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Attorneys for Plaintiff
Luitpold Pharmaceuticals, Inc.

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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|---|---|
| LUITPOLD PHARMACEUTICALS, INC.,<br>Plaintiff,<br><br>v.<br><br>APOTEX CORP., and<br>APOTEX INC.,<br><br>Defendants; and<br><br>RECORDATI IRELAND LIMITED,<br>an Irish company,<br><br>Defendant Patent Owner. | Civil Action No. _____<br><br>Hon. _____, U.S.D.J.<br><br>**COMPLAINT FOR PATENT INFRINGEMENT** |

Plaintiff Luitpold Pharmaceuticals, Inc. ("Luitpold"), by its undersigned attorneys, brings this Complaint and action for patent infringement against defendants Apotex Corp. and Apotex

Inc. ("Defendants"), also naming Recordati Ireland Limited as defendant patent owner, and hereby alleges as follows:

## THE PARTIES

1. Plaintiff Luitpold Pharmaceuticals, Inc. is a corporation organized under the laws of the State of New York and has its principal place of business at One Luitpold Drive, Shirley, New York, 11967.

2. On information and belief, defendant Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Apotex Inc. is in the business of making and selling generic drug products.

3. On information and belief, defendant Apotex Corp. is a Delaware Corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326. Apotex Corp. is in the business of making and selling generic drug products.

4. Defendant patent owner Recordati Ireland Limited ("Recordati") is a company organized under the laws of the Republic of Ireland and has its principal place of business at Raheens East, Ringaskiddy, Cork County, Ireland.

## NATURE OF THE ACTION

5. This is an action for infringement of United States Patent Number 6,333,044 ("the '044 patent"), arising under the United States patent laws, Title 35, United States Code, §§ 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Apotex Corp.'s filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. §355(j) seeking U.S. Food and Drug Administration ("FDA") approval to market a generic pharmaceutical product.

## JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Apotex Inc. under N.J. Court R. 4:4-4. Apotex Inc. has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being hauled into Court here. In addition, on information and belief, Apotex Inc. has engaged in systematic, purposeful, and continuous contacts in this district. On information and belief, Apotex Inc. has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell, and selling or causing others to use, offer to sell, or sell pharmaceutical products throughout the State of New Jersey and therefore within this judicial district. In addition, Apotex Inc. has purposefully availed itself of the laws of this forum by instituting legal proceedings in this judicial district. In addition, Apotex Inc. has been sued for patent infringement, and has consented to personal jurisdiction, in this judicial district. On information and belief, Apotex Inc. will sell—through Apotex Corp.—the generic infringing product that is the subject of the Apotex ANDA complained of herein (No. 205486) (the "Apotex ANDA") throughout the United States, including in this judicial district, following any approval of the Apotex ANDA.

8. This Court has personal jurisdiction over Apotex Corp. under N.J. Court R. 4:4-4. Apotex Corp. has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being hauled into Court here. In addition, on information and belief, Apotex Corp. has engaged in systematic, purposeful, and continuous contacts in this district. On information and belief, Apotex Corp. has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell, and selling or causing others to use,

offer to sell, or sell pharmaceutical products throughout the State of New Jersey and therefore within this judicial district. In addition, Apotex Corp. has purposefully availed itself of the laws of this forum by instituting legal proceedings in this judicial district. In addition, Apotex Corp. has been sued for patent infringement, and has consented to personal jurisdiction, in this judicial district. On information and belief, Apotex Inc. will sell—through Apotex Corp.—the generic infringing product that is the subject of the Apotex ANDA complained of herein (No. 205486) throughout the United States, including in this judicial district, following any approval of the Apotex ANDA.

9. On information and belief, Apotex Corp. is the United States subsidiary, agent, and alter-ego of Apotex Inc. On information and belief, for all purposes relevant to this action, Apotex Inc. and Apotex Corp. are effectively the same entity.

10. Recordati is named as a party to this litigation as a defendant patent owner. Recordati is the lawful assignee of all right, title and interest in the '044 patent and, as detailed below, has granted an exclusive license to practice the '044 patent. The exclusive license and all rights thereunder are held by Luitpold. As a result, Luitpold has the right and standing to enforce the '044 patent and to bring this action. Further, Recordati has an interest in the outcome of this litigation, is subject to personal jurisdiction in this Court, and is a proper party to this action, as a plaintiff, defendant, or involuntary plaintiff, whichever designation is deemed appropriate by the Court.

11. Recordati has acknowledged and does not dispute that Luitpold holds an exclusive license to the '044 patent and has the exclusive right to enforce the '044 patent in the United States.

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

## THE '044 PATENT

13. Luitpold holds an approved New Drug Application ("NDA"), No. 22-382, by which the FDA granted approval under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a), for Ketorolac Tromethamine Nasal Spray, 15.75 mg/spray. The Ketorolac Tromethamine Nasal Spray described in NDA No. 22-382 is marketed and sold by Luitpold in the United States under the trademark SPRIX®.

14. Recordati is the owner of the '044 patent.

15. The '044 patent was duly and legally issued on December 25, 2001. A true and correct copy of the '044 patent is attached hereto as Exhibit A.

16. The '044 patent was assigned by the inventors to Recordati, S.A. Chemical and Pharmaceutical Company, which in 2007 assigned it to Recordati. Thus, Recordati is the lawful assignee of the '044 patent.

17. On or about November 23, 2000, Roxro Pharma, Inc. or its predecessor-in-interest (hereinafter "Roxro") entered into an exclusive license agreement with Recordati or its predecessor-in-interest to the '044 patent, wherein it received an exclusive license to U.S. patent rights relating to the "intranasal formulations of the compound known as Ketorolac as described in Patent Application US 08/383707, filed February 1, 1995," which became the '044 patent. The rights under that exclusive license include, but are not limited to, the right to pursue any infringement claims against infringers of the '044 patent.

18. In December 2010, Luitpold acquired Roxro. Roxro has assigned its rights in and to its exclusive license to the '044 patent to Luitpold such that Luitpold is now the exclusive licensee of the '044 patent.

19. Pursuant to 21 U.S.C. § 355(b)(1) and applicable FDA regulations, the '044 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to SPRIX®.

**COUNT ONE**

**INFRINGEMENT OF THE '044 PATENT**

**(APOTEX CORP.)**

20. Luitpold realleges and incorporates by reference paragraphs 1 through 19 as if fully set forth herein.

21. Apotex Corp. submitted an ANDA (No. 205486) (hereinafter referred to as the "Apotex ANDA") to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic ketorolac tromethamine 15.75 mg/nasal spray (hereinafter referred to as "Apotex's ANDA Product").

22. Apotex Corp. submitted the Apotex ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or important of Apotex's ANDA Product prior to expiration of the '044 patent.

23. The relevant statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) requires that a notice of the paragraph IV certification ("Notice Letter") "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." The FDA's rules and regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

24. Apotex Inc. sent to Luitpold a Notice Letter on behalf of both Apotex Inc. and Apotex Corp. (collectively hereafter, the "Apotex Defendants"), purporting to comply with the provisions of

21 U.S.C. § 355(j)(2)(B)(iv)(II) and the FDA regulations relating thereto, which Notice Letter Luitpold received on May 27, 2014 (the "Apotex Notice Letter").

25. The Apotex Defendants made a certification in the Apotex Notice Letter under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in their opinion and to the best of their knowledge, Apotex's ANDA Product will not directly or indirectly infringe claims 1-50 of the '044 patent, either literally or under the doctrine of equivalents, and that the Apotex Defendants do not induce infringement of claims 11, 12, 14-20 or 36-50 of the '044 patent.

26. The Apotex Defendants also alleged in the Apotex Notice Letter that claims 1-51 of the '044 patent are allegedly invalid for indefiniteness under 35 U.S.C. § 112, and that claims 10 and 12 are allegedly invalid 35 U.S.C. § 112, fourth paragraph because they lack antecedent basis in the claims from which they depend.

27. The Apotex Defendants also alleged in the Apotex Notice Letter that claims 1-51 of the '044 patent are invalid for obviousness under 35 U.S.C. § 103(a).

28. The opinions set forth in the Apotex Notice Letter that the '044 patent is not infringed and is invalid due to indefiniteness, lack of antecedent basis, and obviousness of certain claims as listed in the Apotex Notice Letter are devoid of an objective, good faith basis in either the facts or law. Apotex's Paragraph IV certification is a wholly unjustified infringement of one or more claims of the '044 patent.

29. By filing the Apotex ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Apotex's ANDA Product before expiration of the '044 patent, Apotex Corp. has committed an act of infringement of one or more claims of the '044 patent under 35 U.S.C. § 271(e)(2). Further, unless enjoined by this Court, Apotex Corp., upon FDA approval of the Apotex ANDA, will infringe one or more claims of the

'044 patent by making, using, offering to sell, selling and/or importing Apotex's ANDA Product in the United States.

30. Apotex Corp.'s method of manufacturing Apotex's ANDA Product will infringe one or more claims of the '044 patent, either literally or under the doctrine of equivalents, violating 35 U.S.C. § 271(a), (b), and/or (c).

31. Apotex Corp.'s manufacturing, marketing, offering for sale, sale, and/or importation for sale of Apotex's ANDA Product will induce the infringement of, and/or contributorily infringe, one or more claims of the '044 patent that teach a method in connection with ketorolac tromethamine nasal spray. This will occur at Apotex Corp.'s active behest, and with its specific intent, knowledge and encouragement. On information and belief, Apotex Corp. will actively induce, encourage, aid, abet, and/or contribute to, infringement of one or more claims of the '044 patent with the knowledge that it is in contravention of Luitpold's rights under the '044 patent.

32. On information and belief, prior to filing and when Apotex Corp. filed the Apotex ANDA (No. 205486), Apotex Corp. was aware of the existence of the '044 patent, and was aware that the filing of the Apotex ANDA, including a certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) with respect to the '044 patent and with a request for approval of the Apotex ANDA prior to the expiration date of the '044 patent, was an act of infringement of one or more claims of the '044 patent.

33. Apotex Corp. has violated its duty of care to avoid the known patent rights of the '044 patent.

34. There is a justiciable controversy between the parties hereto as to infringement and validity of certain claims of the '044 patent.

35. Luitpold is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval of the aforementioned Apotex ANDA relating to Apotex's ANDA Product be a date which is not earlier than December 25, 2018, the expiration of the '044 patent, or any later date of exclusivity to which Luitpold is or becomes entitled. Further, Luitpold is entitled to an award of damages for any commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product, and any act committed by Apotex Corp. with respect to the subject matter claimed in the '044 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

36. This is an exceptional case, and Luitpold is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

37. Luitpold will be substantially and irreparably damaged and harmed if Apotex Corp. is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '044 patent. Luitpold does not have an adequate remedy at law.

**COUNT TWO**

**INFRINGEMENT OF THE '044 PATENT**

**(APOTEX INC.)**

38. Luitpold realleges and incorporates by reference paragraphs 1 through 37 as if fully set forth herein.

39. On information and belief, Apotex Inc. initiates, directs and controls the activities of its subsidiary company, Apotex Corp., with regard to the Apotex ANDA (No. 205486) and Apotex's ANDA Product.

40. On information and belief, Apotex Inc., through Apotex Corp. as its agent, initiated, directed, and controlled the preparation and filing of the Apotex ANDA with the FDA.

41. On information and belief, Apotex Inc. has infringed one or more claims of the '044 patent under 35 U.S.C. § 271(e)(2)(A) by initiating, directing, and controlling the preparation and filing of the Apotex ANDA.

42. On information and belief, in the event that the FDA approves the Apotex ANDA (No. 205486), Apotex Inc. stands to benefit directly from such approval by being able to commercially manufacture and distribute Apotex's ANDA Product itself and/or through Apotex Corp. as Apotex Inc.'s agent.

43. On information and belief, Apotex's ANDA Product for which Apotex Inc.—through Apotex Corp., as Apotex Inc.'s agent—seeks approval under the Apotex ANDA, will infringe one or more claims of the '044 patent under 35 U.S.C. § 271(a).

44. On information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product into the United States by Apotex Inc. (itself and/or through Apotex Corp., as Apotex Inc.'s agent) will directly and/or indirectly infringe one or more claims of the '044 patent under 35 U.S.C. § 271(a), (b), and/or (c).

45. On information and belief, the manufacture of Apotex's ANDA Product by Apotex Inc. (itself and/or through through Apotex Corp., as Apotex Inc.'s agent) will infringe one or more claims of the '044 patent, either literally or under the doctrine of equivalents, violating 35 U.S.C. § 271(a), (b), and/or (c).

46. Luitpold is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of the Apotex ANDA (No. 205486) be a date that is not earlier than the later of December 25, 2018, the expiration of the '044 patent, or the expiration of any other later date of exclusivity to which Luitpold is or becomes entitled.

47. On information and belief, prior to the filing of the Apotex ANDA, Apotex Inc. was aware of the existence of the '044 patent, and was aware that the filing of the Apotex ANDA, including a certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) with respect to the '044 patent, infringed one or more claims of the '044 patent.

48. This is an exceptional case, and Luitpold is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

49. Luitpold will be substantially and irreparably damaged and harmed if Apotex Inc. is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '044 patent. Luitpold does not have an adequate remedy at law.

**PRAYER FOR RELIEF**

WHEREFORE, Luitpold respectfully requests the following relief:

A. A judgment declaring that the Apotex Defendants have infringed one or more claims of the '044 patent through the submission of the Apotex ANDA (No. 205486) to the FDA, and that the Apotex Defendants' manufacturing, using, selling, and/or offering for sale in and/or importation into the United States of Apotex's ANDA Product will infringe one or more claims of the '044 patent;

B. A judgment declaring that the Apotex Defendants' manufacture, use, sale, and/or offer for sale in and/or importation into the United States of Apotex's ANDA Product would constitute infringement of one or more claims of the '044 patent;

C. A judgment declaring that the Apotex Defendants' manufacture, use, sale, and/or offer for sale in and/or importation into the United States of Apotex's ANDA Product would induce and/or contribute to infringement of one or more claims of the '044 patent, pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

D. A judgment ordering, pursuant to 35 U.S.C. § 271(e)(4), that the effective date of any FDA approval of the Apotex ANDA (No. 205486) be a date which is not earlier than the expiration of the '044 patent, or the expiration of any other later date of exclusivity to which Luitpold is or becomes entitled;

E. Entry of a preliminary and permanent injunction enjoining the Apotex Defendants and their officers, agents, servants, employees, parent corporations, subsidiaries, and affiliates, and those persons in privity or in active concert or participation with any of them, from making, using, selling, and/or offering to sell in and/or importing into the United States, Apotex's ANDA Product, for which approval is sought in the Apotex ANDA (No. 205486), or any ketorolac tromethamine nasal spray product that infringes and/or induces infringement of and/or contributes to the infringement of one or more claims of the '044 patent, until expiration of the '044 patent, or the expiration of any other later date of exclusivity to which Luitpold is or becomes entitled;

F. If the Apotex Defendants engage in the commercial manufacture, use, sale, and/or offer for sale in and/or importation into the United States of Apotex's ANDA Product or any ketorolac tromethamine nasal spray product that infringes and/or induces infringement of and/or contributes to the infringement of one or more claims of the '044 patent, prior to the expiration of the '044 patent or the expiration of any other later date of exclusivity to which Luitpold is or becomes entitled, a judgment awarding damages to Luitpold resulting from such infringement, together with interest;

G. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

H. An award of costs and expenses in this action; and

I. Such further and other relief as this Court determines to be just and proper.

Dated: July 11, 2014

Respectfully submitted,

RIKER DANZIG SCHERER HYLAND & PERRETTI LLP

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By *s/ Robert J. Schoenberg*

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## CERTIFICATION OF NON-ARBITRABILITY

Pursuant to Local Civil Rule 201.1(d)(1), the undersigned attorney for Plaintiff, Luitpold Pharmaceuticals, Inc., certifies that this action is not eligible for arbitration under Local Civil Rule 201.1 because the relief sought in the Complaint primarily consists of a demand for preliminary and permanent injunctive relief, as well as damages believed to be in excess of $150,000.00, exclusive of interest, costs, and any claim for punitive damages.

## LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for Plaintiff, Luitpold Pharmaceuticals, Inc., certifies that, to the best of his knowledge, the matter in controversy concerning the products and patent at issue herein is not the subject of another action pending in any court or in any arbitration or administrative proceeding.

RIKER DANZIG SCHERER HYLAND
& PERRETTI LLP
Attorneys for Plaintiff
Luitpold Pharmaceuticals, Inc.

By *s/ Robert J. Schoenberg*
ROBERT J. SCHOENBERG

Dated: July 11, 2014