EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH, Plaintiffs, v. AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, Defendants.	C.A. No. 12-CIV-8115-ALC-GWG

SECOND AMENDED COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Grünenthal GmbH ("Grünenthal") for their Second Amended Complaint against Defendants Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal"), alleges as follows:

PARTIES

1. Plaintiff Endo is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Endo is a specialty Pharmaceuticals company engaged in the research, development, sale and marketing of prescription pharmaceuticals used, among other things, to treat and manage pain. Endo markets and distributes OPANA® ER, an innovative crush-resistant opioid (alternatively referred to herein as "Opana ER CRF").

2. Plaintiff Grünenthal GmbH ("Grünenthal") is a corporation organized and existing under the laws of Germany, having an address at 52078 Aachen, Zieglerstaβe 6, North Rhine-Westaphalia, Germany.

3. Upon information and belief, Amneal Pharmaceuticals, LLC ("Amneal Pharmaceuticals") is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 440 U.S. Highway 22 East, Suite 104, Bridgewater, NJ 08897.

4. Upon information and belief, Amneal Pharmaceuticals is a pharmaceutical company engaged in the research, development, production, distribution, and sale of generic pharmaceuticals throughout the United States, including sales within this judicial district.

5. Upon information and belief, Amneal Pharmaceuticals of New York, LLC ("Amneal New York") is a limited liability company organized and existing under the laws of the State of Delaware, and shares a principal place of business with Amneal Pharmaceuticals' administrative offices at 85 Adams Avenue, Hauppauge, New York 11788.

6. Upon information and belief, Amneal New York is a pharmaceutical company engaged in the manufacturing for and the sale of generic prescription pharmaceutical products to Amneal Pharmaceuticals for distribution throughout the United States, including in this judicial district.

NATURE OF ACTION

7. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*. and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) (patent infringement), and 28 U.S.C. §§ 2201 and 2202 (declaratory judgment).

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

10. Upon information and belief, Amneal Pharmaceuticals conducts its North American operations in part through Amneal New York. Together, Amneal Pharmaceuticals and Amneal New York collaborate in the research, development, manufacture, testing, distribution and/or the sale of a number of pharmaceutical products manufactured and sold pursuant to approved abbreviated new drug applications within the United States and the State of New York generally and this judicial district specifically.

11. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, they have committed — or aided, abetted, planned, contributed to, or participated in the commission of — tortious conduct in the State of New York that has led to foreseeable harm and injury to Endo.

12. Upon information and belief, Amneal Pharmaceuticals has submitted to FDA paperwork purporting to constitute an Abbreviated New Drug Application ("ANDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) ("ANDA No. 20-4294" or "Amneal's ANDA"), seeking approval to engage in the commercial manufacture, use, and sale of 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg oxymorphone hydrochloride extended-release tablets, ("Amneal's ANDA Products"), as a generic version of the drug described in Endo's sNDA 201655.

13. Upon information and belief, Amneal both manufactures the Amneal ANDA Products and conducts testing necessary to validate their quality in the State of New York. On further information and belief, Amneal intends to manufacture and test Amneal's ANDA Products produced for commercial sale in the State of New York.

14. Upon information and belief, Amneal New York intends to manufacture generic

Opana ER CRF for distribution and sale in this judicial district should Amneal's ANDA be approved by FDA. Upon information and belief, Amneal Pharmaceuticals intends to distribute and sell generic Opana ER CRF in this judicial district should ANDA No. 20-4294 be approved by FDA.

15. Moreover, Amneal Pharmaceuticals and Amneal New York maintain continuous and systematic contacts with the State of New York and this District.

16. Upon information and belief, Amneal Pharmaceuticals and Amneal New York are registered with the New York State Department of State as corporations actively conducting business within New York and maintain a registered agent within the state.

17. Upon information and belief, Amneal Pharmaceuticals currently sells significant quantities of generic drug products in the Southern District of New York. Those products include, for example, generic versions of Percocet®, Ultracet®, and Neurontin®. A list of generic products manufactured and sold by Amneal Pharmaceuticals in the United States can be found at http://www.amneal.com/index.php.

18. Upon information and belief, Amneal Pharmaceuticals maintains an administrative office at 85 Adams Avenue, Hauppauge, NY 11788; an oral solids manufacturing facility at 75 Adams Avenue, Hauppauge, NY 11788; an oral solids and softgels manufacturing facility at 50 Horseblock Road, Brookhaven, NY 11719; and an oral solids research and development facility at 50 Horseblock Road, Brookhaven, NY 11719.

19. Upon information and belief, Amneal New York's principal place of business is located at 85 Adams Avenue, Hauppauge, New York 11788.

20. Furthermore, Amneal Pharmaceuticals has been sued as a patent infringer in this Court, asserted counterclaims in this Court, and declined to contest that this Court has personal

jurisdiction over it. *See, e.g., Purdue Pharm, L.P., et al. v. Amneal Pharmaceuticals, LLC*, 11-cv-08153-SHS-JLC; *Pfizer Inc., et al. v. Actavis Inc., et al.*, 10-cv-8197-(TPG).

21. Based on the facts and causes alleged herein, and for additional reasons to be developed through discovery, this Court has personal jurisdiction over the Defendants.

FACTUAL BACKGROUND

The Drug Approval Process

22. A company seeking to market a new drug in the United States must first obtain approval from FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, to FDA, and upon approval, FDA then lists such patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

23. On the other hand, a company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an ANDA. *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on the innovator company's data and FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "listed drug" or "branded drug").

24. In conjunction with this "abbreviated" application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, under which an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may

certify, for instance, that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This is known as a "Paragraph IV Certification."

25. The sponsor of an ANDA which is accepted for review by FDA that contains a Paragraph IV Certification must provide notice ("Paragraph IV Notice") to both the owner of the listed patents and the holder of the NDA for the referenced listed drug. The certification must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid or not infringed by the proposed generic product. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95.

26. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is generally subject to a 30-month stay of regulatory approval. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important to innovator companies, such as Endo and Grünenthal, because it protects them from the severe financial harm that could otherwise ensue from FDA granting approval to a potentially infringing product without first providing an opportunity for the innovators to prove infringement and obtain an injunction prohibiting sale of the infringing product. Put another way, the innovator company is assured of a 30-month period during which it may try to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

Endo's Opana ER CRF NDA

27. On December 12, 2011, FDA approved Endo's Supplemental New Drug Application ("sNDA") 201655, under § 505(b) of the Federal Food, Drug and Cosmetic Act, 21

U.S.C. § 355(b), for a new dosage form of Opana ER which is a crush-resistant tablet that contains oxymorphone hydrochloride for the relief of pain (hereinafter, "Opana ER CRF").

28. Opana ER CRF is distributed and sold throughout the United States for relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.

THE ENDO PATENTS

29. On December 14, 2010, the PTO duly and legally issued U.S. Patent No. 7,851,482 ("the '482 Patent"), entitled "Method For Making Analgesics" to Johnson Matthey Public Limited Company ("Johnson Matthey") as assignee. Jen-Sen Dung, Erno M. Keskeny, and James J. Mencel are named as inventors. A true and correct copy of the '482 Patent is attached as Exhibit A.

30. Endo subsequently acquired full title to the '482 Patent, and accordingly, Endo is now the sole owner and assignee of the '482 Patent.

31. On November 13, 2012, the PTO duly and legally issued U.S. Patent No. 8,309,122 ("the '122 Patent"), entitled "Oxymorphone Controlled Release Formulations" to Endo Pharmaceuticals, Inc. as assignee. Huai-Hung Kao, Anand R. Baichwal, Troy McCall, and David Lee are named as inventors. A true and correct copy of the '122 Patent is attached as Exhibit B. Endo is the sole owner and assignee of the '122 Patent.

32. On December 11, 2012, the PTO duly and legally issued U.S. Patent No. 8,329,216 ("the '216 Patent"), entitled "Oxymorphone Controlled Release Formulations" to Endo Pharmaceuticals, Inc. as assignee. Huai-Hung Kao, Anand R. Baichwal, Troy McCall, and David Lee are named as inventors. A true and correct copy of the '216 Patent is attached as Exhibit C. Endo is the sole owner and assignee of the '216 Patent.

33. Information regarding the Endo ’482, ’122, and ’216 Patents (the “Endo Patents”) was submitted to FDA for listing in the Orange Book. Pursuant to 21 C.F.R. § 314.53(e), FDA has listed the Endo Patents in the Orange Book with reference to NDA 201655.

34. Opana ER CRF is covered by one or more claims of each of the Endo Patents.

THE GRÜNENTHAL PATENTS

35. On June 5, 2012, the PTO duly and legally issued U.S. Patent No. 8,192,722 (“the ’722 Patent”), entitled “Abuse-Proofed Dosage Form” to Gruenenthal GmbH, also known as Grünenthal GmbH, as assignee. Elisabeth Arkenau-Marić, Johannes Bartholomäus, and Heinrich Kugelmann are named as inventors. A true and correct copy of the ’722 Patent is attached as Exhibit D.

36. On November 13, 2013, the PTO duly and legally issued U.S. Patent No. 8,309,060 (“the ’060 Patent”), entitled “Abuse-Proofed Dosage Form” to Gruenenthal GmbH, also known as Grünenthal GmbH, as assignee. Elisabeth Arkenau-Marić, Johannes Bartholomäus, and Heinrich Kugelmann are named as inventors. A true and correct copy of the ’060 Patent is attached as Exhibit E.

37. Grünenthal is the assignee and owner of the ’722 and ’060 Patents (“the Grünenthal Patents”).

38. Endo has an exclusive license to the Grünenthal Patents from Grünenthal, including a right to enforce the Grünenthal Patents.

39. Information regarding the Grünenthal Patents was submitted to FDA for listing in the Orange Book. Pursuant to 21 C.F.R. § 314.53(e), FDA has listed the Grünenthal Patents in the Orange Book with reference to NDA 201655.

40. Opana ER CRF is covered by one or more claims of each of the Grünenthal Patents.

AMNEAL'S ANDA FILING

41. Upon information and belief, some time before September 21, 2012, Amneal submitted to FDA paperwork purporting to constitute an Abbreviated New Drug Application ("ANDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg oxymorphone hydrochloride extended-release tablets ("Amneal's ANDA Products"), as a generic version of the products described in sNDA 201655.

42. In a letter dated September 21, 2012 addressed to Endo and received on or about September 24, 2012, and in a separate letter addressed to Grünenthal dated October 10, 2012 and received by Grünenthal on or about that same day, Amneal purported to notify Plaintiffs that Amneal had submitted ANDA No. 20-4294, seeking approval to manufacture, use, or sell Amneal's ANDA Products before the expiration of the '482 and '722 Patents ("Amneal Notice Letters").

43. The Amneal Notice Letters claimed that Amneal's ANDA included a Paragraph IV Certification stating that it was Amneal's opinion that the claims of the '482 and '722 Patents are invalid, unenforceable, or are not infringed by the proposed manufacture, importation, use, sale, or offer for sale of the Amneal ANDA Products.

44. This action, claiming infringement of the '482 and '722 Patents, was commenced before the expiration of forty-five days from the date Endo and Grünenthal received the Amneal Notice Letters. The Plaintiffs' first Amended Complaint, added two Counts, asserting infringement of the '122 and '060 Patents, which the United States Patent and Trademark Office

("USPTO") issued after Plaintiffs filed their original Complaint. This Second Amended Complaint includes one additional Count, asserting infringement of the '216 Patent, which the USPTO issued after Plaintiffs filed their First Amended Complaint.

COUNT I: INFRINGEMENT OF THE '482 PATENT

45. Endo incorporates each of paragraphs 1-44 above as if set forth fully herein.

46. The submission of Amneal's ANDA to FDA, which includes certification under § 505(j)(2)(A)(vii)(IV), constitutes infringement of the '482 Patent under 35 U.S.C. § 271(e)(2)(A).

47. Amneal is seeking FDA approval to engage in the commercial manufacture, use, or sale of Amneal's ANDA Products before the expiration of the '482 Patent. If granted approval, Amneal intends to launch its ANDA Products before expiration of the '482 Patent.

48. Amneal's commercial manufacture, offer for sale, or sale of its ANDA Products would infringe the '482 Patent under 35 U.S.C. § 271(a)-(c).

49. Any launch by Amneal of its ANDA Products before expiration of the '482 Patent would cause Endo to suffer immediate and irreparable harm.

50. Amneal was aware of the existence of the '482 Patent, as demonstrated by its reference to that patent in the Amneal Notice Letters, and was aware that the filing of its Paragraph IV Certification with respect to the '482 Patent would constitute infringement of the patent.

COUNT II: INFRINGEMENT OF THE '722 PATENT

51. Endo incorporates each of paragraphs 1-44 above as if set forth fully herein.

52. The submission of Amneal's ANDA to FDA, which includes certification under § 505(j)(2)(A)(vii)(IV), constitutes infringement of the '722 Patent under 35 U.S.C. § 271(e)(2)(A).

53. Amneal is seeking FDA approval to engage in the commercial manufacture, use,

or sale of its ANDA Products before the expiration of the '722 Patent. If granted approval, Amneal intends to launch Amneal's ANDA Products before expiration of the '722 Patent.

54. Amneal's commercial manufacture, offer for sale, or sale of its ANDA Products would infringe the '722 Patent under 35 U.S.C. § 271(a)-(c).

55. Any launch by Amneal of its ANDA Products before expiration of the '722 Patent would cause Endo to suffer immediate and irreparable harm.

56. Amneal was aware of the existence of the '722 Patent, as demonstrated by its reference to that patent in the Amneal Notice Letters, and was aware that the filing of its Paragraph IV Certification with respect to the '722 Patent would constitute infringement of the patent.

COUNT III: INFRINGEMENT OF THE '122 PATENT

57. Endo incorporates each of paragraphs 1-44 above as if set forth fully herein.

58. The submission of Amneal's ANDA to FDA constitutes infringement of the '122 Patent under 35 U.S.C. § 271(e)(2)(A).

59. Amneal is seeking FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Products before the expiration of the '122 Patent. If granted approval, Amneal intends to launch its ANDA Products before expiration of the '122 Patent.

60. Amneal's commercial manufacture, offer for sale, or sale of its ANDA Products would infringe the '122 Patent under 35 U.S.C. § 271(a)-(c).

61. Any launch by Amneal of its ANDA Products before expiration of the '122 Patent would cause Endo to suffer immediate and irreparable harm.

COUNT IV: INFRINGEMENT OF THE '060 PATENT

62. Plaintiffs incorporate each of paragraphs 1-44 above as if set forth fully herein.

63. The submission of Amneal's ANDA to FDA constitutes infringement of the '060 Patent under 35 U.S.C. § 271(e)(2)(A).

64. Amneal is seeking FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Products before the expiration of the '060 Patent. If granted approval, Amneal intends to launch its ANDA Products before expiration of the '060 Patent.

65. Amneal's commercial manufacture, offer for sale, or sale of its ANDA Products would infringe the '060 Patent under 35 U.S.C. § 271(a)-(c).

66. Any launch by Amneal of its ANDA Products before expiration of the '060 Patent would cause Endo and Grünenthal to suffer immediate and irreparable harm.

COUNT V: INFRINGEMENT OF THE '216 PATENT

67. Endo incorporates each of paragraphs 1-44 above as if set forth fully herein.

68. The submission of Amneal's ANDA to FDA constitutes infringement of the '216 Patent under 35 U.S.C. § 271(e)(2)(A).

69. Amneal is seeking FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Products before the expiration of the '216 Patent. If granted approval, Amneal intends to launch its ANDA Products before expiration of the '216 Patent.

70. Amneal's commercial manufacture, offer for sale, or sale of its ANDA Products would infringe the '216 Patent under 35 U.S.C. § 271(a)-(c).

71. Any launch by Amneal of its ANDA Products before expiration of the '216 Patent would cause Endo to suffer immediate and irreparable harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Endo and Grünenthal respectfully request the following relief:

A. A judgment that Defendants have infringed the '482 Patent, and a declaration that Amneal's commercial manufacture, distribution, use, and sale of its ANDA Products would

infringe the ’482 Patent;

B. A declaration that the ’482 Patent is valid and enforceable;

C. A judgment that Amneal has infringed the ’722 Patent, and a declaration that Amneal’s commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the ’722 Patent;

D. A declaration that the ’722 Patent is valid and enforceable;

E. A judgment that Amneal has infringed the ’122 Patent, and a declaration that Amneal’s commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the ’122 Patent;

F. A declaration that the ’122 Patent is valid and enforceable;

G. A judgment that Amneal has infringed the ’060 Patent, and a declaration that Amneal’s commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the ’060 Patent;

H. A declaration that the ’060 Patent is valid and enforceable;

I. A judgment that Amneal has infringed the ’216 Patent, and a declaration that Amneal’s commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the ’216 Patent;

J. A declaration that the ’216 Patent is valid and enforceable;

K. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Amneal’s ANDA No. 20-4324 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the last expiration date of the ’482, ’722, ’122, ’060, and ’216 Patents, including any extensions;

L. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and

enjoining Amneal, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement of the '482, '722, '122, '060, and '216 Patents for the full terms thereof, including any extensions;

M. An order that damages or other monetary relief be awarded to Endo and Grünenthal if Amneal engages in the commercial manufacture, use, offer to sell, sale, distribution or importation of Amneal's ANDA Products, or in inducing such conduct by others, prior to the expiration of the '482, '722, '122, '060, and '216 Patents, and any additional period of exclusivity to which Plaintiffs are or become entitled, and that any such damages or monetary relief be trebled and awarded to Endo and Grünenthal with prejudgment interest;

N. A declaration that this an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

O. Reasonable attorneys' fees, filing fees, and reasonable costs of suit incurred by Endo and Grünenthal in this action; and

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

Dated: January 9, 2013

By: _____

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