Michael R. Griffinger
Anthony M. Gruppuso
Sheila F. McShane
GIBBONS PC
One Gateway Center
Newark, NJ 07102-5310
Telephone: (973) 596-4701
Facsimile: (973) 639-6294

Richard de Bodo (*pro hac vice*)
Siegmund Y. Gutman (*pro hac vice*)
DLA PIPER LLP
1999 Avenue of the Stars, Suite 400
Los Angeles, CA 90067
Telephone: (310) 595-3000
Facsimile: (310) 595-3300

Attorneys for Plaintiff
APP PHARMACEUTICALS, LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

APP PHARMACEUTICALS, LLC, Plaintiff, v. NAVINTA LLC, SANDOZ INC., SANDOZ AG, Defendants.	)	Civil Action No. **VERIFIED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff APP Pharmaceuticals, LLC ("APP"), by way of Complaint against Navinta LLC ("Navinta"), Sandoz Inc. and Sandoz AG (collectively, "Sandoz"), alleges as follows:

THE PARTIES

1. APP is a limited liability corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173.

2. On information and belief, Navinta is a limited liability corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 1499 Lower Ferry Road, Ewing, New Jersey 08618.

3. On information and belief, Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

4. On information and belief, Sandoz AG is a company organized under the laws of Switzerland, having a principal place of business at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action under 35 U.S.C. § 271(e)(2) and 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

6. On information and belief, Navinta is subject to personal jurisdiction within this District because, among other things, Navinta is incorporated in New Jersey, has its principal place of business in New Jersey, and is registered to do business in New Jersey.

7. On information and belief, Sandoz Inc. is subject to personal jurisdiction within this District because, among other things, Sandoz Inc. has its principal place of business in New Jersey and is registered to do business in New Jersey.

8. On information and belief, Sandoz AG is subject to personal jurisdiction within this District because, among other things, it regularly and systematically conducts business in New Jersey, including through its agent, Sandoz Inc., and because it has purposefully directed its activities at New Jersey and purposefully availed itself of the laws of New Jersey through, among other things, its collaboration with Navinta in the development of generic pharmaceuticals, including the ones at issue in this case, and its activities in connection with its role as the exclusive United States distributor of generic pharmaceuticals developed by Navinta, including the ones at issue in this case.

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

NATURE OF THE ACTION

10. This is a civil action for patent infringement that arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271(e)(2), and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This action relates to one or more Abbreviated New Drug Applications ("ANDA"), including ANDA No. 78-601, submitted by Navinta and Sandoz, either individually and/or acting in concert with each other and/or other parties, that seek approval by the United States Food and Drug Administration ("FDA") to, among other things, market a generic version of APP's ropivacaine hydrochloride injection product, Naropin® ("ANDA Products").

11. ANDA No. 78-601 was submitted to the FDA on or about November 13, 2006.

12. On information and belief, Sandoz will be the exclusive United States distributor of the generic version of Naropin for which Navinta and Sandoz, either individually and/or acting in concert with each other and/or other parties, seek FDA approval, including through ANDA No. 78-601, and will be principally responsible for marketing those products.

PATENTS-IN-SUIT

13. APP holds an approved New Drug Application ("NDA") 20-553 for Naropin. Naropin was approved by the FDA on September 24, 1996. The patents-in-suit relate to Naropin and uses of Naropin.

14. United States Patent No. 5,670,524 ("the '524 patent") (attached hereto as Exhibit A), entitled "Methods and Compositions for the Treatment of Pain Utilizing Ropivacaine," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on September 23, 1997.

15. United States Patent No. 5,834,489 ("the '489 patent") (attached hereto as Exhibit B), entitled "Methods and Compositions for the Treatment of Pain Utilizing Ropivacaine," was duly and legally issued by the USPTO on November 10, 1998.

16. APP owns all rights, title and interest in and to the '524 and '489 patents, including the right to sue and obtain relief for past, present, and future patent infringement.

FIRST CLAIM FOR RELIEF

(Infringement of the '524 Patent Under 35 U.S.C. § 271(e)(2))

17. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 16 above.

18. Navinta and Sandoz, either individually and/or acting in concert with each other and/or other parties, submitted to the FDA one or more ANDAs,

including ANDA No. 78-601, under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, marketing, and/or sale of a generic version of Naropin before the expiration date of the '524 patent.

19. By filing an ANDA, including ANDA No. 78-601, under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, marketing, and/or sale of a generic version of Naropin before the expiration date of the '524 patent, Navinta and Sandoz have committed an act of infringement under 35 U.S.C. § 271, including 35 U.S.C. § 271(e)(2)(A).

20. Navinta's and Sandoz's commercial manufacture, use, marketing, and/or sale of the ANDA Products will infringe one or more claims of the '524 patent under 35 U.S.C. § 271.

21. On information and belief, when Navinta and Sandoz submitted to the FDA its ANDA(s), including ANDA No. 78-601, they were aware of the '524 patent and were aware that, if their ANDA(s), including ANDA No. 78-601, were approved, the manufacture, use, marketing, and/or sale of the ANDA products would infringe the '524 patent.

22. On information and belief, upon FDA approval of its ANDA(s), including ANDA No. 78-601, Navinta and Sandoz will intentionally and actively induce, encourage, contribute to, and aid and abet activities by others that will

infringe the '524 patent, and Navinta and Sandoz will do so with knowledge that the activities by others will infringe the '524 patent.

23. As a result, Navinta and Sandoz are liable for inducing and/or contributing to infringement of the '524 patent under 35 U.S.C. § 271(b) and/or (c).

24. APP will be substantially and irreparably harmed if Navinta and Sandoz are not enjoined from infringing the '524 patent.

25. APP is entitled to the relief provided by 35 U.S.C. § 271, including an injunction preventing Navinta and Sandoz from infringing the '524 patent and/or a Court order that the effective date of any approval of any ANDA that seeks approval for a generic version of Naropin, including ANDA No. 78-601, be a date which is not earlier than the expiration date of the '524 patent, including any extensions.

26. On information and belief, Navinta's and Sandoz's infringement of the '524 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

SECOND CLAIM FOR RELIEF

(Infringement of the '489 Patent Under 35 U.S.C. § 271(e)(2))

27. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 26 above.

28. Navinta and Sandoz, either individually and/or acting in concert with each other and/or other parties, submitted to the FDA one or more ANDAs, including ANDA No. 78-601, under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, marketing, and/or sale of a generic version of Naropin before the expiration date of the '489 patent.

29. By filing an ANDA, including ANDA No. 78-601, under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, marketing, and/or sale of a generic version of Naropin before the expiration date of the '489 patent, Navinta and Sandoz have committed an act of infringement under 35 U.S.C. § 271, including 35 U.S.C. § 271(e)(2)(A).

30. Navinta's and Sandoz's commercial manufacture, use, marketing, and/or sale of the ANDA Products will infringe one or more claims of the '489 patent under 35 U.S.C. § 271.

31. On information and belief, when Navinta and Sandoz submitted to the FDA its ANDA(s), including ANDA No. 78-601, they were aware of the '489 patent and were aware that, if their ANDA(s), including ANDA No. 78-601, were approved, the manufacture, use, marketing, and/or sale of the ANDA Products would infringe the '489 patent.

32. On information and belief, upon FDA approval of its ANDA(s), including ANDA No. 78-601, Navinta and Sandoz will intentionally and actively

induce, encourage, contribute to, and aid and abet activities by others that will infringe the '489 patent, and Navinta and Sandoz will do so with knowledge that the activities by others will infringe the '489 patent.

33. As a result, Navinta and Sandoz are liable for inducing and/or contributing to infringement of the '489 patent under 35 U.S.C. § 271(b) and/or (c).

34. APP will be substantially and irreparably harmed if Navinta and Sandoz are not enjoined from infringing the '489 patent.

35. APP is entitled to the relief provided by 35 U.S.C. § 271, including an injunction preventing Navinta and Sandoz from infringing the '489 patent and/or a Court order that the effective date of any approval of any ANDA that seeks approval for a generic version of Naropin, including ANDA No. 78-601, be a date which is not earlier than the expiration date of the '489 patent, including any extensions.

36. On information and belief, Navinta's and Sandoz's infringement of the '489 patent has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

THIRD CLAIM FOR RELIEF

(Declaratory Judgment of Infringement of the '524 Patent)

37. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 36 above.

38. Navinta and Sandoz have taken significant concrete steps toward infringement of the '524 patent, including submitting ANDA(s), such as ANDA No. 78-601, for FDA approval of and preparing to market and sell the ANDA Products. APP will be substantially and irreparably harmed if Navinta and Sandoz manufacture, use, sell, offer for sale, and/or import into the United States the ANDA Products prior to the expiration date of the '524 patent.

39. On information and belief, Navinta's and Sandoz's infringement of the '524 patent has been and continues to be willful, and such infringement will continue unless and until it is preliminarily and permanently enjoined by this Court.

FOURTH CLAIM FOR RELIEF

(Declaratory Judgment of Infringement of the '489 Patent)

40. APP repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 39 above.

41. Navinta and Sandoz have taken significant concrete steps toward infringement of the '489 patent, including submitting ANDA(s), such as ANDA No. 78-601, for FDA approval and preparing to market and sell the ANDA Products. APP will be substantially and irreparably harmed if Navinta and Sandoz

manufacture, use, sell, offer for sale, and/or import into the United States the ANDA Products prior to the expiration date of the '489 patent.

42. On information and belief, Navinta's and Sandoz's infringement of the '489 has been and continues to be deliberate and willful, and such infringement will continue unless it is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff APP respectfully requests the following relief:

A. Judgment that Navinta and Sandoz have infringed one or more claims of the '524 and/or '489 patents;

B. An order that the effective date of any approval of any ANDA, including ANDA No. 78-601, be a date that is not earlier than the expiration date of the '524 and '489 patents, including any extensions;

C. A declaratory judgment that Navinta and Sandoz would infringe one or more claims of the '524 and/or '489 patents if they manufacture, use, offer for sale, or sell within the United States, or import into the United States, the ANDA Products prior to the expiration date of the '524 and '489 patents;

D. A preliminary and permanent injunction restraining and enjoining Navinta and Sandoz and their officers, agents, attorneys and employees, and those acting in privity or concert with Navinta and/or Sandoz, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or

importation into the United States, of a generic version of Naropin as claimed in the '524 and '489 patents, prior to the expiration date of the '524 and '489 patents, including any extensions;

E. Monetary damages for any acts of infringement by Navinta and/or Sandoz;

F. Pursuant to 35 U.S.C. § 284, an award increasing damages three times the amount found or assessed for infringement of the '524 and/or '489 patents due to the willful and deliberate nature of the infringement by Navinta and/or Sandoz;

G. Judgment that this is an exceptional case and that APP is entitled to its reasonable attorneys fees pursuant to 35 U.S.C. § 285;

H. The costs and expenses in this action; and

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

Dated: January 5, 2011 Respectfully submitted,

s/Anthony M. Gruppuso
Anthony M. Gruppuso
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Telephone: (973) 596-4415
Facsimile: (973) 639-8333

DLA PIPER LLP
1999 Avenue of the Stars, Suite 400
Los Angeles, CA 90067

Telephone: (310) 595-3000
Facsimile: (310) 595-3300

Attorneys for Plaintiff
APP PHARMACEUTICALS, LLC

VERIFICATION

I, Richard E. Mahon, have read the foregoing Verified Complaint, and declare pursuant to 28 U.S.C. § 1746, under penalty of perjury, that the foregoing information stated therein is true and correct to the best of my knowledge, information and belief.

Date: January 5, 2011