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

ENDO PHARMACEUTICALS INC. and GRÜNENTHAL GMBH, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and BARR LABORATORIES, INC., Defendants.	C.A. No. 12-CIV-8060 (TPG)

SECOND AMENDED COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Grünenthal GmbH ("Grünenthal") for their Second Amended Complaint against Defendants Teva Pharmaceuticals USA, Inc. and Barr Laboratories Inc. (collectively "Teva" 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 (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, Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is a company organized and existing under the laws of Israel and maintains its principal place of business at 5 Basel Street, Petah Tikva, Israel.

4. Upon information and belief, Teva Ltd. is a pharmaceutical company engaged in the world-wide development, production, and marketing of generic and branded pharmaceuticals, including in this judicial district.

5. Upon information and belief, Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, is a wholly owned subsidiary of Teva Ltd., and maintains its principal place of business at 1090 Horsham Rd. North Wales, Pennsylvania 19454.

6. Upon information and belief, Teva USA is a pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of generic prescription pharmaceutical products throughout the United States, including in this judicial district.

7. Upon information and belief, Barr Laboratories, Inc. ("Barr") is a corporation organized and existing under the laws of the State of Delaware, is an indirect wholly owned subsidiary of Teva USA and maintains its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey.

8. Upon information and belief, Barr is a pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of generic prescription pharmaceutical products throughout the United States, including in this judicial district.

NATURE OF ACTION

9. 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

10. 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).

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

12. Upon information and belief, Teva Ltd. conducts its North American operations in part through Teva USA and Barr. Together, Teva Ltd., Teva USA, and Barr 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.

13. This Court has personal jurisdiction over both 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.

14. Upon information and belief, Teva USA 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. 20-4324" or "Teva'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 ("Teva's ANDA Products"), as a generic version of the drug described in Endo's sNDA 201655.

15. Upon information and belief, Teva USA and Barr have, in this judicial district, conducted testing necessary to validate the quality of Teva's ANDA Products and its manufacturing process. On further information and belief, Teva USA and Barr intend to conduct similar testing on lots of Teva's ANDA Products produced for commercial sale if Teva's ANDA is approved by FDA.

16. Upon information and belief, Teva intends to distribute and sell its ANDA Products in this judicial district if its ANDA is approved by FDA.

17. Upon information and belief, Teva USA's and Barr's actions relating to ANDA No. 20-4324 were done at the direction of and with the authorization, cooperation, participation, and assistance of, and at least in part, for the benefit of Teva Ltd.

18. Moreover, Teva USA and Barr maintain continuous and systematic contacts with the State of New York and this District.

19. Upon information and belief, Teva USA and Barr 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.

20. Upon information and belief, Teva currently sells significant quantities of generic drug products in the Southern District of New York. Those products include, for example, generic versions of Ambien®, Prozac®, and Zocor®. A list of generic products manufactured and sold by Teva in the United States is provided by Teva at http://www.tevagenerics.com/default.aspx?pageid=3305.

21. On information and belief, Teva USA and Barr maintain facilities for the analytical testing of raw materials and finished drug products at 223 Quaker Road, Pomona, NY 10970.

22. Furthermore, Teva USA, and Barr have availed themselves of the U.S. District Court for the Southern District of New York as plaintiffs in various patent litigations. *See, e.g.*, *TEVA Pharmaceuticals USA, Inc., et al. v. Synthon Pharmaceuticals, Inc., et al.*, 12-cv-2556-BSJ; *TEVA Pharmaceuticals USA, Inc. and Barr Laboratories, Inc. v. Bayer Schering Pharma AG, et al.*, 10-cv-4340-NRB; *Teva Pharmaceuticals USA, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, 09-cv-8824-BSJ; *TEVA Pharmaceuticals USA, Inc., et al. v. Sandoz, Inc., et al.*, 08-cv-7611-BSJ-AJP.

23. 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

24. 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).

25. 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").

26. 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."

27. 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.

28. 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

29. 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").

30. 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

31. 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.

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

33. 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.

34. 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.

35. 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.

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

THE GRÜNENTHAL PATENTS

37. 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.

38. 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.

39. 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.

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

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

42. 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.

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

TEVA'S ANDA FILING

44. Upon information and belief, some time before September 20, 2012, Teva 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, ("Teva's ANDA Products"), as a generic version of the drug described in sNDA 201655.

45. In a letter dated September 20, 2012 addressed to Plaintiffs and received by Endo on September 21, 2012 and Grünenthal on or about September 21, 2012, Teva purported to notify Endo and Grünenthal that Teva had submitted ANDA No. 20-4324, naming Teva USA as the ANDA applicant and seeking approval to manufacture, use, or sell Teva's ANDA Products with respect to the 7.5 mg and 15 mg dosage forms before the expiration of the '482, '383, and

'722 Patents ("First Notice Letter"). In a letter dated October 5, 2012 addressed to Plaintiffs and received by Endo on or about October 8, 2012, and Grünenthal on October 10, 2012, Teva purported to notify Endo and Grünenthal that Teva had submitted an ANDA No. 20-4324, naming Teva USA as the ANDA applicant and seeking approval to manufacture, use, or sell Teva's ANDA Products with respect to the 5 mg, 10 mg, 20 mg, 30 mg, and 40 mg dosage forms before the expiration of the '482, '383, and '722 Patents (("Second Notice Letter")).

46. Teva's First and Second Notice Letters claimed that Teva's ANDA included a Paragraph IV Certification stating that it was Teva's 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 the Teva ANDA Products.

47. 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 Teva Notice Letters. 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.

48. In a letter dated February 5, 2013 addressed to Plaintiffs and received by Endo on or about February 6, 2013, and Grünenthal on February 8, 2013, Teva purported to notify Endo and Grünenthal that Teva had submitted an ANDA No. 20-4324, naming Teva USA as the ANDA applicant and seeking approval to manufacture, use, or sell Teva's ANDA Products with respect to the 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg dosage forms before the expiration of the '060, '122, and '216 Patents ("Third Notice Letter").

49. 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

50. Endo incorporates each of paragraphs 1-49 above as if set forth fully herein.

51. The submission of Teva'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).

52. Teva 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, Teva intends to launch its ANDA Products before expiration of the '482 Patent.

53. Teva'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).

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

55. Teva was aware of the existence of the '482 Patent, as demonstrated by its reference to that patent in the Teva 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

56. Plaintiffs incorporate each of paragraphs 1-49 above as if set forth fully herein.

57. The submission of Teva'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).

58. Teva 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, Teva

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

59. Teva'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).

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

61. Teva was aware of the existence of the '383 Patent, as demonstrated by its reference to that patent in the Teva 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

62. Endo incorporates each of paragraphs 1-49 above as if set forth fully herein.

63. The submission of Teva'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).

64. Teva 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, Teva intends to launch its ANDA Products before expiration of the '722 Patent.

65. Teva'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).

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

67. Teva was aware of the existence of the '722 Patent, as demonstrated by its reference to that patent in the Teva 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

68. Endo incorporates each of paragraphs 1-49 above as if set forth fully herein.

69. The submission of Teva'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)..

70. Teva 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, Teva intends to launch its ANDA Products before expiration of the '122 Patent.

71. Teva'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).

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

COUNT V: INFRINGEMENT OF THE '060 PATENT

73. Plaintiffs incorporate each of paragraphs 1-49 above as if set forth fully herein.

74. The submission of Teva'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).

75. Teva 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, Teva intends to launch its ANDA Products before expiration of the '060 Patent.

76. Teva'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).

77. Any launch by Teva of its 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

78. Endo incorporates each of paragraphs 1-49 above as if set forth fully herein.

79. The submission of Teva's 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).

80. Teva 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, Teva intends to launch its ANDA Products before expiration of the '216 Patent.

81. Teva'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).

82. Any launch by Teva 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 Teva has infringed the '482 Patent, and a declaration that Teva'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 Teva has infringed the '383 Patent, and a declaration that Teva'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 Teva has infringed the '722 Patent, and a declaration that Teva'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 Teva has infringed the '122 Patent, and a declaration that Teva'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 Teva has infringed the '060 Patent, and a declaration that Teva'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 Teva has infringed the '216 Patent, and a declaration that Teva's commercial manufacture, distribution, use, and sale of its 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 Teva'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, '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 Teva, 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 Teva engages in the commercial manufacture, use, offer to sell, sale, distribution or importation of Teva's 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: February 14, 2013

By: _____

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