Donald A. Robinson
ROBINSON WETTRE & MILLER LLC
One Newark Center
Newark, New Jersey 07102
Tel: (973) 690-5400
Fax: (973) 466-2760 (drobinson@rwmlegal.com)

Attorney for Plaintiff Janssen Pharmaceuticals, Inc.

John F. Brenner
PEPPER HAMILTON LLP
Suite 400
301 Carnegie Center
Princeton, New Jersey 08543-5276
Tel: (609) 452-0808
Fax: (609) 452-1147 (brennerj@pepperlaw.com)

Attorney for Plaintiff Grünenthal GmbH

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICALS, INC. and GRÜNENTHAL GMBH, Plaintiffs, v. ALKEM LABORATORIES LIMITED, Defendant.	**Civil Action No.** 13-cv-7803 (CCC) (MF)

FIRST AMENDED COMPLAINT

In this patent infringement action, Plaintiffs Janssen Pharmaceuticals, Inc. ("Janssen") and Grünenthal GmbH ("Grünenthal"), for their complaint against Defendant Alkem Laboratories Limited ("Alkem"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, in response to the submission of an Abbreviated New Drug

Application ("ANDA") with the U.S. Food and Drug Administration ("FDA"), which was amended to seek approval to manufacture and sell generic versions of NUCYNTA® ER prior to the expiration of U.S. Patent No. 8,536,130 B2 ("the '130 Patent").

THE PARTIES

2. Plaintiff Grünenthal is a corporation organized and existing under the laws of Germany, having an address at Zieglerstrasse 6, 52078 Aachen, Germany. Grünenthal owns the '130 Patent.

3. Plaintiff Janssen is a Pennsylvania corporation, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. As discussed below, Janssen is an exclusive licensee of the '130 Patent.

4. Janssen holds FDA-approved NDA No. 200533.

5. Janssen manufactures and markets the drug covered by NDA No. 200533 ("NUCYNTA ER" or the "NUCYNTA ER drug product") in the United States. The active ingredient of NUCYNTA ER is tapentadol hydrochloride. The drug is marketed under the registered trade name NUCYNTA® ER. Under NDA No. 200533, NUCYNTA ER is marketed in 50, 100, 150, 200, and 250 mg tablets.

6. NUCYNTA ER is approved by the FDA for the management of moderate to severe chronic pain in adults and neuropathic pain associated with diabetic peripheral neuropathy in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. It is labeled ER because it has extended-release properties.

7. On information and belief, Defendant Alkem is an Indian company having its principal place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (West), Mumbai, India.

THE PATENT-IN-SUIT

The '130 Patent

8. The '130 Patent, entitled "USE OF 1 PHENYL-3-DIMETHYLAMINO-PROPANE COMPOUNDS FOR TREATING NEUROPATHIC PAIN," was duly and legally issued on September 17, 2013, naming Thomas Christoph, Elmar Friderichs, Babette-Yvonne Koegel, and Murielle Meen as the inventors. A copy of the '130 Patent is attached hereto as Exhibit 1.

9. Plaintiff Grünenthal lawfully owns all right, title and interest in the '130 Patent, including the right to sue and to recover for past infringement thereof.

10. Plaintiff Janssen is an exclusive licensee of the '130 Patent, holding an exclusive license to import, market, distribute, promote, offer to sell or sell pharmaceutical formulations containing tapentadol for human use in the field of pain within the United States, with a right to enforce the '130 Patent.

11. The FDA issues a publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book").

12. In accordance with 21 U.S.C. § 355(b)(1), the '130 Patent is listed in the Orange Book in connection with NDA No. 200533 as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" NUCYNTA ER.

THE DEFENDANT ALKEM'S ANDA No. 205016

13. On information and belief, Alkem submitted ANDA No. 205016 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), and thereafter submitted an amendment ("the initial amendment") seeking FDA approval to engage in the

commercial manufacture, use, importation, offer for sale, or sale of at least generic 100 mg, 200 mg and 250 mg tapentadol hydrochloride extended release tablets.

14. On information and belief, ANDA No. 205016 has been further amended to further seek FDA approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of at least generic 50 mg and 150 mg tapentadol hydrochloride extended release tablets ("the further amendment"). Hereinafter the 50 mg, 100 mg, 150 mg, 200 mg and 250 mg tapentadol hydrochloride extended release tablets that are the subject of ANDA No. 205016 are referred to as the "ANDA No. 205016 Products."

15. On information and belief, ANDA No. 205016 as initially and further amended contains a Paragraph IV certification that the '130 Patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Alkem's ANDA" No. 205016.

16. On information and belief, Alkem is the owner of ANDA No. 205016.

17. On information and belief, if ANDA No. 205016 is approved by the FDA before the expiration of the '130 Patent, Alkem will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA No. 205016 Products, despite the patent.

18. On information and belief, if ANDA No. 205016 is approved by the FDA, Alkem will begin marketing the ANDA No. 205016 Products for the management of moderate to severe chronic pain in adults and neuropathic pain associated with diabetic peripheral neuropathy in adults, and doctors and patients will use each of the dosage strengths of the ANDA No. 205016 Products for the indications marketed by Alkem.

19. Alkem has correctly represented that the Reference Listed Drug of ANDA No. 205016 is NUCYNTA ER.

20. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval, each of the ANDA No. 205016 Products' dosage strengths must have the same strength as one of the approved dosages for NUCYNTA ER. In addition, the ANDA No. 205016 Products must be bioequivalent to NUCYNTA ER.

21. On or about November 14, 2013, Plaintiffs received a letter dated November 13, 2013 (the "November 13, 2013 notice letter"), constituting the notice of Alkem's initial amendment of ANDA No. 205016, including the Paragraph IV certification, required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). On or about July 8, 2014, Janssen received a letter dated July 7, 2014 (the "July 7, 2014 notice letter"), and on or about July 9, 2014, Grünenthal received the July 7, 2014 notice letter, constituting the notice of Alkem's further amendment of ANDA No. 205016, including the Paragraph IV certification, required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). Those notices demonstrate an actual and justiciable controversy. The Paragraph IV certifications alleged that the claims of the '130 Patent are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Alkem's ANDA" No. 205016.

22. This action was commenced within forty-five days of the date of the receipt of the November 13, 2013 notice letter of Alkem's initial amendment of ANDA No. 205016. This Amended Complaint was filed within forty-five days of the date of the receipt of the July 7, 2014 notice letter of Alkem's further amendment of ANDA No. 205016.

23. On information and belief, Alkem was aware of the '130 Patent when its initial and further amendments to ANDA No. 205016 were submitted to the FDA, containing the above-described Paragraph IV certifications concerning this specific patent.

24. Pursuant to 35 U.S.C. § 271(e)(2)(A), the submission of ANDA No. 205016 as initially and further amended to include a Paragraph IV certification seeking approval to market the ANDA No. 205016 Products by Alkem is an act of infringement of one or more claims of the '130 Patent. This infringement entitles Plaintiffs 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 approval for ANDA No. 205016 be a date which is not earlier than the expiration date of the '130 Patent, including any extensions of that date.

SUBJECT MATTER JURISDICTION

25. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally and 35 U.S.C. § 271(e)(2) specifically.

26. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

PERSONAL JURISDICTION

27. This Court has personal jurisdiction over Alkem by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement, and intends a future course of conduct that includes acts of patent infringement in New Jersey by Alkem. This act has led and will lead to foreseeable harm and injury to a New Jersey resident corporation, Plaintiff Janssen, in New Jersey. In particular, on information and belief, Alkem is actively preparing to make the proposed generic copies of NUCYNTA ER that are the subject of ANDA No. 205016, and to import, use, sell and offer to sell such generic copies in this State and this judicial district. This Court has personal jurisdiction over Alkem for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

28. Personal jurisdiction over Alkem is also proper in light of the fact that Alkem has previously availed itself of the benefits of this Court. Plaintiffs sued Alkem in this Court

alleging that the submission of ANDA No. 205016 constituted infringement of U.S. Reissue Patent 39,593 (E) and U.S. Patent Number 7,994,364 B2. *See* Case Number 13-cv-04507 at D.I. 12. Counsel for Alkem represented in connection with that matter that it would not object to jurisdiction in this judicial district for the limited scope of the matters involving ANDA No. 205016 and ANDA No. 205015. *Compare id.* at ¶ 104 (setting forth a basis for jurisdiction) *with* D.I. 17 at ¶ 104 (admitting the allegation in the complaint). Additionally, Alkem asserted counterclaims in that matter. *See* D.I. 17.

VENUE

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

COUNT I: INFRINGEMENT OF THE '130 PATENT BY ALKEM'S SUBMISSION OF ANDA NO. 205016

30. Plaintiffs incorporate and reallege paragraphs 1-29 above.

31. The submission of ANDA No. 205016 as initially and further amended to include a Paragraph IV certification regarding the '130 Patent was an act of infringement by Alkem of one or more claims of the '130 Patent under 35 U.S.C. § 271(e)(2)(A).

32. On information and belief, the use of ANDA No. 205016 Products in accordance with and as directed by the instructions contained in the proposed package insert of Alkem's ANDA No. 205016 is covered by one or more claims of the '130 Patent.

33. On information and belief, Alkem's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 205016 Products before the expiration of the '130 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '130 Patent.

34. On information and belief, the use of Alkem's ANDA No. 205016 Products in accordance with and as directed by Alkem's proposed labeling will infringe one or more claims of the '130 Patent.

35. On information and belief, by seeking approval to distribute the ANDA No. 205016 Products with their proposed labeling, Alkem intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Alkem knows will infringe one or more claims of the '130 Patent.

36. On information and belief, unless enjoined by this Court, Alkem plans and intends to, and will, actively induce infringement of one or more claims of the '130 Patent immediately following approval of ANDA No. 205016.

37. On information and belief, unless enjoined by this Court, Alkem plans and intends to, and will, contribute to the infringement of one or more claims of the '130 Patent immediately following approval of ANDA No. 205016.

38. On information and belief, Alkem knows that its ANDA No. 205016 Products and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '130 Patent, and that the Alkem ANDA No. 205016 Products and their proposed labeling are not suitable for any noninfringing use.

39. On information and belief, Alkem has been aware of the existence of the '130 Patent since before the submission of the initial amendment to ANDA No. 205016.

40. On information and belief, Alkem has no reasonable basis for believing that its ANDA No. 205016 Products will not infringe one or more valid claims of the '130 Patent and no reasonable basis for believing that the infringed claims are invalid.

41. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

42. On information and belief, unless enjoined by this Court, Alkem plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA No. 205016 Products with their proposed labeling immediately following approval of ANDA No. 205016.

43. The acts of infringement by Alkem set forth above will cause Plaintiffs Janssen and Grünenthal irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

44. 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 FDA set the effective date of approval for Alkem's ANDA No. 205016 to be a date which is not any earlier than the expiration date of the '130 Patent, including any extensions of that date.

RELIEF SOUGHT

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment in favor of Plaintiffs and against Alkem;

B. Judgment that the '130 Patent has not been proven invalid and unenforceable;

C. Judgment that Alkem has infringed, literally or by the doctrine of equivalents, the '130 Patent by the submission of ANDA No. 205016 as initially and further amended, and that the commercial importation, sale, offer for sale, use, and/or manufacture of the ANDA No. 205016 Products, in the United States, would infringe, induce infringement of, and/or contribute to the infringement of the '130 Patent;

D. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of approval of ANDA No. 205016 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21

U.S.C. § 355(j)), shall be a date not earlier than the date of expiration of the '130 Patent plus any additional periods of exclusivity;

E. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Alkem Laboratories Ltd. and its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any ANDA No. 205016 Product, and any product that is similar to or only colorably different from those products, before the date of expiration of the '130 Patent and any additional periods of exclusivity;

F. A declaration that this an exceptional case and an award to Plaintiffs Janssen and Grünenthal of their reasonable attorneys' fees and expenses, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

G. Damages or other monetary relief, including prejudgment interest, if Alkem engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of ANDA No. 205016 Products, or any other products that the use of which would infringe the '130 Patent, or the inducement of or contribution to the foregoing, prior to the expiration of the '130 Patent;

H. An award of pre-judgment and post-judgment interest on each and every award;

I. An award of Plaintiffs' taxable costs in bringing and prosecuting this action; and

J. Such other and further relief to Plaintiffs Janssen and Grünenthal as this Court may deem just and proper.

Dated: August 20, 2014

Respectfully submitted,

Donald A. Robinson

s/Donald A. Robinson

ROBINSON WETTRE & MILLER LLC
One Newark Center
Newark, New Jersey 07102
Tel: (973) 690-5400
Fax: (973) 466-2760
(drobinson@rwmlegal.com)
Attorneys for Plaintiff
Janssen Pharmaceuticals, Inc.

Of Counsel for Plaintiff
Janssen Pharmaceuticals, Inc:

SIDLEY AUSTIN LLP

David T. Pritikin
William H. Baumgartner, Jr.
Lisa A. Schneider
Jessica A. Johnson
1 S. Dearborn Street
Chicago, Illinois, 60603
Tel: (312) 853-7000
Fax: (312) 853-7036
(dpritikin@sidley.com)
(wbaumgartner@sidley.com)
(lschneider@sidley.com)
(lfriedlieb@sidley.com)
(shorowitz@sidley.com)

-and-

Rachel H. Townsend
1501 K. Street, N.W.
Washington, DC 20005
Tel: (202) 736-8000
Fax: 202 (736) 8711
(rtownsend@sidley.com)

-and-

Isaac S. Olson
787 Seventh Avenue
New York, NY 10019
Tel: (212) 839-5300
Fax: (212) 839-5599
(iolson@sidley.com)

Dated: August 20, 2014

PEPPER HAMILTON LLP

s/John F. Brenner

John F. Brenner
Suite 400
301 Carnegie Center
Princeton, New Jersey 08543-5276
Tel: (609) 452-0808
Fax: (609) 452-1147
(brennerj@pepperlaw.com)
Attorneys for Plaintiff
Grünenthal GmbH

Of Counsel for Grünenthal GmbH:

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP

Basil J. Lewris
Linda A. Wadler
Joann M. Neth
Jennifer H. Roscetti
Krista E. Bianco
901 New York Avenue, N.W.
Washington, DC 20001
Tel: (202) 408-4000
Fax: (202) 408-4400
(bill.lewris@finnegan.com)
(linda.wadler@finnegan.com)
(joann.neth@finnegan.com)
(jennifer.roscetti@finnegan.com)
(krista.bianco@finnegan.com)

Anthony C. Tridico
FINNEGAN EUROPE LLP

16 Old Bailey
London EC4M 7EG
United Kingdom
Tel: 011 44 20 3178 7883 (anthony.tridico@finnegan.com)