IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ICEUTICA PTY LTD and IROKO PHARMACEUTICALS, LLC, Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendant	C. A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

For their Complaint against Defendant Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin"), Plaintiffs iCeutica Pty Ltd ("iCeutica") and Iroko Pharmaceuticals, LLC ("Iroko") (collectively, "Plaintiffs"), by their attorneys, allege as follow:

NATURE OF ACTION

1. This is an action for infringement of United States Patent No. 8,679,544 ("the '544 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including §§ 271(e)(2) and 271(a), and for a declaratory judgment of infringement of the '544 patent under 28 U.S.C. §§ 2201 and 2202 relating to Plaintiffs' commercially successful nonsteroidal anti-inflammatory drug, ZORVOLEX® (diclofenac) Capsules 18 mg and 35 mg.

THE PARTIES

2. Plaintiff iCeutica Pty Ltd is a company organized and existing under the laws of Australia with a principal place of business at Unit 2, 32 Mumford Place, Balcatta Western Australia 6021.

3. Plaintiff Iroko Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of Delaware, with a principal place of business at One Kew Place, 150 Rouse Boulevard, Philadelphia, PA, 19112.

4. Upon information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of India, with a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

5. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. ("LPI") is a corporation organized under the laws of the Commonwealth of Virginia, having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

6. Upon information and belief, LPI is a wholly-owned subsidiary of Lupin Limited.

7. Upon information and belief, Lupin Limited is in the business of, among other things, developing, manufacturing, packaging, and selling generic versions of branded pharmaceutical products for the United States market, including in this judicial district and the State of Maryland, through its own systemic, continuous, constant and pervasive actions and through those of its agents and operating subsidiaries, including its wholly-owned subsidiary, LPI.

8. On information and belief, Lupin Limited has previously submitted to this Court's jurisdiction. *See, e.g.*, *Genzyme Corp. v. Lupin Ltd. et al.*, C.A. No. 10-cv-01906-JFM (D. Md. July 14, 2010); *Medicis Pharm. Corp. v. Lupin Ltd. et al.*, C.A. No. 09-cv-3062 (D. Md. Nov. 17, 2009).

9. Lupin Limited has purposefully availed itself of the jurisdiction of this Court by, *inter alia*, asserting counterclaims in lawsuits filed against it in this District. *See, e.g.*, *Genzyme*

Corp. v. Lupin Ltd. et al., C.A. No. 10-cv-01906-JFM (D. Md. July 14, 2010); *Medicis Pharm. Corp. v. Lupin Ltd. et al.*, C.A. No. 09-cv-3062 (D. Md. Nov. 17, 2009).

10. Upon information and belief, LPI is the United States marketing and sales agent for Lupin Limited, and is engaged in the sale and distribution of generic versions of branded pharmaceutical products, including those manufactured by Lupin Limited, in the United States, including in this judicial district and the State of Maryland, through its own systematic, continuous, constant and pervasive actions and through those of its agents.

11. Upon information and belief, LPI has previously submitted to this Court's jurisdiction. *See, e.g.*, *Genzyme Corp. v. Lupin Ltd. et al.*, C.A. No. 10-cv-01906-JFM (D. Md. July 14, 2010); *Medicis Pharm. Corp. v. Lupin Ltd. et al.*, C.A. No. 09-cv-3062 (D. Md. Nov. 17, 2009).

12. LPI has purposefully availed itself of the jurisdiction of this Court by, *inter alia*, asserting counterclaims in lawsuits filed against it in this District. *See, e.g.*, *Genzyme Corp. v. Lupin Ltd. et al.*, C.A. No. 10-cv-01906-JFM (D. Md. July 14, 2010); *Medicis Pharm. Corp. v. Lupin Ltd. et al.*, C.A. No. 09-cv-3062 (D. Md. Nov. 17, 2009).

13. Upon information and belief, LPI is a licensed wholesale drug distributor in Maryland.

14. Upon information and belief, Lupin's drug products are listed on the Maryland Preferred Drug List.

JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq*., including §§ 271(e)(2) and 271(a), and 28 U.S.C. §§

2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

16. This Court has personal jurisdiction over Lupin Limited by virtue of, *inter alia*, the fact Lupin Limited has engaged in purposeful systematic and continuous contacts with the State of Maryland. This Court has personal jurisdiction over Lupin Limited for the additional reasons set forth in this Complaint and for other reasons that will be presented to the Court if jurisdiction is challenged.

17. This Court has personal jurisdiction over Lupin Limited because, upon information and belief, Lupin Limited regularly does business in Maryland and has engaged in a persistent course of purposeful conduct within Maryland by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Maryland, and/or by directly selling pharmaceutical products in Maryland.

18. This Court has personal jurisdiction over Lupin Limited because Lupin Limited has previously been sued in this district and has not challenged personal jurisdiction, and Lupin Limited has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district.

19. This Court also has personal jurisdiction over Lupin Limited by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of Maryland law, and has engaged in systematic, continuous, constant and pervasive contacts with the State, and does business through its agent, LPI, a Maryland resident.

20. This Court has personal jurisdiction over LPI by virtue of, *inter alia*, the fact that it has a principal place of business in Maryland and is at home in Maryland.

21. This Court has personal jurisdiction over LPI by virtue of, *inter alia*, LPI has engaged in purposeful systematic and continuous contacts with the State of Maryland. This Court has personal jurisdiction over LPI for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

22. This Court has personal jurisdiction over LPI because, upon information and belief, LPI is a resident of Maryland, regularly does business in Maryland and has engaged in a persistent court of conduct within Maryland by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Maryland, and/or by directly selling pharmaceutical products in Maryland.

23. This Court has personal jurisdiction over LPI by virtue of, *inter alia*, the fact that LPI distributes drug products for sale throughout the United States, including in this judicial district.

24. The Court has personal jurisdiction over LPI because LPI has previously been sued in this district and has not challenged personal jurisdiction, and LPI has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district.

25. This Court has personal jurisdiction over LPI by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of Maryland law, and has engaged in systematic, continuous, constant and pervasive contacts with the State.

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

FACTUAL BACKGROUND

27. The ’544 patent, entitled “Formulation of Diclofenac,” issued on March 25, 2014 and names Aaron Dodd, Felix Meiser, Marck Norret, Adrian Russell, and H. William Bosch as inventors.

28. iCeutica Pty Ltd, as assignee, owns the entire right, title and interest in the ’544 patent.

29. Iroko Pharmaceuticals, LLC is the exclusive licensee to the ’544 patent in the United States.

30. Iroko Pharmaceuticals, LLC is the holder of an approved New Drug Application (“NDA”) No. 20-4592 for Diclofenac capsules 18 mg and 35 mg, sold under the ZORVOLEX® registered trademark.

31. In conjunction with that NDA, Iroko Pharmaceuticals, LLC has listed with the FDA the ’544 patent. The FDA has published the ’544 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.”

32. ZORVOLEX® is covered by at least one claim of the ’544 patent.

33. On or about November 24, 2014, Plaintiffs received a letter, dated November 24, 2014, signed on behalf of Lupin Limited by Joseph Reisman (“Lupin’s Paragraph IV Letter”).

34. Lupin’s Paragraph IV Letter stated that Lupin Limited had submitted, and the FDA had received, an Abbreviated New Drug Application (“ANDA”) under section 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of Diclofenac capsules 18 mg and 35 mg, a generic version of Plaintiffs’ ZORVOLEX® product, prior to expiration of the ’544 patent. The ANDA Number for Lupin’s application is 207393.

35. On information and belief, LPI is the authorized representative for Lupin Limited concerning ANDA No. 207393.

36. Lupin's Paragraph IV Letter stated that the '544 patent is invalid and/or would not be infringed by the commercial manufacture, importation, use, sale, or offer for sale of Lupin's proposed Diclofenac capsules 18 mg and 35 mg.

37. Attached to Lupin's Paragraph IV Letter was a statement of the factual and legal bases for Lupin's opinion that the '544 patent is invalid, unenforceable, and/or would not be infringed by the commercial manufacture, importation, use, sale, or offer for sale of Lupin's proposed generic Diclofenac capsules 18 mg and 35 mg.

38. In filing its ANDA No. 207393, Lupin has requested the FDA's approval to market a generic version of Plaintiffs' ZORVOLEX® product throughout the United States, including in this judicial district.

39. On information and belief, following FDA approval of ANDA No. 207393, Lupin Limited will manufacture, sell, offer to sell, and/or import the approved generic version of Plaintiffs' ZORVOLEX® product throughout the United States, including in this judicial district.

40. On information and belief, following FDA approval of ANDA No. 207393, LPI, as the marketing and sales agent for Lupin Limited, will sell and/or offer to sell the approved generic version of Plaintiffs' ZORVOLEX® product manufactured by Lupin Limited throughout the United States, including in this judicial district.

41. Since receiving Lupin's Paragraph IV Letter, Plaintiffs attempted to procure a copy of ANDA No. 207393 from Lupin Limited. Because the terms of the proposed Offer would not allow Plaintiffs to meaningfully process the information contained in the ANDA, including by not allowing Plaintiffs' counsel to review the ANDA, and because Lupin Limited

stated that it would not agree or admit to "the competency, relevance, or materiality of the ANDA," Plaintiffs could not agree to the terms of the original Offer. On December 11, 2014, counsel for Plaintiffs sent Lupin Limited's counsel a letter in an attempt to negotiate the Plaintiffs' access to ANDA 207393. As of December 23, 2014, Lupin Limited had not responded. On December 23, 2014, Plaintiffs filed a Complaint in the United States District Court for the District of Delaware.

42. Upon information and belief, after having reviewed the Complaint in Delaware, counsel for Lupin Limited offered to negotiate the Offer. However, given the statutory deadline for filing suit and the intervening holidays, the negotiations would not have allowed time for Plaintiffs to meaningfully analyze the substance of the ANDA, even assuming an agreement could be reached. While Plaintiffs believe jurisdiction and venue are proper in Delaware, out of an abundance of caution, Plaintiffs have filed the instant suit.

43. Plaintiffs are not aware of any other means for obtaining information regarding Lupin's proposed Diclofenac capsules 18 mg and 35 mg. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present the Court evidence that Lupin's proposed Diclofenac capsules 18 mg and 35 mg fall within the scope of one or more claims of the '544 patent.

44. Because they have been unable to obtain a copy of ANDA 207393, Plaintiffs allege the causes herein based primarily on the representations contained in Lupin's Paragraph IV Letter and the other facts alleged herein.

COUNT I

(Infringement of the '554 Patent Under 35 U.S.C. § 271(e)(2) by Lupin's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)

45. Paragraphs 1-44 are incorporated herein as set forth above.

46. Lupin Limited submitted ANDA No. 207393 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic Diclofenac capsules 18 mg and 35 mg throughout the United States. By submitting this application, Lupin Limited has committed an act of infringement of the '544 patent under 35 U.S.C. § 271(e)(2)(A).

47. On information and belief, LPI participated in, contributed to, aided, abetted and/or induced the submission of ANDA No. 207393. LPI's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 207393 constitutes an act of infringement of the '544 patent under 35 U.S.C. § 271(e)(2)(A).

48. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's proposed generic Diclofenac capsules 18 mg and 35 mg will constitute an act of direct infringement of the '544 patent.

49. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

50. Unless and until Lupin is enjoined from infringing the '544 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT II

(Declaratory Judgment of Infringement of the '554 Patent Under 35 U.S.C. § 271(a) by Lupin's Proposed Generic Diclofenac Capsules 18 mg and 35 mg)

51. Paragraphs 1-50 are incorporated herein as set forth above.

52. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

53. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

54. On information and belief, Lupin will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Diclofenac capsules 18 mg and 35 mg immediately and imminently upon approval of ANDA No. 207393.

55. Lupin's actions, including but not limited to, the development of its proposed generic Diclofenac capsules 18 mg and 35 mg, the filing of an ANDA with a Paragraph IV certification, and, on information and belief, the manufacture of exhibit batches of its proposed generic Diclofenac capsules 18 mg and 35 mg, indicate a refusal to change the course of its actions in the face of acts by Plaintiffs.

56. On information and belief, Lupin has made and will continue to make, substantial preparation in the United States, including the District of Maryland, to manufacture, sell, offer to sell, and/or import Lupin's proposed generic Diclofenac capsules 18 mg and 35 mg.

57. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's proposed generic Diclofenac capsules 18 mg and 35 mg will constitute an act of direct infringement of the '544 patent.

58. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's proposed generic Diclofenac capsules 18 mg and 35 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

59. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Lupin's proposed generic Diclofenac

capsules 18 mg and 35 mg before patent expiration by Lupin will constitute direct infringement of the ’554 patent.

60. Unless and until Lupin is enjoined from infringing the ’544 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby request a trial by jury of all issues so triable.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Lupin has infringed the ’554 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 207393 under section 505(j) of the FDCA, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Lupin’s proposed generic Diclofenac capsules 18 mg and 35 mg will constitute an act of infringement of the ’554 patent;

b. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Lupin’s ANDA No. 207393 shall be a date which is not earlier than the expiration date of the ’554 patent, as extended by any applicable period of exclusivity;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Lupin, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the ’554 patent;

d. If Lupin engages in the commercial manufacture, use, offer to sell, sale, or importation of Lupin's generic product disclosed in its ANDA No. 207393 prior to the expiration of the '554 patent, as extended by any applicable period of exclusivity, a preliminary injunction and/or permanent injunction be entered enjoining such conduct pursuant to 35 U.S.C. § 283;

e. If Lupin engages in the commercial manufacture, use, offer to sell, sale, or importation of Lupin's generic product disclosed in its ANDA No. 207393 prior to the expiration of the '554 patent, as extended by any applicable period of exclusivity, judgment awarding Plaintiffs damages or other monetary relief resulting from such infringement under 35 U.S.C. § 271(e)(4)(C);

f. That a declaration be issued under 28 U.S.C. § 2201 that if Lupin, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's proposed generic Diclofenac capsules 18 mg and 35 mg prior to patent expiration, it will constitute an act of infringement of the '554 patent;

g. That this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs;

h. An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and

i. That this Court award such other and further relief as It may deem just and proper.

Dated: January 7, 2015

FISH & RICHARDSON P.C.

By: */s/ Ahmed J. Davis*

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