IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

APOPHARMA INC., APOPHARMA USA, INC., and APOTEX TECHNOLOGIES INC., Plaintiffs, v. TARO PHARMACEUTICAL INDUSTRIES, LTD. and TARO PHARMACEUTICALS U.S.A., INC., Defendants.	Civil Action No: 2:16-cv-528 **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs ApoPharma Inc., ApoPharma USA, Inc., and Apotex Technologies Inc. (collectively, "Plaintiffs"), by and through their attorneys, for their complaint against Defendants Taro Pharmaceutical Industries, Ltd. ("Taro Ltd.") and Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") (collectively, "Defendants"), hereby allege as follows:

THE NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 7,049,328, arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*

THE PARTIES

2. ApoPharma Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 200 Barmac Drive, Toronto, Ontario M9L 2Z7, Canada.

3. ApoPharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 9605 Medical Center Drive, Suite 390, Rockville, Maryland 20850, United States.

4. Apotex Technologies Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

5. On information and belief, Taro Pharmaceutical Industries Ltd. ("Taro Ltd.") is a corporation organized and existing under the laws of Israel, having a principal place of business at 14 Hakitor Street, Haifa Bay 2624761, Israel.

6. On information and belief, Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 3 Skyline Drive, Hawthorne, New York, 10532. On information and belief, Taro USA may be served with process by and through its registered agent for service of process, C T Corporation System, 111 Eighth Avenue, New York, New York, 10011.

JURISDICTION AND VENUE

7. This is a complaint for patent infringement. This Court has jurisdiction over the subject matter of the claims asserted pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue in this Court is proper under 28 U.S.C. §§ 1391 and 1400(b).

8. This Court has personal jurisdiction over Taro USA because Taro USA offers for sale, markets, sells and distributes pharmaceutical products throughout the United States, including in the State of Texas and this judicial district. Taro USA submitted Abbreviated New Drug Application ("ANDA") No. 208800, which describes a generic deferiprone (500 mg) oral tablet product developed by Taro Ltd. and includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a technical act of infringement under 35 U.S.C. § 271(e)(2)), that Taro USA seeks to import, offer for sale, and sell the generic deferiprone (500 mg) oral tablet product

throughout the United States, including in this judicial district, before the expiration of U.S. Patent No. 7,049,328.

9. On information and belief, Taro USA regularly conducts business in the State of Texas and has a state-issued license to sell and/or distribute pharmaceutical products in the State of Texas, including in this judicial district.

10. On information and belief, Taro USA has established contracts with wholesale and retail distributors, as well as contracts with Texas state agencies to sell and/or distribute its pharmaceutical products in the State of Texas, including in this judicial district.

11. On information and belief, Taro USA is the U.S. Food & Drug Administration ("FDA") approval holder for various pharmaceutical products available for purchase in retail pharmacies in the State of Texas, including in this judicial district, and Taro USA derives substantial revenue from the sale of such FDA-approved pharmaceutical products in the State of Texas, including from sales in this judicial district.

12. On information and belief, various FDA-approved pharmaceutical products imported, offered for sale, sold, and/or distributed by Taro USA appear on the Formulary Index of the Texas Medicaid/CHIP Vendor Drug Program, which provides services for over 4,000 Texas pharmacies, including pharmacies in this judicial district.

13. On information and belief, Taro USA has entered into arrangements with Texas entities to have its products appear on the formulary list of BlueCross BlueShield of Texas, a managed care and health plan with patients who reside in this judicial district.

14. On information and belief, as a Medicaid participant, Taro USA sells pharmaceutical products to Veterans Health Administration Public Health Services facilities, of

which there are over 200 in the State of Texas, and the Department of Veteran Affairs Formulary lists Taro USA's pharmaceutical products as being available to its participants.

15. On information and belief, various pharmaceutical products imported, offered for sale, sold, and/or distributed by Taro USA appear on the Preferred Drug List for the State of Texas Medicaid program and are available to the millions of residents who reside in the State of Texas and in this judicial district and participate in the Texas Medicaid program.

16. On information and belief, Taro USA's extensive sales of pharmaceutical products in the State of Texas and in this judicial district are evidenced by its payment, in 2014, of $19.5 million to the State of Texas to settle claims that Taro USA knowingly set, reported, and/or maintained, or caused to be set, reported, and/or maintained false, fraudulent, and/or inflated prices for certain pharmaceutical products reported to the State of Texas Medicaid program, as reported in Taro Ltd.'s 2015 Form 20-F filed with the U.S. Securities and Exchange Commission. *See* Taro Pharm. Indus. Ltd., Annual Report (Form 20-F) 65 (July 1, 2015); *see also* Press Release, The Attorney General of Texas, Attorney General Abbot Recovers $19.5 Million for State of Texas, U.S. (Aug. 11, 2014), *available at* https://www.texasattorneygeneral.gov/oagnews/release.php?id=4814.

17. On information and belief, Taro USA directly offers for sale, sells, and distributes FDA-approved pharmaceutical products, many of which were developed and manufactured by Taro Ltd., throughout the United States and in this judicial district, and upon FDA-approval, this judicial district is a likely destination for the generic deferiprone (500 mg) oral tablets that are described in ANDA No. 208800.

18. This Court has personal jurisdiction over Defendant Taro Ltd. because its pharmaceutical products that are developed and manufactured by them are regularly imported,

offered for sale, sold, and distributed throughout the United States by Taro USA, including in this judicial district, from which Taro Ltd. derives a substantial portion of its revenue.

19. On information and belief, Defendants Taro Ltd. and Taro USA collaborate to manufacture, import, offer for sale, sell, and/or distribute pharmaceutical products throughout the United States, including in this judicial district, pursuant to FDA-approval of various ANDAs filed and maintained by Taro USA on behalf of Taro Ltd.

20. On information and belief, Taro USA regularly acts as Taro Ltd.'s U.S. Agent for filings with the FDA, and together they work in active concert with respect to the development, regulatory approval, importation, marketing, sale, and distribution of pharmaceutical products, including the generic deferiprone (500 mg) oral tablets described in ANDA No. 208800.

21. On information and belief, Taro Ltd. and Taro USA operate as an integrated business, as evidenced by Taro Ltd.'s 2015 Form 20-F (July 1, 2015), which indicates that Taro Ltd. files a single annual report to the U.S. Securities and Exchange Commission for itself and its subsidiaries, such as Taro USA. On information and belief, Taro Ltd. holds approximately 96.9% of the economic shares and 50% of the voting shares of Taro USA. On information and belief, Taro USA therefore acts under the direction, control, and influence of Taro Ltd., and the acts and conduct of Taro USA complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of Taro Ltd. *See* Taro Pharm. Indus. Ltd., Annual Report (Form 20-F) 10 (July 1, 2015).

22. On information and belief, Taro Ltd.'s net sales in the United States for the year ended March 31, 2015, 2014, and 2013, were approximately $777,191,000; $669,481,000; and $587,851,000, respectively. *See* Taro Pharm. Indus. Ltd., Annual Report (Form 20-F) 26 (July 1, 2015). On information and belief, Taro Ltd.'s sales in the United States for the years ended

March 31, 2015, 2014, and 2013, respectively, were wholly from the importation, offer for sale, sale, and/or distribution of its pharmaceutical products by Taro USA, including from the sale of Taro Ltd.'s pharmaceutical products in this judicial district. *See* Taro Pharm. Indus. Ltd., Annual Report (Form 20-F) 10 (July 1, 2015).

23. On information and belief, Taro Ltd. developed Defendants' proposed generic deferiprone (500 mg) oral tablets described in ANDA No. 208800, and upon regulatory approval by the FDA will manufacture commercial quantities of Defendants' generic deferiprone (500 mg) oral tablets for importation, offer for sale, sale, and/or distribution throughout the United States, including in this judicial district.

24. On information and belief, Taro Ltd. works in the development, formulation, manufacturing, and regulatory approval of generic pharmaceutical products, including the generic deferiprone tablets described in ANDA No. 208800, and Taro USA directly or indirectly imports, markets, and distributes generic pharmaceutical products manufactured by Taro Ltd. for sale and use throughout the United States, including to customers in this judicial district. *See* Taro Pharm. Indus. Ltd., Annual Report (Form 20-F) 22 (July 1, 2015). On information and belief, Taro Ltd. directly, or indirectly through its subsidiaries such as Taro USA, manufactures, imports, markets, sells and/or distributes generic drug products throughout the United States and in his judicial district, and this judicial district is a likely destination for Defendants' generic deferiprone (500 mg) oral tablets.

25. On information and belief, Taro USA actively participated in the product development and preparation of ANDA No. 208800 and submitted ANDA No. 208800 to the FDA, including a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to sell the generic deferiprone (500 mg) oral tablets developed and manufactured by Taro Ltd.

throughout the United States, including in this judicial district before the expiration of U.S. Patent No. 7,049,328.

26. On information and belief, following FDA-approval of ANDA No. 208800, Defendants' proposed generic deferiprone (500 mg) oral tablets will be commercially marketed, distributed, used and sold throughout the United States, including sales directed into this judicial district. On information and belief, based on its development of a generic deferiprone (500 mg) oral tablet product and the filing of ANDA No. 208800, Defendants know and intend for the proposed generic deferiprone (500 mg) oral tablet product that is the subject of ANDA No. 208800 to be imported, offered for sale, sold, and used in the United States, including offers for sale, sales, distribution and/or use in this judicial district.

27. On information and belief, Defendants' actions will concretely injure Plaintiffs by displacing at least some, if not all, of their sales of FERRIPROX® in this judicial district, as well as resulting in price erosion and loss of goodwill with the purchasers and distributors of FERRIPROX® in this judicial district.

28. Venue is proper in this district because Defendants are corporations presently subject to personal jurisdiction in this district for claims arising out of an act of infringement (*i.e.*, Defendants' submission of ANDA No. 208800) that, by its filing, confirms Defendants' plans to commit real-world acts in this judicial district (*i.e.*, importation, offers for sale, sales, and/or distribution to users of the pharmaceutical product) that would make them liable for patent infringement if committed without Plaintiffs' permission.

BACKGROUND

29. U.S. Patent No. 7,049,328 ("the '328 patent") is entitled "Use For Deferiprone," and was issued by the U.S. Patent Office to inventors Michael Spino and Antonio Piga on May 23, 2006. A copy of the '328 patent is attached to this Complaint as Exhibit A.

30. The inventors Antonio Piga and Michael Spino assigned the entire right, title, and interest in the '328 patent to Apotex Inc. by way of assignments dated May 26, 2006 and June 13, 2006, respectively, which assigned the entire right, title, and interest in the '328 patent to Apotex Technologies Inc. by way of assignment dated May 17, 2016.

31. As of the date of this complaint, Apotex Technologies Inc. holds the entire right, title, and interest in the '328 patent, including the right to enforce the '328 against potential infringers and to seek damages.

32. The '328 patent is valid, enforceable, and has not expired.

33. The '328 patent is listed in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book," in conjunction with NDA No. 021825.

34. ApoPharma Inc. is the approval holder of New Drug Application ("NDA") No. 021825 for the deferiprone (500 mg) oral tablet product that is marketed under the FERRIPROX® trademark, which is distributed and sold by ApoPharma USA, Inc. throughout the United States, including in this judicial district.

35. The product FERRIPROX® and its FDA-approved use are covered by at least one claim of the '328 patent.

36. By letter dated March 31, 2016, Taro USA sent a letter to Plaintiffs as required by 21 U.S.C. § 355(j)(2)(B) ("Defendants' Notice Letter") signed on behalf of Taro USA by Huiya

Wu, Partner at Goodwin Proctor LLP and agent for Taro USA. Defendants' Notice Letter states that Taro USA submitted ANDA No. 208800 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act seeking approval to market a generic version of ApoPharma Inc.'s FERRIPROX® brand deferiprone (500 mg) oral tablet product before expiration of the '328 patent.

37. The stated purpose of Defendants' Notice Letter was to notify Plaintiffs that ANDA No. 208800 contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '328 patent. Defendants' Notice Letter alleged that the claims of the '328 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale, and/or offer for sale of Taro USA's proposed generic deferiprone (500 mg) oral tablets.

38. Attached to Defendants' Notice Letter was a detailed factual and legal statement concerning Taro USA's opinion that the claims of the '328 patent would not be infringed by the manufacture, use, importation, sale, and/or offer for sale of Taro USA's proposed generic deferiprone (500 mg) oral tablets. Defendants' Notice Letter did not include any statements concerning the unenforceability or invalidity of the '328 patent.

39. In view of the certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '328 patent contained in ANDA No. 208800, Defendants had knowledge of the '328 patent at least since the date on which ANDA No. 208800 was filed with the FDA.

40. In filing ANDA No. 208800, Defendants have requested the FDA's approval to market a generic version of ApoPharma Inc.'s FERRIPROX® brand deferiprone (500 mg) oral tablet product throughout the United States, including in Texas and in this judicial district prior to the expiration of the '328 patent.

COUNT I
(Infringement of the ’328 Patent Under 35 U.S.C. § 271(e)(2)(A))

41. Paragraphs 1-40 are incorporated herein as set forth above.

42. The use of Defendants’ deferiprone (500 mg) oral tablet product described in ANDA No. 208800 is covered by one or more claims of the ’328 patent.

43. The submission of ANDA No. 208800 to the FDA with a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’328 patent for the purpose of obtaining FDA-approval to engage in the commercial manufacture, importation, offer for sale, sale, and/or use of Defendants’ proposed generic deferiprone (500 mg) oral tablets throughout the United States before expiration of the ’328 patent constitutes infringement of one or more claims of the ’328 patent under 35 U.S.C. § 271(e)(2)(A).

44. Unless enjoined by this Court, Defendants intend to, and will, engage in the manufacture, importation, offer for sale, sale, marketing, distribution, and/or use of Defendants’ proposed generic deferiprone (500 mg) oral tablets immediately and imminently upon FDA-approval of the ANDA No. 208800.

45. Defendants had knowledge of the ’328 patent and are knowingly and willfully infringing the ’328 patent.

46. Defendants’ statements of the factual and legal bases for its opinion regarding the non-infringement of the ’328 patent contained in Defendants’ Notice Letter is devoid of any objective good-faith basis in either the facts or the law.

47. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’328 patent, actively inducing infringement of the ’328 patent, and/or contributing to the infringement by others of the ’328 patent.

48. This case is therefore “exceptional,” as that term is used in 35 U.S.C. § 285.

49. Unless Defendants are enjoined from infringing the ’328 patent, Plaintiffs will suffer irreparable injury for which Plaintiffs have no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Federal Rule of Civil Procedure 65, a preliminary and permanent injunction should be entered to thereby prevent further infringement by Defendants of the ’328 patent.

50. Plaintiffs are entitled 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 the FDA’s final approval of ANDA No. 208800 be a date that is not earlier than the expiration date of the ’328 patent, or any later expiration of exclusivity for the ’328 patent to which Plaintiffs are or may become entitled.

51. This action is being commenced within forty-five (45) days from the date Plaintiffs’ received Defendants’ Notice Letter, which Plaintiffs received on or about April 14, 2016.

COUNT II
(Declaratory Judgment of Infringement of the ’328 Patent Under 35 U.S.C. §§ 271(b)-(c))

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

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

54. 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.

55. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, and import into, offer for sale, sell, and/or distribute into the United States, Defendants’ proposed generic deferiprone (500 mg) oral tablets described in ANDA No. 208800.

56. Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Plaintiffs.

57. The use of Defendants' deferiprone (500 mg) oral tablet product described in ANDA No. 208800 is covered by one or more claims of the '328 patent.

58. The commercial importation, offer for sale, sale, marketing, distribution, and/or use of Defendants' proposed generic deferiprone (500 mg) oral tablets described in ANDA No. 208800 in conjunction with Defendants' labeling and instructions for the use thereof contained in Defendants' proposed package insert before the expiration of the '328 patent will constitute an act of inducement of infringement of one or claims of the '328 patent by doctors and/or patients, including in this judicial district.

59. Defendants know that the proposed generic deferiprone (500 mg) oral tablets when used in conjunction with the proposed labeling are especially made or adapted for use in infringing the '328 patent, and that the product described in Defendants' ANDA No. 208800 and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Defendants intend to, and will, contribute to the infringement of the '328 patent immediately and imminently upon FDA-approval of ANDA No. 208800.

60. Defendants' foregoing actions prior to the expiration of the '328 patent constitute and/or will constitute active inducement of infringement and/or contribution to the infringement by others under 35 U.S.C. §§ 271(b) and/or (c).

61. Plaintiffs are entitled to a declaratory judgment that the future commercial importation, offer for sale, sale, and/or use of Defendants' proposed generic deferiprone (500 mg) oral tablets in the United States will constitute active inducement of infringement and/or

contribution to the infringement by others of the ’328 patent under 35 U.S.C. §§ 271(b) and/or (c).

62. Unless enjoined by this Court, Defendants intend to, and will, actively induce infringement of the ’328 patent and/or contribute to the infringement of the ’328 patent by others when Defendants’ ANDA No. 208800 is approved by the FDA, and Defendants intend to, and will, do so immediately and imminently upon FDA-approval.

63. Unless Defendants are enjoined from actively inducing infringement of the ’328 patent and/or contributing to the infringement of the ’328 patent, Plaintiffs will suffer irreparable injury for which Plaintiffs have no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Federal Rule of Civil Procedure 65, a preliminary and permanent injunction should be entered to thereby prevent further active inducement of infringement and/or contribution to the infringement by others of the ’328 patent by Defendants.

64. Plaintiffs will be irreparably harmed by Defendants’ active inducement of infringement and/or contribution to the infringement by others of the ’328 patent unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

65. Defendants had knowledge of the ’328 patent and are knowingly and willfully making substantial preparations to induce infringement of the ’328 patent and/or contribute to the infringement of the ’328 patent.

66. Defendants’ statements of the factual and legal bases for its opinion regarding the non-infringement of the ’328 patent contained in Defendants’ Notice Letter is devoid of any objective good-faith basis in either the facts or the law.

67. Defendants acted without a reasonable basis for believing that they would not be liable for actively inducing infringement of the ’328 patent and/or contributing to the infringement by others of the ’328 patent.

68. This case is therefore “exceptional,” as that term is used in 35 U.S.C. § 285.

JURY TRIAL DEMAND

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment be entered that Defendants have infringed the ’328 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 208800;

B. A Declaration that importing, offering to sell, marketing, selling, distributing, and/or using the proposed generic deferiprone (500 mg) oral tablets described in ANDA No. 208800 in conjunction with Defendants’ proposed package insert that contains instructions for use, will constitute active inducement of infringement of the ’328 patent under 35 U.S.C. § 271(b);

C. A Declaration that importing, offering to sell, marketing, selling, distributing, and/or using the proposed generic deferiprone (500 mg) oral tablets described in ANDA No. 208800 in conjunction with Defendants’ proposed package insert that contains instructions for use will constitute contributory infringement of the ’328 patent under 35 U.S.C. § 271(c);

D. A permanent injunction be issued, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, restraining and enjoining Defendants, their officers, agents, attorneys, and employees, those in active concert, or acting in privity with them, from engaging in the commercial manufacture,

importation, offer for sale, sale, and/or use within the United States, of the drug product described in ANDA No. 208800 before expiration of the ’328 patent, including any extensions and/or exclusivity period associated therewith;

E. An Order that the FDA may not approve ANDA No. 208800 prior to expiration of the ’328 patent, including any extensions and/or exclusivity period associated therewith;

F. If Defendants attempt to engage in the commercial manufacture, importation, offer for sale, sale, and/or use of Defendants’ generic product described in ANDA No. 208800 prior to the expiration of the ’328 patent, including any extensions and/or exclusivity period associated therewith, that judgment be entered awarding Plaintiffs damages, including prejudgment interest, resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

G. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys’ fees pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Date: May 18, 2016

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