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

ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH, Plaintiffs, v. IMPAX LABORATORIES, INC. and THORX LABORATORIES, INC., Defendants.	C.A. No. 12-CIV-8317-TPG

AMENDED COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Grünenthal GmbH ("Grünenthal") for their Amended Complaint against Defendants Impax Laboratories, Inc. and ThoRx Laboratories, Inc. (collectively "Defendants"), allege 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 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, Impax Laboratories, Inc. ("Impax Labs") is a

Delaware corporation, having its principal place of business at 30831 Huntwood Avenue, Hayward, CA 94544. Impax Labs is a pharmaceutical company engaged in the research, development, manufacture, sale and marketing of generic and brand prescription pharmaceuticals for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, ThoRx Laboratories, Inc. ("ThoRx") is a California corporation that shares its principal place of business with Impax Labs at 30831 Huntwood Avenue, Hayward, California, 94544 and is a wholly owned subsidiary of Impax Labs.

5. Upon information and belief, Impax Labs controls and directs the operations of ThoRx and ThoRx serve as Impax Labs' alter ego, agent, and department that filed ANDA No. 20-4334 for the benefit of Impax Labs.

NATURE OF ACTION

6. This is an action 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

7. 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).

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

9. 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 which will lead to foreseeable harm and injury to Plaintiffs in the State of New York.

10. Upon information and belief, ThoRx 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. 20-4334 " or "Defendants' 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, ("Defendants' ANDA Products"), as a generic version of the drug described in Endo's sNDA 201655.

11. Upon information and belief, Impax Labs intends to distribute and sell Defendants' ANDA Products in this judicial district if FDA approves Defendants' ANDA.

12. Because Defendants have not offered Plaintiffs confidential access to their ANDA filing, Plaintiffs cannot assess, without an opportunity to take discovery, each Defendant's respective involvement in the research and development of their ANDA products or in the preparation of their ANDA.

13. Upon information and belief, at least some of the persons responsible for the research and development of Defendants' ANDA and/or for the preparation of Defendants' ANDA are Impax Labs employees.

14. Impax Labs maintains continuous and systematic contacts with the State of New York and this District.

15. Upon information and belief, Impax Labs currently sell significant quantities of generic drug products in the Southern District of New York. Those products include, for example, generic versions of Wellbutrin SR®, Adderall XR®, and Flomax®. A list of generic products manufactured and sold by Impax through its generic drug division, Global Pharmaceuticals, in the United States is provided by Impax at http://www.globalphar.com/products/product_catalogue.

16. This Court has previously found that Impax is subject to personal jurisdiction in this Judicial District in patent litigation concerning an earlier Abbreviated New Drug Application ("ANDA") that Impax Labs submitted to the FDA. *See Purdue Pharma L.P. v. Impax Laboratories, Inc.*, No. 02 Civ. 2803(SHS), 2003 WL 22070549 (S.D.N.Y. Sept. 4, 2003).

17. Impax Labs has availed itself of New York State courts as a plaintiff, which was subsequently removed to this Court in *Impax Laboratories, Inc. v. Shire LLC, et al.*, 10-cv-08386-MGC (S.D.N.Y.). Furthermore, refused to contest this Court's personal jurisdiction over it as recently as last year in the patent litigation *Purdue Pharma L.P., et al. v. Impax Laboratories, Inc.*, 11-cv-2400 (S.D.N.Y.).

18. Upon information and belief, ThoRx has no facilities independent of Impax Labs' facilities.

19. Upon information and belief, ThoRx's actions relating to ANDA No. 20-4334 were done at the direction of and with the authorization, cooperation, participation, and assistance of Impax Labs for Impax Labs' benefit.

20. Accordingly, this Court has personal jurisdiction over ThoRx, *inter alia*, by virtue of the fact that this Court has personal jurisdiction over Impax Labs and ThoRx is merely Impax Labs' alter ego, agent, and department that filed ANDA No. 20-4334 for the benefit of Impax Labs.

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 Opana ER CRF, a crush-resistant tablet that contains oxymorphone hydrochloride for the relief of pain.

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 the Endo Patents.

THE GRÜNENTHAL PATENTS

35. On February 14, 2012, the PTO duly and legally issued U.S. Patent No. 8,114,383 ("the '383 Patent"), entitled "Abuse-Proofed Dosage Form" to Gruenenthal GmbH, also known

as Grünenthal GmbH, as assignee. Johannes Bartholomäus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić are named as inventors. A true and correct copy of the '383 Patent is attached as Exhibit D.

36. 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 E.

37. 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 F.

38. Grünenthal is the assignee and owner of the '383, '722, and '060 Patents ("the Grünenthal Patents").

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

40. 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.

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

DEFENDANTS' ANDA FILING

42. Upon information and belief, some time before October 29, 2012, Defendants submitted their ANDA to FDA, seeking approval to engage in the commercial manufacture, use, and sale of their ANDA Products.

43. In a letter dated October 29, 2012 addressed to Plaintiffs and received by Endo on or about November 1, 2012 and by Grünenthal on or about October 31, 2012, Defendants purported to notify Endo and Grünenthal that Defendants had submitted ANDA No. 20-4334 , naming ThoRx as the ANDA applicant and seeking approval to manufacture, use, or sell Defendants' ANDA Products before the expiration of the '482, '383, and '722 Patents ("Defendants' Notice Letter").

44. Defendants' Notice Letter claimed that Defendants' ANDA included a Paragraph IV Certification stating that it was Defendants' opinion that the claims of the '482, '383, and '722 Patents are invalid, unenforceable, or are not infringed by the proposed manufacture, importation, use, sale, or offer for sale of their ANDA Products.

45. This action, claiming infringement of the '482, '383, and '722 Patents, was commenced before the expiration of forty-five days from the date Endo and Grünenthal received the ThoRx Notice Letters. The Complaint also included two Counts asserting infringement of the '122 and '060 Patents. This Amended Complaint includes one additional Count, asserting infringement of the '216 Patent, which the USPTO issued after Plaintiffs filed their Original Complaint.

COUNT I: INFRINGEMENT OF THE '482 PATENT

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

47. The submission of Defendants' 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).

48. Defendants are seeking FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Products before the expiration of the '482 Patent. If granted approval, Defendants intend to launch their ANDA Products before expiration of the '482 Patent.

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

50. Any launch by Defendants of their ANDA Products before expiration of the '482 Patent would cause Endo to suffer immediate and irreparable harm.

51. Defendants were aware of the existence of the '482 Patent, as demonstrated by their reference to that patent in the Defendants' Notice Letter, and were aware that the filing of their Paragraph IV Certification with respect to the '482 Patent would constitute infringement of the patent.

COUNT II: INFRINGEMENT OF THE '383 PATENT

52. Plaintiffs incorporate each of paragraphs 1-45 above as if set forth fully herein.

53. The submission of Defendants' ANDA to FDA, which includes certification under § 505(j)(2)(A)(vii)(IV), constitutes infringement of the '383 Patent under 35 U.S.C. § 271(e)(2)(A).

54. Defendants are seeking FDA approval to engage in the commercial manufacture, use, or sale of their ANDA Products before the expiration of the '383 Patent. If granted approval, Defendants intend to launch their ANDA Products before expiration of the '383 Patent.

55. Defendants' commercial manufacture, offer for sale, or sale of their ANDA Products would infringe the '383 Patent under 35 U.S.C. § 271(a)-(c).

56. Any launch by Defendants of their ANDA Products before expiration of the '383 Patent would cause Endo and Grünenthal to suffer immediate and irreparable harm.

57. Defendants were aware of the existence of the '383 Patent, as demonstrated by their reference to that patent in the Defendants Notice Letter, and were aware that the filing of their Paragraph IV Certification with respect to the '383 Patent would constitute infringement of the patent.

COUNT III: INFRINGEMENT OF THE '722 PATENT

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

59. The submission of Defendants' 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).

60. Defendants are seeking FDA approval to engage in the commercial manufacture, use, or sale of their ANDA Products before the expiration of the '722 Patent. If granted approval, Defendants intend to launch their ANDA Products before expiration of the '722 Patent.

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

62. Any launch by Defendants of their ANDA Products before expiration of the '722 Patent would cause Endo to suffer immediate and irreparable harm.

63. Defendants were aware of the existence of the '722 Patent, as demonstrated by their reference to that patent in the Defendants Notice Letter, and were aware that the filing of their Paragraph IV Certification with respect to the '722 Patent would constitute infringement of the patent.

COUNT IV: INFRINGEMENT OF THE '122 PATENT

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

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

66. Defendants are seeking FDA approval to engage in the commercial manufacture, use, or sale of their ANDA Products before the expiration of the '122 Patent. If granted approval, Defendants intend to launch their ANDA Products before expiration of the '122 Patent.

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

68. Any launch by Defendants of their ANDA Products before expiration of the '122 Patent would cause Endo to suffer immediate and irreparable harm.

COUNT V: INFRINGEMENT OF THE '060 PATENT

69. Plaintiffs incorporate each of paragraphs 1-45 above as if set forth fully herein.

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

71. Defendants are seeking FDA approval to engage in the commercial manufacture, use, or sale of their ANDA Products before the expiration of the '060 Patent. If granted approval, Defendants intend to launch their ANDA Products before expiration of the '060 Patent.

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

73. Any launch by Defendants of their ANDA Products before expiration of the '060 Patent would cause Endo and Grünenthal to suffer immediate and irreparable harm.

COUNT VI: INFRINGEMENT OF THE '216 PATENT

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

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

76. Defendants are 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, Defendants intend to launch its ANDA Products before expiration of the '216 Patent.

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

78. Any launch by Defendants of their 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 Defendants' commercial manufacture, distribution, use, and sale of their ANDA Products would infringe the '482 Patent;

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

C. A judgment that Defendants have infringed the '383 Patent, and a declaration that Defendants' commercial manufacture, distribution, use, and sale of their ANDA Products would infringe the '383 Patent;

D. A declaration that the '383 Patent is valid and enforceable;

E. A judgment that Defendants have infringed the '722 Patent, and a declaration that Defendants' commercial manufacture, distribution, use, and sale of their ANDA Products would infringe the '722 Patent;

F. A declaration that the '722 Patent is valid and enforceable;

G. A judgment that Defendants have infringed the '122 Patent, and a declaration that Defendants' commercial manufacture, distribution, use, and sale of their ANDA Products would infringe the '122 Patent;

H. A declaration that the '122 Patent is valid and enforceable;

I. A judgment that Defendants have infringed the '060 Patent, and a declaration that Defendants' commercial manufacture, distribution, use, and sale of their ANDA Products would infringe the '060 Patent;

J. A declaration that the '060 Patent is valid and enforceable;

K. A judgment that Defendants have infringed the '216 Patent, and a declaration that Defendants' commercial manufacture, distribution, use, and sale of their ANDA Products would infringe the '216 Patent;

L. A declaration that the '216 Patent is valid and enforceable;

M. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Defendants' ANDA No. 20-4334 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, '383, '722, '122, '060, and '216 Patents, including any extensions;

N. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement of the '482, '383, '722, '122, '060, and '216 Patents, for the full terms thereof, including any extensions;

O. An order that damages or other monetary relief be awarded to Endo and Grünenthal if Defendants engage in the commercial manufacture, use, offer to sell, sale, distribution or importation of Defendants' ANDA Products, or in inducing such conduct by

others, prior to the expiration of the '482, '383, '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;

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

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

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

Dated: January 24, 2013

By: _____

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