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

ENDO PHARMACEUTICALS INC.,  
and GRÜNENTHAL GMBH,

Plaintiffs,

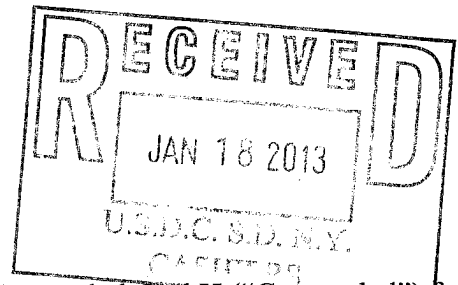
v.

ACTAVIS INC., ACTAVIS SOUTH  
ATLANTIC LLC, and WATSON  
PHARMACEUTICALS, INC.,

Defendants.

C.A. No. \_\_\_\_\_

COMPLAINT



Plaintiffs Endo Pharmaceuticals Inc. (“Endo”), and Grünenthal GmbH (“Grünenthal”) for their Complaint against defendants Actavis Inc., Actavis South Atlantic LLC, and Watson Pharmaceuticals, Inc. (collectively “Actavis” or “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 tablet (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, Zieglerstraße 6, North Rhine-Westphalia, Germany.

3. Upon information and belief, defendant Actavis Inc. is a corporation organized and existing under the laws of the State of Delaware, having its headquarters and principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960. Actavis Inc. is a pharmaceutical company engaged in the development, manufacture, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Actavis South Atlantic LLC (“ASA”) is a limited liability company, organized and existing under the laws of the State of Delaware, having its principal place of business at 13800 N.W. 2nd Street, Suite 190, Sunrise, FL 33325. ASA is a pharmaceutical company engaged in the development, manufacture, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

5. Upon information and belief, defendant Watson Pharmaceuticals, Inc. (“Watson”) is a Nevada corporation, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Watson is a pharmaceutical company engaged in the development, manufacture, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

6. Upon information and belief, Watson is the direct or indirect corporate parent of Actavis Inc. and ASA (collectively, the “Actavis Defendants”). Upon further information and belief, Watson controls and directs the operations of the Actavis Defendants, and the acts of ASA complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of Actavis Inc. and Watson.

**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. 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 Plaintiffs.

11. Moreover, Defendants maintain continuous and systematic contacts with the State of New York and this District. Defendants market and sell pharmaceutical products through the United States, including the State of New York, and regularly, systematically, and currently transact business in the Southern District of New York, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, pharmaceutical products. Defendants derive substantial revenue from goods used or consumed or services rendered in this judicial district.

12. Upon information and belief, the Actavis Defendants currently sell significant quantities of generic drug products in the Southern District of New York. Those products include, for example, generic versions of Wellbutrin XL®, Xanax®, and Cardizem® CD. A list

of generic products manufactured and sold by the Actavis Defendants in the United States is provided at <http://www.actavis.us/en/products/new.htm>.

13. Moreover, the Actavis Defendants have either admitted or declined to contest personal jurisdiction in New York. *See Pfizer Inc., et al. v. Actavis Inc., et al.*, 10-cv-8197-PAE (S.D.N.Y.)(refusing to contest personal jurisdiction); *Braun v. Actavis South Atlantic LLC, et al.*, 08-cv-4126-LDW (E.D.N.Y.)(admitting personal jurisdiction).

14. Upon information and belief, Watson currently sells significant quantities of generic drug products in the Southern District of New York. Those products include, for example, generic versions of Wellbutrin XL®, Lipitor®, and Concerta®. A list of generic products manufactured and sold by Watson in the United States is provided at <http://www.watson.com/products/product-database-detail.asp?group=generic&c=Rx>.

15. Upon information and belief, shares in Watson trade on the New York Stock Exchange under the ticker symbol “WPI.”

16. Furthermore, Watson recently availed itself of the U.S. District Court for the Southern District of New York as plaintiff in a patent litigation. *See Takeda Pharmaceutical Co., Ltd. et al. v. Mylan, Inc.*, 12-cv-00024-DLC (S.D.N.Y.).

17. Upon information and belief, Actavis Inc., ASA and Watson 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.

18. Upon information and belief, ASA 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. 20-3930” or “Actavis’ 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 (“Actavis’ ANDA Product”), as a generic version of the drug described in Endo’s sNDA 201655. Upon information and belief, ASA’s actions relating to ANDA No. 20-3930 were done at the direction of and with the authorization, cooperation, participation, and assistance of, and at least in part, for the benefit of Actavis Inc. and Watson.

19. Upon information and belief, Defendants intend to distribute and sell Actavis’ ANDA Product in this judicial district if ANDA No. 20-3930 is approved by FDA.

20. 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**

21. A company seeking to market a new pharmaceutical 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).

22. 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").

23. 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."

24. When an applicant submits an ANDA to FDA, FDA has 60 days to preliminarily review the application to ensure that it is sufficiently complete to permit substantive review. 21 C.F.R. § 314.101. Only after FDA notifies the applicant that its ANDA is substantially complete is the ANDA deemed to have been "filed." *Id.*

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. Mencil 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 was submitted to FDA for listing in the Orange Book. Pursuant to 21 C.F.R. § 314.53(e), FDA has listed the '482, '122, and '216 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 '482, '122, and '216 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 Gruenthal 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 Gruenthal 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, 2012, the PTO duly and legally issued U.S. Patent No. 8,309,060 (“the '060 Patent”), entitled “Abuse-Proofed Dosage Form” to Gruenthal 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 '383, '722, and '060 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.

#### **ACTAVIS' ANDA FILING**

42. Upon information and belief, some time before December 5, 2012, Actavis 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 oxymorphone

hydrochloride extended-release tablets, (“Actavis’ ANDA Product”), as a generic version of the drug described in sNDA 201655.

43. In a letter dated December 5, 2012 addressed to Plaintiffs and received by Endo on December 6, 2012 and Grünenthal on or about December 6, 2012, Actavis purported to notify Endo and Grünenthal that Actavis had submitted ANDA No. 20-3930, naming ASA as the ANDA applicant and seeking approval to manufacture, use, or sell Actavis’ ANDA Product before the expiration of the ’482, ’122, ’383, ’722, and ’060 Patents. The Actavis Notice Letters claimed that Actavis’ ANDA included a Paragraph IV Certification stating that it was Actavis’ opinion that the claims of the ’482, ’122, ’383, ’722, and ’060 Patents are invalid, unenforceable, and/or are not infringed by the proposed manufacture, importation, use, sale, or offer for sale of the Actavis ANDA Products.

44. In a letter dated December 14, 2012 addressed to Plaintiffs and received by Endo on December 17, 2012, Actavis purported to notify Endo that Actavis had submitted ANDA No. 20-3930, naming ASA as the ANDA applicant and seeking approval to manufacture, use, or sell Actavis’ ANDA Product before the expiration of the ’216 Patent. The Actavis Notice Letter claimed that Actavis’ ANDA included a Paragraph IV Certification stating that it was Actavis’ opinion that the claims of the ’216 Patent are invalid, unenforceable, and/or are not infringed by the proposed manufacture, importation, use, sale, or offer for sale of the Actavis ANDA Products.

45. This action, claiming infringement of the ’482, ’122, ’383, ’722, ’060, and ’216 Patents, is being commenced before the expiration of forty-five days from the date Endo and Grünenthal received the Actavis Notice Letters.

**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 Actavis' 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. Actavis 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, Actavis intends to launch its ANDA Products before expiration of the '482 Patent.

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

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

51. Actavis was aware of the existence of the '482 Patent, as demonstrated by its reference to that patent in the Actavis 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**

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

53. The submission of Actavis' 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. Actavis 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,

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

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

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

57. Actavis was aware of the existence of the '383 Patent, as demonstrated by its reference to that patent in the Actavis 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**

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

59. The submission of Actavis' 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. Actavis 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, Actavis intends to launch its ANDA Products before expiration of the '722 Patent.

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

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

63. Actavis was aware of the existence of the '722 Patent, as demonstrated by its reference to that patent in the Actavis 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**

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

65. The submission of Actavis' 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).

66. Actavis 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, Actavis intends to launch its ANDA Products before expiration of the '122 Patent.

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

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

**COUNT V: INFRINGEMENT OF THE '216 PATENT**

69. Endo incorporates each of Paragraphs 1-45 above as if set forth fully herein.

70. The submission of Actavis' ANDA to FDA, which includes certification under § 505(j)(2)(A)(vii)(IV), constitutes infringement of the '216 Patent under 35 U.S.C. § 271(e)(2)(A).

71. Actavis 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, Actavis intends to launch its ANDA Products before expiration of the '216 Patent.

72. Actavis' commercial manufacture, offer for sale, or sale of its ANDA Products

would infringe the '216 Patent under 35 U.S.C. § 271(a)-(c).

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

**COUNT VI: INFRINGEMENT OF THE '060 PATENT**

74. Plaintiffs incorporate each of Paragraphs 1-45 above as if set forth fully herein.

75. The submission of Actavis' 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).

76. Actavis 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, Actavis intends to launch its ANDA Products before expiration of the '060 Patent.

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

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

**PRAYER FOR RELIEF**

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

A. A judgment that Actavis has infringed the '482 Patent, and a declaration that Actavis' 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 Actavis has infringed the '383 Patent, and a declaration that Actavis' 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 Actavis has infringed the '722 Patent, and a declaration that Actavis' 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 Actavis has infringed the '122 Patent, and a declaration that Actavis' 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 Actavis has infringed the '216 Patent, and a declaration that Actavis' commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the '122 Patent;

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

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

L. A declaration that the '060 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 Actavis' ANDA No. 20-3930 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, '216, and '060 Patents, including any extensions;

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

enjoining Actavis, 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, '216, and '060 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 Actavis engages in the commercial manufacture, use, offer to sell, sale, distribution or importation of Actavis' ANDA Products, or in inducing such conduct by others, before the expiration of the '482, '383, '722, '122, '216, and '060 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.

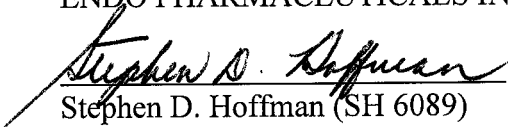


Dated: January 17, 2013

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