UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

SHIRE PHARMACEUTICAL DEVELOPMENT INC., SHIRE DEVELOPMENT LLC, COSMO TECHNOLOGIES LIMITED, and NOGRA PHARMA LIMITED, **Plaintiffs,** **v.** **LUPIN LIMITED, LUPIN PHARMACEUTICALS INC., LUPIN INC., and LUPIN ATLANTIS HOLDINGS SA** **Defendants.**	**Civil Action No. _____**

COMPLAINT

Plaintiffs Shire Pharmaceutical Development Inc., Shire Development LLC (collectively, "Shire"), Cosmo Technologies Limited ("Cosmo"), and Nogra Pharma Limited ("Nogra") (collectively, "Plaintiffs") by their undersigned attorneys, for their Complaint against defendants Lupin Limited ("Lupin Ltd."), Lupin Pharmaceuticals Inc. ("LPI"), Lupin Inc. ("Lupin Inc."), and Lupin Atlantis Holdings SA ("Lupin Atlantis") (collectively "Lupin" or "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 Exhibit A.

THE PARTIES

2. 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 1200 Morris Drive, Wayne, PA 19087.

3. 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 735 Chesterbrook Boulevard and 1200 Morris Drive, Wayne, Pennsylvania 19087.

4. Plaintiff Cosmo is a company organized and existing under the laws of Ireland, having its principal place of business at The Connolly Building, 42-43 Amiens Street, Dublin 1, Ireland.

5. Plaintiff Nogra 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, Lupin Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

7. Upon information and belief, Lupin Ltd. is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States—including throughout the state of Maryland—directly and/or through its subsidiaries, affiliates and/or agents, including Lupin Atlantis, Lupin Inc., and LPI.

8. Lupin Ltd.'s 2015 Annual Report states that "Lupin is the 6th largest generics company in the US" and has derived over $891 million USD of sales in the United States during fiscal year 2015, which accounts for 45% of its global revenue. Lupin Ltd.'s website states that "[t]he US continues to be the principal growth engine for the Company and our performance in

the US over the last 10 years has been one of the most exciting growth stories in the pharmaceutical industry; that of the creation of a top 10 global generic powerhouse . . . ." Lupin Ltd.'s 2015 Annual Report further states that Lupin Ltd. "now has 99 ANDAs pending for approval and launch addressing a total market size of over USD 62 billion." Lupin Ltd.'s 2015 Annual Report identifies LPI, Lupin Atlantis, and Lupin Inc. as subsidiaries of Lupin Ltd.

9. Upon information and belief, LPI is a corporation organized and existing under the laws of the Commonwealth of Virginia, having its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st floor, Baltimore, Maryland 21202.

10. Upon information and belief, LPI is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States—including throughout the state of Maryland—directly and/or through its affiliates and/or agents, including Lupin Ltd., Lupin Atlantis, and Lupin Inc.

11. Upon information and belief, LPI is a wholly owned subsidiary and agent of Lupin Ltd. Upon information and belief, LPI acts at the direction of, under the control of, and for the direct benefit of Lupin Ltd. and is controlled and/or dominated by Lupin Ltd. Upon information and belief, LPI and Lupin Ltd. have at least one officer or director in common. Lupin Ltd.'s 2015 Annual Report states that "[t]he shares of [LPI] are held by Lupin Inc.[] (97%) and Lupin Limited (3%) . . . The entire shareholdings in Lupin Inc. . . . are held by Lupin Atlantis[], the wholly owned subsidiary of [Lupin Ltd.]"

12. Upon information and belief, LPI is Lupin Ltd.'s marketing and sales agent in the United States, engaged in the sale and distribution of generic pharmaceutical products throughout the United States, including in the state of Maryland.

13. LPI's website states that since 2003, it has "received more than 75 FDA approvals and ha[s] become one of the fastest growing pharmaceuticals companies in the US." Upon information and belief, LPI was "founded on the strengths of [its] parent company Lupin Limited [and] intends to bring a portfolio of generics as well as branded products to the US market." Upon information and belief, LPI "is the exclusive US distributor for all of the products developed and manufactured by its parent company, Lupin Ltd., and other affiliate companies."

14. Upon information and belief, LPI has Authorized Distributors for its Generics Division located in the state of Maryland. Upon information and belief, LPI derives substantial revenue from articles sold, used, and/or consumed in this judicial district. Upon information and belief, CVS/pharmacy sells at least Lupin's Cefdinir capsules (300mg), Cefuroxime tablets (250mg, 500mg), Cephalexin capsules (250mg and 500mg), Lisinopril tablets (2.5mg, 5mg, 10mg, 20mg, 30mg, 40mg), Ramipril capsules (1.25mg, 2.5mg, 5mg, 10mg), and Simvastatin tablets (10mg, 20mg, 80mg). CVS/pharmacy has at least 175 locations in the state of Maryland.

15. Upon information and belief, Lupin Inc. is a corporation organized and existing under the laws of the state of Maryland, having its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, MD 21202.

16. Upon information and belief, Lupin Inc. is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States—including throughout the state of Maryland—directly and/or through its subsidiaries, affiliates and/or agents, including Lupin Ltd., Lupin Atlantis, and LPI.

17. Upon information and belief, Lupin Inc. is a wholly owned subsidiary and agent of Lupin Ltd. Upon information and belief, Lupin Inc. acts at the direction of, under the control of, and for the benefit of Lupin Ltd. and is controlled and/or dominated by Lupin Ltd. Upon

information and belief, Lupin Inc. and Lupin Ltd. have at least one officer or director in common.

18. Upon information and belief, Lupin Inc. derives substantial revenue from articles sold, used, and/or consumed in this judicial district. Upon information and belief, Lupin Inc. and LPI elected to be included in a consolidated tax return for the United States Internal Revenue Service, such that taxes of Lupin Inc. and LPI would be paid on a consolidated basis by Lupin Inc.

19. Upon information and belief, Lupin Atlantis is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Mülentalstrasse 2, 8200 Schaffhuasen, Switzerland.

20. Upon information and belief, Lupin Atlantis is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States—including throughout the state of Maryland—directly and/or through its subsidiaries, affiliates and/or agents, including Lupin Ltd., Lupin Inc., and LPI.

21. Upon information and belief, Lupin Atlantis is a wholly owned subsidiary and agent of Lupin Ltd. Upon information and belief, Lupin Atlantis acts at the direction of, under the control of, and for the benefit of Lupin Ltd. and is controlled and/or dominated by Lupin Ltd.

22. Upon information and belief, Lupin Atlantis is engaged in the filing of Abbreviated New Drug Applications ("ANDAs") for the development, manufacture, importation, and sale of generic pharmaceutical products throughout the United States and in this judicial district.[1]

[1] "Lupin admits that Lupin Atlantis filed ANDA No. 208348 to gain approval for Oseltamivir Phosphate Capsules . . . ." *Gilead Sci., Inc., et al. v. Lupin Pharms., Inc., et al.*, Civ. Case No. 15-1956, D.I. 24, at 7 (D. Md. Sep. 8, 2015); "Lupin Atlantis Holdings SA admits that it submitted ANDA No. 205589 to the FDA . . . ." *Otsuka Pharm. Co., Ltd.* v. *Lupin Ltd., et al.*, Civ. Case No. 14-7105, D.I. 37, at 5 (D.N.J. Mar. 9, 2015).

23. Upon information and belief, Lupin Atlantis and Lupin Ltd. derive substantial revenue from articles sold, used, and/or consumed in this judicial district. Upon information and belief, CVS/pharmacy sells at least Lupin's Antara (fenofibrate) capsules (30mg and 90mg), fenofibrate (micronized) capsules (43mg and 130mg), and Fenofibrate tablets (48mg and 145mg). CVS/pharmacy has at least 175 locations in the state of Maryland.

24. Upon information and belief, Defendants hold themselves out as a single entity for the purposes of the manufacture, sale, marketing, distribution, and importation of generic drug products.

25. Upon information and belief, Defendants work in concert with each other to obtain regulatory approval, at least regarding the filing of ANDAs with the United States Food and Drug Administration ("FDA") in Maryland. Upon information and belief, Defendants work in concert with each other with respect to the manufacture, sale, marketing, distribution, and importation of generic drug products throughout the United States, including in the state of Maryland.

JURISDICTION AND VENUE

26. 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(b) and (c), and § 1400(b).

27. This Court has personal jurisdiction over Lupin Ltd. because, *inter alia*: (i) Lupin Ltd. is doing business in Maryland and maintains continuous and systematic contacts with this judicial district; (ii) Lupin Ltd. is in the business of manufacturing, marketing, importing, selling, and distributing pharmaceutical drug products, including generic drug products, directly or indirectly, and in partnership or agency with Lupin Atlantis, Lupin Inc., and LPI in the state of

Maryland; (iii) Lupin Ltd., together with its agents and/or affiliates Lupin Atlantis, Lupin Inc., and LPI, has committed, induced, or contributed to acts of patent infringement in Maryland, for example, ANDA No. 205-100 was filed with the FDA in Maryland; (iv) Lupin Ltd. has submitted to the jurisdiction of this Court at least eight (8) prior Maryland actions;[2] and (v) Lupin Ltd. has availed itself to the rights, benefits, and privileges of this Court by asserting claims and/or counterclaims in at least nine (9) prior Maryland actions.[3]

28. This Court has personal jurisdiction over LPI because, *inter alia*: (i) LPI's principal place of business is located in Maryland; (ii) LPI is doing business in Maryland and maintains continuous and systematic contacts with this judicial district; (iii) LPI is in the business of manufacturing, marketing, importing, selling, and distributing pharmaceutical drug products, including generic drug products, directly or indirectly, and in partnership or agency with Lupin Ltd., Lupin Inc., and Lupin Atlantis in the state of Maryland; (iv) LPI, together with its agents and/or affiliates Lupin Ltd., Lupin Inc., and Lupin Atlantis, has committed, induced, or contributed to acts of patent infringement in Maryland, for example, ANDA No. 205-100 was filed with the FDA in Maryland; (v) LPI has submitted to the jurisdiction of this Court in at least seven (7) prior Maryland litigations;[4] and (vi) LPI has availed itself to the rights, benefits, and

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[2] *See Flamel Techs. S.A. v. Lupin Ltd., et al.*, Civil Action No. 11-1200; *Genzyme Corp. v. Lupin Ltd., et al.*, Civil Action No. 10-1906; *Medicis Pharm. Co. v. Lupin Ltd., et al.*, Civil Action No. 09-3062; *Genzyme Corp .v. Lupin Ltd., et al.*, Civil Action No. 09-1258; *Genzyme Corp. v. Lupin Ltd., et al.*, Civil Action No. 09-0563; *Sciele Pharma, Inc., et al. v. Lupin Ltd., et al.*, Civil Action No. 09-0105; *Oscient Pharms. Corp., et al. v. Lupin Ltd., et al.*, Civil Action No 09-0083; *Wyeth v. Lupin Ltd., et al.*, Civil Action No. 07-0632

[3] *See Flamel Techs. S.A. v. Lupin Ltd., et al.*, Civil Action No. 11-1200; *Lupin Pharms., Inc. et al. v. Richards*, Civil Action No. 15-1281; *Genzyme Corp. v. Lupin Ltd., et al.*, Civil Action No. 10-1906; *Medicis Pharm. Co. v. Lupin Ltd., et al.*, Civil Action No. 09-3062; *Genzyme Corp .v. Lupin Ltd., et al.*, Civil Action No. 09-1258; *Genzyme Corp. v. Lupin Ltd., et al.*, Civil Action No. 09-0563; *Sciele Pharma, Inc., et al. v. Lupin Ltd., et al.*, Civil Action No. 09-0105; *Oscient Pharms. Corp., et al. v. Lupin Ltd., et al.*, Civil Action No 09-0083; *Wyeth v. Lupin Ltd., et al.*, Civil Action No. 07-0632

[4] *See Flamel Techs. S.A. v. Lupin Ltd., et al.*, Civil Action No. 11-1200; *Genzyme Corp. v. Lupin Ltd., et al.*, Civil Action No. 10-1906; *Medicis Pharm. Co. v. Lupin Ltd., et al.*, Civil Action No. 09-3062; *Genzyme Corp .v. Lupin Ltd., et al.*, Civil Action No. 09-1258; *Genzyme Corp. v. Lupin Ltd., et al.*, Civil Action No. 09-0563; *Sciele Pharma, Inc., et al. v. Lupin Ltd., et al.*, Civil Action No. 09-0105; *Oscient Pharms. Corp., et al. v. Lupin Ltd., et al.*, Civil Action No 09-0083.

privileges of this Court by asserting claims and/or counterclaims in at least either (8) prior Maryland actions.[5]

29. This Court has personal jurisdiction over Lupin Inc. because, *inter alia*: (i) Lupin Inc. is incorporated under the laws of the state of Maryland and has its principal office in Maryland; (ii) Lupin Inc. is doing business in Maryland and maintains continuous and systematic contacts with this judicial district; (iii) Lupin Inc. is in the business of manufacturing, marketing, importing, selling, and distributing pharmaceutical drug products, including generic drug products, directly or indirectly, and in partnership or agency with Lupin Ltd., Lupin Atlantis and LPI in the state of Maryland; and (iv) Lupin Inc., together with its agents and/or affiliates Lupin Ltd., Lupin Atlantis, and LPI, has committed, induced, or contributed to acts of patent infringement in Maryland, for example, ANDA No. 205-100 was filed with the FDA in Maryland.

30. This Court has personal jurisdiction over Lupin Atlantis because, *inter alia*: (i) Lupin Atlantis is doing business in Maryland and maintains continuous and systematic contacts with this judicial district; (ii) Lupin Atlantis is in the business of manufacturing, marketing, importing, selling, and distributing pharmaceutical drug products, including generic drug products, directly or indirectly, and in partnership or agency with Lupin Ltd., Lupin Inc., and LPI in the state of Maryland; (iii) Lupin Atlantis, together with its agents and/or affiliates Lupin Ltd., Lupin Inc., and LPI, has committed, induced, or contributed to acts of patent infringement in Maryland, for example, ANDA No. 205-100 was filed with the FDA in Maryland; (iv) Lupin

[5] *See Flamel Techs. S.A. v. Lupin Ltd., et al.*, Civil Action No. 11-1200; *Lupin Pharms., Inc. et al. v. Richards*, Civil Action No. 15-1281; *Genzyme Corp. v. Lupin Ltd., et al.*, Civil Action No. 10-1906; *Medicis Pharm. Co. v. Lupin Ltd., et al.*, Civil Action No. 09-3062; *Genzyme Corp .v. Lupin Ltd., et al.*, Civil Action No. 09-1258; *Genzyme Corp. v. Lupin Ltd., et al.*, Civil Action No. 09-0563; *Sciele Pharma, Inc., et al. v. Lupin Ltd., et al.*, Civil Action No. 09-0105; *Oscient Pharms. Corp., et al. v. Lupin Ltd., et al.*, Civil Action No 09-0083.

Atlantis has submitted to jurisdiction of those court in at least one (1) prior Maryland action;[6] and (v) Lupin Atlantis has availed itself to the rights, benefits, and privileges of this Court by asserting counterclaims in at least one (1) prior Maryland action.[7]

FACTS AS TO ALL COUNTS

31. 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 1.2 g 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.

32. 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 Cosmo Pharmaceuticals S.p.A. (now known as Cosmo Pharmaceuticals S.A.) upon assignment from inventors Roberto Villa, Massimo Pedrani, Mauro Ajani, and Lorenzo Fossati. Cosmo S.p.A. granted Giuliani S.p.A. an exclusive license to the '720 patent. Giuliani S.p.A., in turn, granted Shire Pharmaceutical Development Inc. an exclusive sublicense to the '720 patent. Subsequently, Giuliani S.p.A. assigned the license agreement with Shire Pharmaceutical Development Inc. to Nogra (formerly known as "Giuliani International Limited"), and Cosmo became the owner of the '720 patent on assignment from Cosmo Pharmaceuticals S.p.A.

[6] *See Gilead Sciences, Inc., et al., v. Lupin Pharms., Inc., et al.*, Civil Action No. 15-1956.
[7] *See id.*

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

34. Upon information and belief, Defendants worked in concert to prepare, submit, and file ANDA No. 205-100 with the FDA in Maryland 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 1.2 g of mesalamine as the active ingredient (the "Lupin ANDA Product") and included a "paragraph IV" certification seeking approval before patent expiration. The filing of an ANDA with a paragraph IV certification is an act of infringement. *See* 35 U.S.C. § 271(e)(2).

35. Upon information and belief, following any FDA approval of an ANDA, Lupin Ltd., Lupin Atlantis, Lupin Inc., and LPI will act in concert to distribute and sell the Lupin ANDA Product throughout the United States, including within Maryland. Upon information and belief, Lupin knows and intends that the Lupin ANDA Product will be distributed and sold in the United States, including in the state of Maryland.

36. An ANDA applicant is required to provide notice to the patent owner and the holder of the approved application that the ANDA contains a paragraph IV certification along with "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." *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II); *see also* 21 C.F.R. § 314.95(c)(6). The detailed statement must 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 ground supporting the allegation." 21 C.F.R. § 314.95(c)(6)(i)-(ii).

37. Lupin Ltd. sent letters addressed to Shire Development LLC, Shire Development Inc., and Cosmo Technologies Ltd. dated September 28, 2015, purportedly pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, regarding the Lupin ANDA Product (the "Lupin Notice Letter").

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

39. Plaintiffs believe that infringement of valid patent claims exist, but must resort to the judicial process to fully assess Lupin's potential defenses to Plaintiffs' claims, in light of Lupin's denial of confidential access to the Lupin ANDA in its entirety and the limited information provided in the Lupin 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)

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

41. Upon information and belief, Defendants seek FDA approval for the manufacture, use, sale, offer for sale, distribution, and/or importation into the United States of the Lupin ANDA Product.

42. Upon information and belief, ANDA No. 205-100 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 Lupin ANDA Product before the expiration of the '720 patent.

43. Upon information and belief, Lupin Ltd., LPI, Lupin Inc., and/or Lupin Atlantis will commercially manufacture, sell, offer for sale, and/or import the Lupin ANDA Product immediately upon FDA approval.

44. Upon information and belief, as of the date of the Lupin 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).

45. The submission and filing of ANDA No. 205-100 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 Lupin ANDA Product before the expiration of the '720 patent is an act of infringement by Lupin Ltd., LPI, Lupin Inc., and/or Lupin Atlantis of one or more claims of the '720 patent under 35 U.S.C. § 271(e)(2)(A).

46. Upon information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Lupin ANDA Product that is the subject of ANDA No. 205-100 will infringe one or more claims of the '720 patent under 35 U.S.C. § 271.

47. Upon information and belief, the manufacture, use, sale, offer for sale, and/or importation in the United States of the Lupin ANDA Product by Lupin Ltd., LPI, Lupin Inc., and/or Lupin Atlantis would induce and/or contribute to third-party infringement of one of more claims of the '720 patent under 35 U.S.C. § 271.

48. Upon information and belief, as of the date of the Lupin Notice Letter, Defendants 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.

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

SECOND COUNT
(Induced and/or Contributory Infringement of the '720 Patent)

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

51. Lupin Ltd. is jointly and severally liable for LPI's, Lupin Inc.'s, and/or Lupin Atlantis' infringement of one or more claims of the '720 patent.

52. Upon information and belief, Lupin Ltd. knowingly induced LPI, Lupin Inc., and/or Lupin Atlantis to infringe and/or contributed to LPI's, Lupin Inc.'s, and/or Lupin Atlantis' infringement of one of more claims of the '720 patent.

53. Upon information and belief, Lupin Ltd. actively induced, encouraged, aided, or abetted LPI's, Lupin Inc.'s, and/or Lupin Atlantis' preparation, submission, and filing of ANDA No. 205-100 with a paragraph IV certification to the '720 patent.

54. Lupin Ltd.'s inducement, encouragement, aiding, or abetting of LPI's, Lupin Inc.'s, and/or Lupin Atlantis' preparation, submission, and filing of ANDA No. 205-100 with a paragraph IV certification constitutes infringement of the '720 patent under 35 U.S.C. § 271(e)(2)(A). Further, Lupin Ltd.'s commercial use, sale, offer for sale, and/or importation of the Lupin ANDA Product into the United States would induce and/or contribute to LPI's, Lupin

Inc.'s, and/or Lupin Atlantis' infringement of the '720 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

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

56. Upon information and belief, Lupin Ltd. has, continues to, and will actively induce encourage, aid, or abet LPI's, Lupin Inc.'s, and/or Lupin Atlantis' infringement of the '720 patent with knowledge that it is in contravention of the rights of Plaintiffs.

57. Upon information and belief, as of the date of the Lupin Notice Letter, Lupin Ltd. 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 LPI's, Lupin Inc.'s, and/or Lupin Atlantis' infringement, thus rendering this case "exceptional" under 35 U.S.C. § 285.

58. The acts of infringement set forth above will cause Plaintiffs irreparable harm for which none has an adequate remedy at law, unless Lupin Ltd. 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. 205-100 with a paragraph IV certification to the FDA to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into

the United States of the products that are the subject of ANDA No. 205-100 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 into the United States of the products that are the subject of ANDA No. 205-100 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), Lupin Ltd. has and continues to induce and/or contribute to LPI's, Lupin Inc.'s, and/or Lupin Atlantis' infringement of the '720 patent based on the submission to the FDA of ANDA No. 205-100 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the products that are the subject of ANDA No. 205-100 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 into the United States of the products that are the subject of ANDA No. 205-100 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), Lupin Ltd. would induce and/or contribute to LPI's, Lupin Inc.'s, and/or Lupin Atlantis' infringement of the '720 patent based on the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the products that are the subject of ANDA No. 205-100 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), Lupin Ltd.'s inducement, encouragement, aiding, or abetting of LPI's, Lupin Inc.'s, and/or Lupin Atlantis' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the products that are the subject of ANDA No. 205-100 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), 281, and 283, the effective date of any approval of the produce that is the subject of ANDA No. 205-100 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), 281, and 283, 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 for sale, and/or importation in the United States of the Lupin ANDA Product 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 the subject of ANDA No. 205-100 prior to the expiration of the '720 patent;

(k) If Defendants commercially manufacture, use, sell, offer to sell, and/or import any products that are the subject of ANDA No. 205-100 prior to the expiration of the '720 patent, a Judgment declaring that Defendants' infringement of the '720 patent based on ANDA No. 205-100 is willful;

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

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

Dated: November 10, 2015.

Respectfully submitted,

By: s/*James P. Ulwick*

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