which none has an adequate remedy at law, unless Watson Pharmaceuticals 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. 203817 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. 203817 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. 203817 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), Watson Pharmaceuticals has and continues to induce and/or contribute to Watson Florida's infringement of the '720 patent based on the submission to the FDA of ANDA No. 203817 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. 203817 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. 203817 by Defendants 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), Watson Pharmaceuticals would induce and/or contribute to Watson Florida's 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. 203817 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), Watson Pharmaceuticals' inducement, encouragement, aiding, or abetting of Watson Florida's commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 203817 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. 203817 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. 203817 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 any products that are the subject of ANDA No. 203817 prior to the expiration of the ’720 patent;

(k) A judgment declaring that Defendants’ infringement of the ’720 patent based on ANDA No. 203817 is willful if Defendants commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 203817 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.

Dated this 8th day of May, 2012.

Respectfully submitted,

s./ W. Barry Blum

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