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

Attorneys 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. WATSON LABORATORIES, INC., Defendant.	Civil Action No. ___

COMPLAINT

In this patent infringement action, Plaintiffs Janssen Pharmaceuticals, Inc. ("Janssen") and Grünenthal GmbH ("Grünenthal"), for their complaint against Defendant Watson Laboratories, Inc. ("Watson"), 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") seeking approval to manufacture and sell a generic version of NUCYNTA® Oral Solution prior to the expiration of U.S. Reissue Patent No. 39,593 E ("the RE593 Patent") and U.S. Patent No. 7,994,364 B2 ("the '364 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 all rights, title, and interest in the RE593 Patent and the '364 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 RE593 Patent and the '364 Patent.

4. Janssen holds FDA-approved New Drug Application ("NDA") No. 203794.

5. Janssen has FDA approval to manufacture and market the drug covered by NDA No. 203794 ("NUCYNTA® Oral Solution" or the "NUCYNTA® Oral Solution drug product") in the United States. The active ingredient of NUCYNTA® Oral Solution is tapentadol hydrochloride.

6. NUCYNTA® Oral Solution is approved by the FDA for the management of moderate to severe acute pain in adults.

7. On information and belief, Defendant Watson is a corporation existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

THE PATENTS-IN-SUIT

RE593 Patent

8. The RE593 Patent, entitled "1-PHENYL-3-DIMETHYLAMINOPROPANE COMPOUNDS WITH A PHARMACOLOGICAL EFFECTS," was duly and legally issued on April 24, 2007, naming Helmut Buschmann, Elmar Friderichs, and Wolfgang Strassburger as inventors. A copy of the RE593 Patent is attached hereto as Exhibit 1.

9. The RE593 Patent is a reissue of U.S. Patent No. 6,248,737, issued on June 19, 2001.

10. Plaintiff Grünenthal lawfully owns all right, title and interest in the RE593 Patent, including the right to sue and to recover for past infringement thereof.

11. Plaintiff Janssen is an exclusive licensee of the RE593 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 RE593 Patent.

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

13. In accordance with 21 U.S.C. § 355(b)(1), the RE593 Patent is listed in the Orange Book in connection with NDA No. 203794 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® Oral Solution.

The '364 Patent

14. The '364 Patent, entitled "CRYSTALLINE FORMS OF (-)-(1R,2R)-3-(3-DIMETHYLAMINO-1-ETHYL-2-METHYLPROPYL)-PHENOL HYDROCHLORIDE," was duly and legally issued on August 9, 2011, naming Andreas Fischer, Helmut Buschmann, Michael Gruss, and Dagmar Lischke as inventors. A copy of the '364 Patent is attached hereto as Exhibit 2.

15. Plaintiff Grünenthal lawfully owns all right, title and interest in the '364 Patent, including the right to sue and to recover for past infringement thereof.

16. Plaintiff Janssen is an exclusive licensee of the '364 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 '364 Patent.

17. In accordance with 21 U.S.C. § 355(b)(1), the '364 Patent is listed in the Orange Book in connection with NDA No. 203794 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® Oral Solution.

WATSON'S ANDA

18. On information and belief, Watson submitted ANDA No. 206657 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic tapentadol oral solution of 20 mg/mL (the "ANDA No. 206657 Product").

19. On information and belief, Watson's ANDA No. 206657 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") alleging that the RE593 and '364 patents "are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, importation, offer for sale or sale of the" ANDA No. 206657 Product.

20. On information and belief, Watson is the owner of ANDA No. 206657.

21. On information and belief, if ANDA No. 206657 is approved by the FDA before the expiration of the RE593 Patent and the '364 Patent, Watson will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA No. 206657 Product, despite the Orange Book listed patents.

22. On information and belief, if ANDA No. 206657 is approved by the FDA before the expiration of the RE593 patent, Watson will begin marketing of the ANDA No. 206657 Product for the management of moderate to severe acute pain in adults, and doctors and patients will use the ANDA No. 206657 Product for the indications marketed by Watson.

23. On information and belief, if ANDA No. 206657 is approved by the FDA before the expiration of the '364 patent, Watson will begin causing third parties to manufacture, offer for sale, and sell tapentadol hydrochloride for use in Watson’s manufacture of the ANDA No. 206657 Product.

24. Watson has correctly represented that the Reference Listed Drug of ANDA No. 206657 is NUCYNTA® Oral Solution.

25. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval, the ANDA No. 206657 Product's dosage strength must have the same strength as the approved

dosage for NUCYNTA® Oral Solution. In addition, the ANDA No. 206657 Product must be bioequivalent to NUCYNTA® Oral Solution.

26. On or about June 12, 2014, Plaintiff Janssen received a letter dated June 11, 2014 (the "June 11, 2014 notice letter"), constituting notice of ANDA No. 206657, including the Paragraph IV certification, required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). On or about June 24, 2014, Plaintiff Grünenthal received a letter dated June 11, 2014 from Watson, constituting notice of ANDA No. 206657, including the Paragraph IV certification, required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). That notice demonstrates an actual and justiciable controversy under 35 U.S.C. § 271(e)(2)(A). The Paragraph IV certification alleged that the claims of the RE593 Patent and the '364 Patent, "are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the" ANDA No. 206657 Product.

27. By the filing of this Complaint, an action was commenced within forty-five (45) days of the date of receipt of the June 11, 2014 notice letter of ANDA No. 206657.

28. On information and belief, Watson was aware of the RE593 Patent and the '364 Patent when ANDA No. 206657 was submitted to the FDA, containing the above-described Paragraph IV certification concerning these specific patents.

29. Pursuant to 35 U.S.C. § 271(e)(2)(A), the submission of ANDA No. 206657 with a Paragraph IV certification seeking approval to market the ANDA No. 206657 Product is an act of infringement by Watson of one or more claims of the RE593 Patent and the '364 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. 206657 be a date

which is not earlier than the expiration date of the last expiring of the RE593 Patent and the '364 Patent, including any extensions of that date.

SUBJECT MATTER JURISDICTION

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

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

PERSONAL JURISDICTION

32. This Court has personal jurisdiction over Watson by virtue of the fact that, *inter alia*, Watson has committed a tortious act of patent infringement, and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to a New Jersey resident corporation, Plaintiff Janssen, in New Jersey. For example, on information and belief, Watson is actively preparing to make the proposed generic copies of NUCYNTA® Oral Solution that are the subject of ANDA No. 206657, and to use, sell and offer for sale such generic copies in this State and this judicial district.

33. Personal jurisdiction over Watson is proper because counsel for Watson has stated that Watson will not contest jurisdiction in this judicial district for purposes of the above-listed action.

34. On information and belief, Watson has a principal place of business in New Jersey.

35. On information and belief, Watson has previously consented to personal jurisdiction in New Jersey, and, in at least some of those actions, has filed counterclaims.

36. On information and belief, Watson distributes numerous generic drugs throughout the United States, including in this judicial district. On information and belief, Watson has purposely availed itself of this forum by shipping, offering to sell, or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities.

VENUE

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

COUNT I: INFRINGEMENT OF THE RE593 PATENT BY WATSON'S SUBMISSION OF ANDA NO. 206657

38. Plaintiffs incorporate and reallege Paragraphs 1-37 above.

39. The submission of ANDA No. 206657 with a Paragraph IV certification regarding the RE593 Patent was an act of infringement by Watson of one or more claims of the RE593 Patent under 35 U.S.C. § 271(e)(2)(A).

40. On information and belief, the ANDA No. 206657 Product is covered by one or more claims of the RE593 Patent.

41. On information and belief, Watson's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 206657 Product before the expiration of the RE593 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the RE593 Patent.

42. On information and belief, the use of Watson's ANDA No. 206657 Product in accordance with and as directed by Watson's proposed labeling will infringe one or more claims of the RE593 Patent.

43. On information and belief, by seeking approval to distribute the ANDA No. 206657 Product with its proposed labeling, Watson intends to cause others, specifically, for

example, medical professionals and patients, to perform acts that Watson knows will infringe one or more claims of the RE593 Patent.

44. On information and belief, unless enjoined by this Court, Watson plans and intends to, and will, actively induce infringement of one or more claims of the RE593 Patent immediately following the FDA's approval of ANDA No. 206657.

45. On information and belief, unless enjoined by this Court, Watson plans and intends to, and will, contribute to the infringement of one or more claims of the RE593 Patent immediately following the FDA's approval of ANDA No. 206657.

46. On information and belief, Watson knows that its ANDA No. 206657 Product and its proposed labeling is especially made or adapted for use in infringing one or more claims of the RE593 Patent, and that Watson's ANDA No. 206657 Product and its proposed labeling is not suitable for any substantial noninfringing use.

47. On information and belief, Watson has been aware of the existence of the RE593 Patent since before the submission of ANDA No. 206657.

48. On information and belief, Watson has no reasonable basis for believing that its ANDA No. 206657 Product will not infringe one or more valid claims of the RE593 Patent and no reasonable basis for believing that the infringed claims are invalid.

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

50. On information and belief, unless enjoined by this Court, Watson plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA No. 206657 Product with its proposed labeling immediately following the FDA's approval of ANDA No. 206657.

51. The acts of infringement by Watson 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.

52. 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 Watson's ANDA No. 206657 to be a date which is not any earlier than the expiration date of the RE593 Patent, including any extensions of that date.

COUNT II: INFRINGEMENT OF THE '364 PATENT BY WATSON'S SUBMISSION OF ANDA NO. 206657

53. Plaintiffs incorporate and reallege Paragraphs 1-37 above.

54. The submission of ANDA No. 206657 with a Paragraph IV certification regarding the '364 Patent was an act of infringement by Watson of one or more claims of the '364 Patent under 35 U.S.C. § 271(e)(2)(A).

55. On information and belief, the active ingredient used by Watson to manufacture the ANDA No. 206657 Product and Watson's use of that active ingredient to manufacture the ANDA No. 206657 Product is covered by one or more claims of the '364 Patent.

56. On information and belief, Watson's commercial manufacture of the ANDA No. 206657 Product before the expiration of the '364 Patent would infringe one or more claims of the '364 Patent.

57. On information and belief, Watson's commercial manufacture, use, sale, and/or offer for sale of the ANDA No. 206657 Product before the expiration of the '364 Patent would induce the infringement of one or more claims of the '364 Patent.

58. On information and belief, by seeking approval to manufacture and distribute the ANDA No. 206657 Product, Watson intends to cause others, specifically, for example, third-

party drug manufacturers, to perform acts that Watson knows will infringe one or more claims of the '364 Patent.

59. On information and belief, unless enjoined by this Court, Watson plans and intends to, and will, actively induce infringement of one or more claims of the '364 Patent immediately following the FDA's approval of ANDA No. 206657.

60. On information and belief, Watson knows that the manufacture, use, importation, offer for sale, or sale of the tapentadol hydrochloride active ingredient used to manufacture its ANDA No. 206657 Product will infringe one or more claims of the '364 Patent.

61. On information and belief, Watson has been aware of the existence of the '364 Patent since before the submission of ANDA No. 206657.

62. On information and belief, Watson has no reasonable basis for believing that (1) the active ingredient used to manufacture its ANDA No. 206657 Product and/or (2) Watson's use of that active ingredient to manufacture its ANDA No. 206657 Product will not infringe one or more valid claims of the '364 Patent and has no reasonable basis for believing that the infringed claims are invalid.

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

64. On information and belief, unless enjoined by this Court, Watson plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, and/or distribution, of the ANDA No. 206657 Product immediately following the FDA's approval of ANDA No. 206657.

65. The acts of infringement by Watson 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.

66. 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 Watson's ANDA No. 206657 to be a date which is not any earlier than the expiration date of the '364 Patent, including any extensions of that date.

RELIEF SOUGHT

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment in favor of Plaintiffs and against Watson;

B. Judgment that the RE593 Patent and the '364 Patent have not been proven invalid and unenforceable;

C. Judgment that Watson has infringed, literally or by the doctrine of equivalents, the RE593 Patent by the submission of ANDA No. 206657, and that the commercial importation, sale, offer for sale, use, and/or manufacture of the ANDA No. 206657 Product, in the United States, would infringe, induce infringement of, and/or contribute to the infringement of the RE593 Patent;

D. Judgment that Watson has infringed, literally or by the doctrine of equivalents, the '364 Patent by the submission of ANDA No. 206657, and that the commercial manufacture, sale, offer for sale, and/or use of the ANDA No. 206657 Product in the United States would infringe and/or induce infringement of the '364 Patent;

E. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of approval of ANDA No. 206657 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 latest of the RE593 Patent and the '364 Patent plus any additional periods of exclusivity;

F. 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 Watson, 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. 206657 Product, and any product that is similar to or only colorably different from those products, before the date of expiration of the RE593 Patent and any additional periods of exclusivity;

G. 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 Watson, 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 (1) any commercial manufacture, offer for sale, or sale within the United States of any ANDA No. 206657 Product, and (2) any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any active ingredient that is similar to or only colorably different from the active ingredient described in ANDA No. 206657, before the date of expiration of the '364 Patent and any additional periods of exclusivity;

H. A declaration that this is 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

I. Damages or other monetary relief, including prejudgment interest, if Watson engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of ANDA No. 206657 Product, or any other products that infringe the RE593 Patent or the '364 Patent, or the inducement of or contribution to the foregoing, prior

to the expiration of the RE593 Patent and/or the '364 Patent;

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

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

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

Dated: July 23, 2014

Respectfully submitted,

s/Donald A. Robinson

Donald A. Robinson
Keith J. Miller
ROBINSON WETTRE & MILLER LLC
One Newark Center
Newark, New Jersey 07102
Tel: (973) 690-5400
Fax: (973) 466-2760
(drobinson@rwmlegal.com)
(kmiller@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
Steven J. Horowitz
Jessica Ann 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)
(shorowitz@sidley.com)
(jessica.johnson@sidley.com)

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
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, New York 10017
Tel: (212) 839-5300
Fax: (212) 839-5599
(bdonovan@sidley.com)
(iolson@sidley.com)

Dated: July 23, 2014

s/John F. Brenner

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)
Attorneys for Plaintiff
Grünenthal GmbH

Of Counsel for Plaintiff
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)