IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE DEVELOPMENT LLC, SHIRE CANADA INC., SHIRE INTERNATIONAL LICENSING B.V., and SHIRE LLC, **Plaintiffs,** **v.** **ALKEM LABORATORIES LTD.,** **Defendant.**	**Civil Action No. _____**

COMPLAINT

Plaintiffs Shire Development LLC, Shire Canada Inc., Shire International Licensing B.V., and Shire LLC (collectively "Shire" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Alkem Laboratories Ltd. ("Alkem") 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 Nos. 5,968,976 ("the '976 patent"), 7,465,465 ("the '465 patent"), 8,980,327 ("the '327 patent"), and 9,023,397 ("the '397 patent") attached hereto as Exhibits A, B, C, and D, respectively.

THE PARTIES

2. Plaintiff Shire Development LLC is a limited-liability company organized and existing under the laws of Delaware, and its principal place of business is located at 300 Shire Way, Lexington, MA 02421.

3. Plaintiff Shire Canada Inc. is a corporation organized and existing under the laws of Canada, and its principal place of business is located at 2250, boul. Alfred-Nobel, bureau 500, Ville St-Laurent, QC H4S 2C9, Canada.

4. Plaintiff Shire International Licensing B.V. is a corporation organized and existing under the laws of the Netherlands, and its principal place of business is located at Strawinskylaan 659, 1077 XX Amsterdam, Noord-Holland, The Netherlands.

5. Plaintiff Shire LLC is a limited-liability company organized and existing under the laws of Kentucky, and its principal place of business is located at 9200 Brookfield Ct., Suite 108, Florence, KY 41042.

6. Upon information and belief, Defendant Alkem Laboratories Ltd. is a corporation organized and existing under the laws of India, and its principal place of business is located at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai – 400 013, India.

7. Upon information and belief, Alkem 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 Delaware.

JURISDICTION AND VENUE

8. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Alkem at least under Fed. R. Civ. P. 4(k)(2).

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FACTS AS TO ALL COUNTS

11. Shire Development LLC owns New Drug Application ("NDA") No. 204734 for lanthanum carbonate oral powder, which was approved on September 24, 2014. Shire markets this oral powder under the name Fosrenol®.

12. Fosrenol is indicated to reduce serum phosphate in patients with end stage renal disease.

13. The '976 patent, entitled "Pharmaceutical Composition Containing Selected Lanthanum Carbonate Hydrates," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on October 19, 1999. Shire International Licensing B.V. owns all rights, title, and interest in the '976 patent.

14. The '465 patent, entitled "Pharmaceutical Formulation Comprising Lanthanum Compounds," was duly and legally issued by the USPTO on December 16, 2008. Shire Canada Inc. owns all rights, title, and interest in the '465 patent.

15. The '327 patent, entitled "Capsule and Powder Formulations Containing Lanthanum Compounds," was duly and legally issued by the USPTO on March 17, 2015. Shire LLC owns all rights, title, and interest in the '327 patent.

16. The '397 patent, entitled "Capsule and Powder Formulations Containing Lanthanum Compounds," was duly and legally issued by the USPTO on May 5, 2015. Shire LLC owns all rights, title, and interest in the '397 patent.

17. Pursuant to 21 U.S.C. § 355(b)(1), the ’976, ’465, ’327, and ’397 patents are listed in the United States Food and Drug Administration’s (“FDA”) publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “*Orange Book*”) as covering Fosrenol oral powder.

18. Alkem prepared, submitted, and filed an Abbreviated New Drug Application (“ANDA”) under § 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (codified at 21 U.S.C. § 355(j)), seeking approval from the FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Lanthanum Carbonate Oral Powder (“ANDA No. 209163”). Alkem included a “paragraph IV” certification seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Lanthanum Carbonate Oral Powder, 750 mg and 1000 mg (EQ 750 mg and EQ 1000 mg lanthanum base) (“Alkem’s ANDA Products”) before the expiration of the ’976, ’465, ’327, and ’397 patents. And upon information and belief, upon approval of ANDA No. 209163, Alkem will be involved, directly and/or indirectly, in the manufacture, use, sale, offer for sale, and/or importation of Alkem’s ANDA Products, including, but not limited to, conducting such activities in Delaware.

19. 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 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 grounds supporting the allegation." 21 C.F.R. § 314.95(c)(6)(i)-(ii).

20. Shire received a letter dated July 11, 2016 that was purportedly sent pursuant to § 505(j)(2)(B)(ii) of the FDCA, 21 U.S.C. § 505(j)(2)(B)(ii), regarding Alkem's ANDA Products and the '976, '465, '327, and '397 patents (the "July 11 Notice Letter").

21. The July 11 Notice Letter included an Offer of Confidential Access ("OCA") purportedly pursuant to 21 U.S.C. § 355(j)(5)(C). Plaintiffs objected to certain provisions of Alkem's OCA as unreasonable and in violation of 21 U.S.C. § 355(j)(5)(C)(i)(III). By way of example only, Alkem's OCA contains a patent-prosecution bar, even though no facts have been provided to show that there is good cause to impose such a bar.

FIRST COUNT
(Infringement of the '976 Patent)

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

23. Upon information and belief, Alkem's submission of ANDA No. 209163 to the FDA is for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of Alkem's ANDA Products—products (1) that are claimed in the '976 patent and (2) whose use is claimed in the '976 patent—before the expiration of the '976 patent.

24. Upon information and belief, Alkem included in ANDA No. 209163 a paragraph IV certification to the '976 patent to obtain approval to engage in the commercial manufacture, use, or sale of Alkem's ANDA Products before the expiration of the '976 patent.

25. Upon information and belief, Alkem will commercially manufacture, use, sell, offer for sale, and/or import its ANDA Products upon, or in anticipation of, FDA approval.

26. The submission and filing of ANDA No. 209163 with a paragraph IV certification to the ’976 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Alkem’s ANDA Products before the expiration of the ’976 patent is an act of infringement by Alkem—literally and/or under the doctrine of equivalents—of one or more claims of the ’976 patent under 35 U.S.C. § 271(e)(2).

27. Upon information and belief, the sale or offer for sale of Alkem’s ANDA Products by Alkem would induce and/or contribute to third-party infringement of one or more claims of the ’976 patent under 35 U.S.C. § 271.

28. As of the date of the July 11 Notice Letter, Alkem was aware of the existence of the ’976 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not infringe one or more claims of the ’976 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

SECOND COUNT
(Infringement of the ’465 Patent)

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

30. Upon information and belief, Alkem’s submission of ANDA No. 209163 to the FDA is for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of Alkem’s ANDA Products—products (1) that are claimed in the ’465 patent and (2) whose use is claimed in the ’465 patent—before the expiration of the ’465 patent.

31. Upon information and belief, Alkem included in ANDA No. 209163 a paragraph IV certification to the ’465 patent to obtain approval to engage in the commercial manufacture, use, or sale of Alkem’s ANDA Products before the expiration of the ’465 patent.

32. Upon information and belief, Alkem will commercially manufacture, use, sell, offer for sale, and/or import its ANDA Products upon, or in anticipation of, FDA approval.

33. The submission and filing of ANDA No. 209163 with a paragraph IV certification to the '465 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Alkem's ANDA Products before the expiration of the '465 patent is an act of infringement by Alkem—literally and/or under the doctrine of equivalents—of one or more claims of the '465 patent under 35 U.S.C. § 271(e)(2).

34. Upon information and belief, the sale or offer for sale of Alkem's ANDA Products by Alkem would induce and/or contribute to third-party infringement of one or more claims of the '465 patent under 35 U.S.C. § 271.

35. As of the date of the July 11 Notice Letter, Alkem was aware of the existence of the '465 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not infringe one or more claims of the '465 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

THIRD COUNT
(Infringement of the '327 Patent)

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

37. Upon information and belief, Alkem's submission of ANDA No. 209163 to the FDA is for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of Alkem's ANDA Products—products (1) that are claimed in the '327 patent and (2) whose use is claimed in the '327 patent—before the expiration of the '327 patent.

38. Upon information and belief, Alkem included in ANDA No. 209163 a paragraph IV certification to the ’327 patent to obtain approval to engage in the commercial manufacture, use, or sale of Alkem’s ANDA Products before the expiration of the ’327 patent.

39. Upon information and belief, Alkem will commercially manufacture, use, sell, offer for sale, and/or import its ANDA Products upon, or in anticipation of, FDA approval.

40. The submission and filing of ANDA No. 209163 with a paragraph IV certification to the ’327 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Alkem’s ANDA Products before the expiration of the ’327 patent is an act of infringement by Alkem—literally and/or under the doctrine of equivalents—of one or more claims of the ’327 patent under 35 U.S.C. § 271(e)(2).

41. Upon information and belief, the sale or offer for sale of Alkem’s ANDA Products by Alkem would induce and/or contribute to third-party infringement of one or more claims of the ’327 patent under 35 U.S.C. § 271.

42. As of the date of the July 11 Notice Letter, Alkem was aware of the existence of the ’327 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not infringe one or more claims of the ’327 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

FOURTH COUNT
(Infringement of the ’397 Patent)

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

44. Upon information and belief, Alkem’s submission of ANDA No. 209163 to the FDA is for the purpose of obtaining FDA approval to engage in the commercial manufacture,

use, or sale of Alkem's ANDA Products—products (1) that are claimed in the '397 patent and (2) whose use is claimed in the '397 patent—before the expiration of the '397 patent.

45. Upon information and belief, Alkem included in ANDA No. 209163 a paragraph IV certification to the '397 patent to obtain approval to engage in the commercial manufacture, use, or sale of Alkem's ANDA Products before the expiration of the '397 patent.

46. Upon information and belief, Alkem will commercially manufacture, use, sell, offer for sale, and/or import its ANDA Products upon, or in anticipation of, FDA approval.

47. The submission and filing of ANDA No. 209163 with a paragraph IV certification to the '397 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Alkem's ANDA Products before the expiration of the '397 patent is an act of infringement by Alkem—literally and/or under the doctrine of equivalents—of one or more claims of the '397 patent under 35 U.S.C. § 271(e)(2).

48. Upon information and belief, the sale or offer for sale of Alkem's ANDA Products by Alkem would induce and/or contribute to third-party infringement of one or more claims of the '397 patent under 35 U.S.C. § 271.

49. As of the date of the July 11 Notice Letter, Alkem was aware of the existence of the '397 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not infringe one or more claims of the '397 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 209163 with a paragraph IV certification for the purpose of

obtaining FDA approval to engage in the commercial manufacture, use, or sale of Alkem's ANDA Products—products (1) that are claimed in the '976 patent and (2) whose use is claimed in the '976 patent—before the expiration of the '976 patent—constitutes an act of infringement of the '976 patent, directly and indirectly, including by inducement and/or contributory infringement by Alkem;

B. An Order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Alkem's ANDA Products shall be no earlier than the date on which the '976 patent expires, including any regulatory extensions;

C. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 209163 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of Alkem's ANDA Products—products (1) that are claimed in the '465 patent and (2) whose use is claimed in the '465 patent—before the expiration of the '465 patent—constitutes an act of infringement of the '465 patent, directly and indirectly, including by inducement and/or contributory infringement by Alkem;

D. An Order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Alkem's ANDA Products shall be no earlier than the date on which the '465 patent expires, including any regulatory extensions;

E. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 209163 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of Alkem's ANDA Products—products that are claimed in the '327 patent—before the expiration of the '327

patent— constitutes an act of infringement of the ’327 patent, directly and indirectly, including by inducement and/or contributory infringement by Alkem;

F. An Order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Alkem’s ANDA Products shall be no earlier than the date on which the ’327 patent expires, including any regulatory extensions;

G. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 209163 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of Alkem’s ANDA Products—products that are claimed in the ’397 patent—before the expiration of the ’397 patent— constitutes an act of infringement of the ’397 patent, directly and indirectly, including by inducement and/or contributory infringement by Alkem;

H. An Order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Alkem’s ANDA Products shall be no earlier than the date on which the ’397 patent expires, including any regulatory extensions;

I. Injunctive relief pursuant to 35 U.S.C. § 271(e)(4)(B) precluding Alkem from manufacturing, using selling, offering to sell, or importing Alkem’s ANDA Products prior to the date on which the ’976, ’465, ’327, and ’397 patents have all expired, including any regulatory extensions;

J. A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Plaintiffs their attorneys’ fees;

K. A Judgment awarding Plaintiffs their costs under Fed. R. Civ. P. 54(d) and 28 U.S.C. § 1920; and

L. Such other and further relief as this Court may deem just and proper.

Dated: August 24, 2016

Respectfully submitted,

/s/ Francis DiGiovanni

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