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

ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH,

Plaintiffs,

v.

IMPAX LABORATORIES, INC.,

Defendant.

C.A. No. 13 CIV 435

COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Grünenthal GmbH ("Grünenthal") for their Complaint against Defendant Impax Laboratories, Inc. ("Impax" or "Defendant"), 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 is a Delaware corporation, having its

principal place of business at 30831 Huntwood Avenue, Hayward, CA 94544. Impax 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.

NATURE OF ACTION

4. 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

5. 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).

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

7. This Court has personal jurisdiction over Impax by virtue of the fact that, *inter alia*, it has 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.

8. Upon information and belief, Impax 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. 20-4211 " or "Impax'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, ("Impax's ANDA Products"), as a generic version of the drug described in Endo's sNDA 201655.

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

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

11. Upon information and belief, Impax 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.

12. 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 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).

13. Impax 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, Impax very recently conceded that this Court has personal jurisdiction over it in related patent case involving Opana ER CRF that Plaintiffs filed against Impax and its subsidiary, ThoRx Laboratories, Inc. *See Endo Pharmaceuticals, Inc., et al. v. Impax Laboratories, Inc., et al.*, 12-cv-08317-PKC (S.D.N.Y.). Impax's Answer, Affirmative Defenses, and Counterclaims, D.I. #8 at ¶ 9.

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

FACTUAL BACKGROUND

The Drug Approval Process

15. 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).

16. 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").

17. 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."

18. 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.

19. 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

20. 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.

21. 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

22. 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.

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

24. 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.

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

26. 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.

27. Upon issuance, information regarding the Endo '216 Patent was submitted to

FDA for listing in the Orange Book.

28. Opana ER CRF is covered by one or more claims of each of the '482, '122, and '216 Patents.

THE GRÜNENTHAL PATENTS

29. 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.

30. 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.

31. On November 13, 2012, 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.

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

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

34. 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 '383, '722, and '060 Patents in the Orange Book with reference to NDA 201655.

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

IMPAX'S ANDA FILING

36. Upon information and belief, some time before December 5, 2012, Impax submitted its ANDA to FDA, seeking approval to engage in the commercial manufacture, use, and sale of its ANDA Products.

37. In a letter dated December 5 addressed to Plaintiffs and received by Endo on or about December 6, 2012 and by Grünenthal on or about December 6, 2012, Impax purported to notify Endo and Grünenthal that it had submitted ANDA No. 20-4211, naming Impax as the ANDA applicant and seeking approval to manufacture, use, or sell Impax's ANDA Products before the expiration of, *inter alia*, the '482, '122, '383, '722, and the '060 Patents ("Impax's Notice Letter").

38. Impax's Notice Letter claimed that Impax's ANDA included a Paragraph IV Certification stating that it was Impax's opinion that the claims of the '482, '122, '383, '722, and the '060 Patents are invalid, unenforceable, or are not infringed by the proposed manufacture, importation, use, sale, or offer for sale of their ANDA Products.

39. This action is being commenced before the expiration of forty-five days from the date Endo and Grünenthal received Impax's Notice Letter. This Complaint also includes a Count asserting infringement of the '216 Patent which issued after Impax sent its Notice Letter to Endo and Grünenthal.

COUNT I: INFRINGEMENT OF THE '482 PATENT

40. Endo incorporates each of paragraphs 1-39 above as if set forth fully herein.

41. The submission of Impax'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).

42. Impax is 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, Impax intends to launch its ANDA Products before expiration of the '482 Patent.

43. Impax'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).

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

45. Impax was aware of the existence of the '482 Patent, as demonstrated by its reference to that patent in the Impax 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 '383 PATENT

46. Plaintiffs incorporate each of paragraphs 1-39 above as if set forth fully herein.

47. The submission of Impax's 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).

48. Impax is seeking FDA approval to engage in the commercial manufacture, use, or sale of its ANDA Products before the expiration of the '383 Patent. If granted approval, Impax

intends to launch its ANDA Products before expiration of the '383 Patent.

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

50. Any launch by Impax of its ANDA Products before expiration of the '383 Patent would cause Endo and Grünenthal to suffer immediate and irreparable harm.

51. Impax was aware of the existence of the '383 Patent, as demonstrated by its reference to that patent in the Impax Notice Letters, and was aware that the filing of its Paragraph IV Certification with respect to the '383 Patent would constitute infringement of the patent.

COUNT III: INFRINGEMENT OF THE '722 PATENT

52. Endo incorporates each of paragraphs 1-39 above as if set forth fully herein.

53. The submission of Impax'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).

54. Impax 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, Impax intends to launch its ANDA Products before expiration of the '722 Patent.

55. Impax'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).

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

57. Impax was aware of the existence of the '722 Patent, as demonstrated by its reference to that patent in the Impax 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 IV: INFRINGEMENT OF THE '122 PATENT

58. Endo incorporates each of paragraphs 1-39 above as if set forth fully herein.

59. The submission of Impax's ANDA to FDA, which includes certification under § 505(j)(2)(A)(vii)(IV), constitutes infringement of the '122 Patent under 35 U.S.C. § 271(e)(2)(A).

60. Impax 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, Impax intends to launch its ANDA Products before expiration of the '122 Patent.

61. Impax'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).

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

63. Impax was aware of the existence of the '122 Patent, as demonstrated by its reference to that patent in the Impax Notice Letters, and was aware that the filing of its Paragraph IV Certification with respect to the '122 Patent would constitute infringement of the patent.

COUNT V: INFRINGEMENT OF THE '060 PATENT

64. Plaintiffs incorporate each of paragraphs 1-39 above as if set forth fully herein.

65. The submission of Impax's ANDA to FDA, which includes certification under § 505(j)(2)(A)(vii)(IV), constitutes infringement of the '060 Patent under 35 U.S.C. § 271(e)(2)(A).

66. Impax 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, Impax intends to launch its ANDA Products before expiration of the '060 Patent.

67. Impax'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).

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

69. Impax was aware of the existence of the '060 Patent, as demonstrated by its reference to that patent in the Impax Notice Letters, and was aware that the filing of its Paragraph IV Certification with respect to the '060 Patent would constitute infringement of the patent.

COUNT VI: INFRINGEMENT OF THE '216 PATENT

70. Endo incorporates each of paragraphs 1-39 above as if set forth fully herein.

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

72. Impax 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, Impax intends to launch its ANDA Products before expiration of the '216 Patent.

73. Impax'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).

74. Any launch by Impax 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 Impax has infringed the '482 Patent, and a declaration that Impax'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 Impax has infringed the '383 Patent, and a declaration that Impax's commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the '383 Patent;

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

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

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

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

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

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

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

K. A judgment that Impax has infringed the '216 Patent, and a declaration that

Impax's commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the '122 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 Impax's ANDA No. 20-4340 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 Impax, its 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 Impax engages in the commercial manufacture, use, offer to sell, sale, distribution or importation of Impax's ANDA Products, or in inducing such conduct by others, before 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 is 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 17, 2013

By: _____

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