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ATTORNEYS FOR PLAINTIFF ENDO PHARMACEUTICALS INC.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ENDO PHARMACEUTICALS INC.,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,

Defendant.

Civil Action No.: _____

COMPLAINT

Plaintiff Endo Pharmaceuticals Inc. ("Endo"), for its Complaint against defendant Impax Laboratories, Inc. ("Impax"), alleges as follows:

INTRODUCTION

1. Endo brings this action seeking redress for Impax's breach of its contractual obligation and the common law duty of good faith and fair dealing, to uphold the sanctity of settlements entered into before this Court, and to remedy Impax's willful and unauthorized use of Endo's patents. In settling prior litigation before this Court, Impax agreed that should pending patent applications owned by Endo mature into issued patents, it would negotiate with Endo in good faith to compensate Endo for Impax's exploitation of those patents. Now that the time has come to make good on its promise, Impax has refused to negotiate in good faith, forcing Endo to

bring this litigation to vindicate its rights. Endo seeks redress for Impax's wanton disregard of its contractual obligations and Endo's patent rights.

PARTIES

2. Plaintiff Endo is a Delaware corporation, having its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. 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 extended release opioid painkiller that contains oxymorphone hydrochloride as its sole active ingredient.

3. Defendant Impax is a Delaware corporation, having its principal place of business at 30831 Huntwood Avenue, Hayward, California 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 District. Impax makes and sells generic extended release oxymorphone hydrochloride tablets in competition with Endo's OPANA® ER.

NATURE OF ACTION

4. This is an action for breach of contract and breach of the implied duty of good faith and fair dealing arising under the laws of the State of New Jersey.

5. This is also 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

6. 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), and because the Court retained jurisdiction to resolve disputes arising out of the parties' Settlement and License Agreement (described below) pursuant to the Stipulation of Dismissal and Order dated June 15, 2010 and entered by the Court in *Endo Pharmaceuticals Inc., et al. v. Impax Laboratories, Inc.*, Civil Action Nos. 09-cv-831, 832, 833 (KSH-PS).

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

8. This Court has personal jurisdiction over Impax by virtue of the fact that, *inter alia*, Impax has committed—or aided, abetted, planned, contributed to, or participated in the commission of—tortious conduct in this District that has led to foreseeable harm and injury to Endo. Impax distributes and sells its generic extended release oxymorphone hydrochloride tablets throughout the United States, including in this District, and Impax maintains continuous and systematic contacts with the State of New Jersey and this District.

THE DRUG APPROVAL PROCESS

9. A company seeking to market a new drug in the United States must first obtain approval from the United States Food and Drug Administration ("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 commonly referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

10. 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 Abbreviated New Drug Application, known as 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 findings of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "reference listed drug" or "branded drug").

11. In conjunction with this "abbreviated" application process, Congress implemented 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."

12. The sponsor of an ANDA that is accepted for review by FDA and 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.

ENDO'S OPANA® ER NDA

13. On June 22, 2006, FDA approved Endo's NDA No. 21-610 for OPANA® ER, an extended release pain reliever containing oxymorphone HCl, a semi-synthetic opioid analgesic ("Original OPANA® ER"). Oxymorphone is a Schedule II Controlled Substance. The Controlled Substances Act defines Schedule II Controlled Substances as drugs that have "a high potential for abuse" which may lead "to severe psychological or physical dependence." 21 U.S.C. § 812(b)(2). FDA approved the Original OPANA® ER tablets for the relief of

moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.

14. In July 2006, Endo launched Original OPANA® ER and began selling it throughout the United States.

15. FDA determined that the Original OPANA® ER tablets were safe and effective when used properly and according to the indications on their label. However, the Original OPANA® ER tablets were subject to possible abuse or misuse in ways that posed health risks.

16. Congress, FDA, the White House and numerous other private and public organizations have recognized that the misuse and abuse of prescription pain relievers – such as by crushing tablets into a fine powder and inhaling or dissolving and injecting them so as to produce a faster, more powerful sense of euphoria – has reached crisis levels over the last decade. This misuse and abuse has serious public health consequences, including the possibility of addiction, overdose and even death.

17. In recognition of increased reports of this crisis, Endo invested significant resources in developing a reformulated version of OPANA® ER that incorporated a proprietary tablet hardness technology developed by Grünenthal GmbH, which Grünenthal calls "INTAC Technology." Ordinary tablets, like Original OPANA® ER, typically require a force of less than 200 newtons to break, while tablets made using Grünenthal's INTAC Technology have a breaking strength of greater than 500 newtons.

18. On July 7, 2010, Endo submitted NDA No. 201655 to FDA for its reformulated version of OPANA® ER, which employs INTAC Technology and has a significantly higher breaking strength ("OPANA® ER CRF"). FDA approved the NDA for OPANA® ER CRF on December 9, 2011.

19. Endo ceased manufacturing and selling the Original OPANA® ER tablets, and in February 2012, Endo began shipping its harder, reformulated OPANA® ER CRF tablets. Since May 2012, Endo has only sold its OPANA® ER CRF tablets.

THE DISTRICT OF NEW JERSEY LITIGATION

20. In June 2007, Impax submitted ANDA No. 79-087 to FDA ("Impax ANDA"), seeking approval to engage in the commercial manufacture, use and sale of generic extended-release oxymorphone hydrochloride tablets as generic versions of Original OPANA® ER ("Impax Generic Oxymorphone ER Tablets").

21. Thereafter, Impax sent Endo a notice stating it had submitted its ANDA seeking approval to manufacture, use or sell the Impax Generic Oxymorphone ER Tablets prior to the expiration of the patents then listed in the Orange Book for Original OPANA® ER.

22. On November 15, 2007, Endo (along with co-plaintiff Penwest Pharmaceuticals Co., which was subsequently acquired by Endo) filed the first of several patent infringement suits against Impax in the District of Delaware, each arising out of Impax's submission of its ANDA and asserting that the Impax Generic Oxymorphone ER Tablets would infringe U.S. Patent Nos. 5,662,933 ("the '933 patent") and 5,958,456 ("the '456 patent"). These actions were assigned to the Honorable Katharine S. Hayden of the District of New Jersey pursuant to an intra-circuit program to relieve court congestion in the District of Delaware. In February 2009, these matters were administratively transferred to the District of New Jersey and remained assigned to Judge Hayden (under Civil Action Nos. 09-cv-831, 832 and 833 (KSH-PS), ultimately consolidated under 09-cv-831).

23. Judge Hayden consolidated Endo's claims against Impax with related suits against other generics and set the cases for a consolidated trial in June 2010. The cases against Impax settled during trial, and on June 8, 2010, Endo and Impax executed the final Settlement and

License Agreement. A true and correct copy of a redacted copy of the executed Settlement and License Agreement as filed with the Securities and Exchange Commission is attached hereto as Exhibit A.

24. Judge Hayden thereafter dismissed the cases with prejudice (except as specified in the Settlement and License Agreement) by Stipulation of Dismissal and Order, dated June 15, 2010. Pursuant to that Order, "the Court retain[ed] jurisdiction over [the] Stipulation of Dismissal and Order, and the interpretation of the Settlement and License Agreement as it pertains to this Stipulation of Dismissal and Order, in the event of any dispute concerning it."

THE SETTLEMENT AND LICENSE AGREEMENT

25. Pursuant to the Settlement and License Agreement, Endo granted Impax a license to begin sales of the Impax Generic Oxymorphone ER Tablets on January 1, 2013, and Impax agreed to pay a contingent royalty during the 180-day exclusivity period following the launch date. The '456 and '933 patents at issue in the litigation were set to expire on September 9, 2013.

26. At the time of trial and settlement, Endo had pending before the United States Patent & Trademark Office ("PTO") several patent applications directed to extended release oxymorphone formulations that, if issued, would cover both OPANA® ER and the Impax Generic Oxymorphone ER Tablets and which, if issued, would extend patent protection for the product until at least 2021. The parties were aware of the pending patent applications at the time of settlement, but because the applications had not issued, and indeed might never issue, the parties were unable to reach an agreement on the compensation to be paid by Impax for the use of such patents.

27. In order to resolve the dispute relating to the pending patent applications, the parties entered into a compromise pursuant to which Impax and Endo agreed that Impax would have a license to any patents issuing from the pending patent applications and other patents Endo might acquire, but that once the scope of the future patents rights became known with certainty, the parties would negotiate in good faith over the terms of an amended license to such future patents.

28. The general license grant of the Settlement and License Agreement, Section 4.1(a), granted to Impax "a non-transferable (except in accordance with Section 9.6), non-sublicensable and royalty-free (except as set forth in Section 4.3) license (the 'License'), under the Opana® ER Patents, any continuations, continuations in part, or divisionals thereof, and any patents and patent applications owned by Endo . . . that cover or could potentially cover the manufacture, use, sale, offer for sale, importation, marketing or distribution of products (or any components thereof) that are the subject of the Impax ANDA (the issued patents being the 'Existing Patents' and the patent applications (and any patents issued thereunder) being the 'Pending Applications' and the Existing Patents and Pending Applications being collectively the 'Licensed Patents'), during the License Term, to make, have made, offer to sell, sell, have sold, market, distribute, import and use the Impax Products solely in or for the Territory."

29. At Endo's insistence, however, and in order to effectuate the compromise described above, the Settlement and License Agreement also included Section 4.1(d), pursuant to which Impax "agrees to negotiate in good faith an amendment to the terms of the License to any patents which issue from any Pending Applications for the time period following the Exclusivity Period." In other words, Endo had agreed to grant Impax rights under its future patents to

resolve the dispute, but Impax was obligated to negotiate the price for the license in good faith to compensate Endo if Endo succeeded in obtaining new, relevant patent rights.

ENDO'S FUTURE PATENTS

30. Endo ultimately succeeded in obtaining several new patents covering OPANA® ER and the Impax Generic Oxymorphone ER Tablets, including the following.

The '122 Patent

31. On November 13, 2012, the PTO duly and legally issued to Endo Pharmaceuticals Inc. as assignee U.S. Patent No. 8,309,122 ("the '122 patent"), entitled "Oxymorphone Controlled Release Formulations," from U.S. Application No. 11/680,432 filed on February 28, 2007. A true and correct copy of the '122 patent is attached as Exhibit B.

32. Endo is the sole owner and assignee of the '122 patent.

The '216 Patent

33. On December 11, 2012, the PTO duly and legally issued to Endo Pharmaceuticals Inc. as assignee U.S. Patent No. 8,329,216 ("the '216 patent"), entitled "Oxymorphone Controlled Release Formulations," from U.S. Application No. 11/427,438 filed on June 29, 2006. A true and correct copy of the '216 patent is attached as Exhibit C.

34. Endo is the sole owner and assignee of the '216 patent.

The '737 Patent

35. On August 19, 2014, the PTO duly and legally issued to Endo Pharmaceuticals Inc. as assignee U.S. Patent No. 8,808,737 ("the '737 patent"), entitled "Method of Treating Pain Utilizing Controlled Release Oxymorphone Pharmaceutical Compositions and Instruction on Dosing for Renal Impairment," from U.S. Application No. 12/716,973 filed on March 3, 2010. A true and correct copy of the '737 patent is attached as Exhibit D.

36. Endo is the sole owner and assignee of the '737 patent.

THE NEW YORK LITIGATION

37. As a result of the Settlement and License Agreement, Endo has competed in the marketplace with Impax since January 2013, with Endo selling its harder, reformulated OPANA® ER CRF tablets and Impax selling its Generic Oxymorphone ER Tablets, which have a much lower breaking strength than OPANA® ER CRF tablets.

38. Seeking to copy Endo for a second time, Impax developed a hardened tablet of its own, and in 2012, Impax filed an ANDA with FDA, No. 20-4211, seeking FDA approval to make and sell those tablets as a generic version of OPANA® ER CRF ("Impax Generic Oxymorphone ER CRF Tablets").

39. Endo filed suit against Impax and a number of other generic manufacturers in the United States District Court for the Southern District of New York asserting that each of the defendants' respective generic versions of Original OPANA® ER and/or OPANA® ER CRF (including Impax's hardened Generic Oxymorphone ER CRF Tablets) infringe or would infringe the '122 and '216 patents (the "New York Litigation"). The cases were tried over five weeks in April 2015 and May 2015 before the Honorable Thomas P. Griesa.

40. On August 14, 2015, Judge Griesa issued an opinion holding, *inter alia*, that Impax infringed claims 2, 3, 19 and 20 of the '122 Patent and claims 1, 22, 50, 54, 57, 62, 64 and 71 of the '216 Patent (the "Impax Infringed Claims"). Judge Griesa issued an injunction against any future commercial manufacture or sale of the Impax Generic Oxymorphone ER CRF Tablets. That judgment and injunction are the subject of pending post-trial motions.

41. During the New York Litigation, Impax challenged the validity of the Impax Infringed Claims, a defense that Judge Griesa rejected. Accordingly, Impax is collaterally estopped from challenging the validity of the Impax Infringed Claims.

IMPAX'S BREACH OF ITS OBLIGATION TO NEGOTIATE AN AMENDMENT TO THE LICENSE FOR ENDO'S FUTURE PATENTS

42. With the New York Litigation behind the parties, and the validity of the '122 and '216 patents confirmed, Endo approached Impax on October 1, 2015, seeking to negotiate an amendment to the License, as expressly required under Section 4.1(d) of the Settlement and License Agreement, for the Endo patents that issued after the parties' settlement—*i.e.*, the '122, '216, and '737 patents ("New Patents").

43. Endo sent Impax a request to commence negotiations and provided a proposed term sheet setting forth its proposal to amend the License for the New Patents. The term sheet included customary license terms, including a provision for payment of a reasonable royalty based upon Impax's sales of its Generic Oxymorphone ER Tablets.

44. Impax refused to respond to the term sheet, refused to negotiate and spurned Endo's request for a meeting. In violation of Section 4.1(d) of the Settlement and License Agreement, Impax has refused to make any counterproposal, taking the unreasonable and contractually baseless position that it can exploit the New Patents without payment of compensation.

45. In an effort to avoid its contractual obligation to engage in a good faith negotiation over the price of a license for the Impax Generic Oxymorphone ER Tablets under the New Patents, Impax has unjustifiably requested an expanded license that would cover its proposed Generic Oxymorphone ER CRF Tablets, which have yet to be approved by FDA and which it is enjoined from selling by virtue of the judgment and injunction entered in the New York Litigation. Endo is unwilling to grant such a license and is under no obligation to do so.

46. On April 19, 2016, Endo notified Impax that Impax's: (i) refusal to negotiate the terms of the License to use the New Patents for the Impax Generic Oxymorphone ER Tablets,

and (ii) attempt to instead expand the License to cover the previously unknown Impax Generic Oxymorphone ER CRF Tablets, are wholly inconsistent with both the history of the parties' negotiations and the express language of Section 4.1(d) of the Settlement and License Agreement. Despite Impax's obstructive behavior, Endo reiterated its offer to negotiate, stating:

> We are willing to be reasonable here, and the amount of the royalty and other terms relating to the Impax Product are negotiable, but we can't negotiate without a partner. Unless we receive Impax's unequivocal confirmation that it is dropping the spurious demand that we include additional products in the License by April 26, and a legitimate monetary offer to compensate Endo for its patent rights, we will assume that Impax has no intention of negotiating an amendment in good faith and proceed accordingly.

47. To date, Endo has not received any further communications from Impax on this issue.

48. By refusing to negotiate the required amendment to the License for the Impax Generic Oxymorphone ER Tablets under the New Patents in good faith, Impax has materially breached the Settlement and License Agreement.

49. The amount of the damages caused by Impax's breach and owed to Endo at this time is unknown with certainty absent discovery; however, given sales of Impax's product and the number of years left before expiration of the New Patents, the amount due from Impax over the life of the patents is well in excess of $100 million.

COUNT I: BREACH OF CONTRACT

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

51. At all times, Endo has fully performed its obligations under the Settlement and License Agreement.

52. Impax refused to negotiate in good faith with Endo concerning an amendment to the License for the Impax Generic Oxymorphone ER Tablets under the New Patents, as it was obligated to do under Section 4.1(d) of the Settlement and License Agreement, and thereby

breached the Settlement and License Agreement. That breach constitutes a material breach of the Settlement and License Agreement.

53. Endo has been, and will continue to be, significantly harmed by Impax's material breach of the Settlement and License Agreement, including by Impax's manufacture, use, and sale of its Generic Oxymorphone ER Tablets, without properly compensating Endo for its rights under the License with respect to the New Patents.

54. Endo is entitled to a declaration that Impax has materially breached the Settlement and License Agreement and to recover damages for Impax's sales of its Generic Oxymorphone ER Tablets without authorization in violation of Endo's rights under the New Patents, as well as any other appropriate relief.

COUNT II: BREACH OF IMPLIED DUTY OF GOOD FAITH AND FAIR DEALING

55. Endo incorporates each of paragraphs 1-54 above as if fully set forth herein.

56. In connection with its entry into the Settlement and License Agreement with Endo, Impax had an implied duty of good faith and fair dealing, which included an obligation to negotiate in good faith with Endo in the event that Endo succeeded in obtaining future patents based upon the patent applications pending before the PTO at the time of the parties' settlement, and to properly compensate Endo for any infringement upon Endo's rights under such future patents should they be issued by the PTO.

57. By refusing to negotiate in good faith with Endo concerning an amendment to the License for the Impax Generic Oxymorphone ER Tablets under the New Patents, Impax acted in bad faith with the purpose of depriving Endo of rights or benefits under the Settlement and License Agreement, in violation of Impax's duty of good faith and fair dealing.

58. Impax's breach of the duty of good faith and fair dealing is evidenced by Impax's refusal to negotiate an amendment to the License for its Generic Oxymorphone ER Tablets under

the New Patents, and its insistence instead that Endo agree to grant it a license under the New Patents for additional products never contemplated or discussed by the parties at the time they entered into the Settlement and License Agreement.

59. Impax's demands with respect to paragraph 58 are in direct conflict with the express language of the Settlement and License Agreement and the parties' negotiating history, and were made in bad faith.

60. Endo has been, and will continue to be, significantly harmed by Impax's breach, including by Impax's manufacture, use, and sale of its Generic Oxymorphone ER Tablets.

61. Endo is entitled to a declaration that Impax has breached the implied duty of good faith and fair dealing and to recover damages for Impax's sales of its Generic Oxymorphone ER Tablets without authorization in violation of Endo's rights under the New Patents, as well as any other appropriate relief.

COUNT III: INFRINGEMENT OF '122 PATENT

62. Endo incorporates each of paragraphs 1-61 above as if fully set forth herein.

63. Impax has had knowledge of the '122 patent since no later than January 18, 2013.

64. The Impax Generic Oxymorphone ER Tablets are covered by the '122 patent, and Impax has made and sold and will continue to make and sell such Tablets without authorization of Endo thereunder by virtue of its failure to negotiate in good faith concerning an amendment to the License for such Tablets.

65. Accordingly, Impax has directly infringed, either literally or under the doctrine of equivalents, one or more claims of the '122 patent under 35 U.S.C. § 271(a)-(c) by making, selling, and/or offering to sell its Generic Oxymorphone ER Tablets in the United States, and under 35 U.S.C. § 271(e) by submitting to FDA an ANDA for the purpose of obtaining approval to sell its Generic Oxymorphone ER Tablets prior to expiration of the '122 patent.

66. In particular and without limitation, the Impax Generic Oxymorphone ER Tablets infringe at least the Impax Infringed Claims for at least the same reasons and in the same way that Judge Griesa found in the New York Litigation that the Impax Generic Oxymorphone ER CRF Tablets infringe those claims.

67. Upon information and belief, Impax continues to sell, and intends to continue to make, use, and sell, its infringing Generic Oxymorphone ER Tablets in the United States.

68. Impax is collaterally estopped from challenging the validity of the '122 patent, and Impax's infringement has been, and continues to be, willful.

69. Endo has been, and will continue to be, harmed by Impax's infringement and is entitled to recover damages to compensate for the infringement as well as any other appropriate relief. Further, any damages award should be enhanced in view of Impax's willful infringement.

COUNT IV: INFRINGEMENT OF '216 PATENT

70. Endo incorporates each of paragraphs 1-69 above as if fully set forth herein.

71. Impax has had knowledge of the '216 patent since no later than January 18, 2013.

72. The Impax Generic Oxymorphone ER Tablets are covered by the '216 patent, and Impax has made and sold and will continue to make and sell such Tablets without authorization of Endo thereunder by virtue of its failure to negotiate in good faith concerning an amendment to the License for such Tablets.

73. Accordingly, Impax has directly infringed, either literally or under the doctrine of equivalents, one or more claims of the '216 patent under 35 U.S.C. § 271(a)-(c) by making, selling, and/or offering to sell its Generic Oxymorphone ER Tablets in the United States, and under 35 U.S.C. § 271(e) by submitting to FDA an ANDA for the purpose of obtaining approval to sell its Generic Oxymorphone ER Tablets prior to expiration of the '216 patent.

74. In particular and without limitation, the Impax Generic Oxymorphone ER Tablets infringe at least the Impax Infringed Claims for at least the same reasons and in the same way that Judge Griesa found in the New York Litigation that the Impax Generic Oxymorphone ER CRF Tablets infringe those claims.

75. Upon information and belief, Impax continues to sell, and intends to continue to make, use, and sell, its infringing Generic Oxymorphone ER Tablets in the United States.

76. Impax is collaterally estopped from challenging the validity of the '216 patent, and Impax's infringement has been, and continues to be, willful.

77. Endo has been, and will continue to be, harmed by Impax's infringement and is entitled to recover damages to compensate for the infringement as well as any other appropriate relief. Further, any damages award should be enhanced in view of Impax's willful infringement.

COUNT V: INFRINGEMENT OF '737 PATENT

78. Endo incorporates each of paragraphs 1-77 above as if fully set forth herein.

79. Impax has had knowledge of the '737 patent since no later than November 7, 2014.

80. The Impax Generic Oxymorphone ER Tablets are covered by the '737 patent, and Impax has made and sold and will continue to make and sell such tablets without authorization of Endo thereunder by virtue of its failure to negotiate in good faith concerning an amendment to the License for such Tablets.

81. Accordingly, Impax has directly infringed, either literally or under the doctrine of equivalents, one or more claims of the '737 patent under 35 U.S.C. § 271(b) by selling its Generic Oxymorphone ER Tablets in the United States and inducing physicians and patients suffering from renal impairment to use those Generic Oxymorphone ER Tablets in an infringing manner in the United States by performing all of the recited steps of one or more of claims 1-6 of

the ‘737 patent, and under 35 U.S.C. § 271(e) by submitting to FDA an ANDA for the purpose of obtaining approval to sell its Generic Oxymorphone ER Tablets prior to expiration of the ‘737 patent.

82. In particular and without limitation, the ’737 patent is directed to methods of treating pain with a particular drug (oxymorphone) in a particular patient population (renally impaired patients) by using a particular treatment regimen that is different than is used for patients with normal renal function. Broadly speaking, the claimed methods include the steps of: (a) providing a controlled release dosage form of oxymorphone; (b) measuring a patient’s creatinine clearance rate (which is a measure of the degree of a patient’s renal insufficiency); and (c) administering to the patient, depending on the severity of the renal impairment as measured by the patient’s creatinine clearance rate, a lower dosage of the oxymorphone dosage form to provide pain relief. The product label and packaging information included by Impax along with the Impax Generic Oxymorphone ER Tablets affirmatively instruct physicians and patients, among others, to perform all of the recited steps of the claimed inventions of claims 1– 6 of the ‘737 patent.

83. In litigation currently pending in the District of Delaware, the court has entered a ruling finding that the claims of the ‘737 patent are invalid on the grounds that they are directed to unpatentable subject matter. No final judgment has been entered in that litigation. Endo respectfully disagrees with that ruling and intends to challenge the ruling on appeal. Endo contends that the claims of the ‘737 patent are valid and enforceable, and that as described herein, Impax is liable for inducing infringement of the ‘737 patent.

84. Upon information and belief, Impax continues to sell, and intends to continue to make, use, and sell, its infringing Generic Oxymorphone ER Tablets in the United States.

85. Endo has been, and will continue to be, harmed by Impax's infringement and is entitled to recover damages to compensate for the infringement as well as any other appropriate relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Endo respectfully requests the following relief:

A. A declaration and judgment that Impax has materially breached the Settlement and License Agreement;

B. A declaration and judgment that Impax has breached the implied covenant of good faith and fair dealing arising in connection with its obligations under the Settlement and License Agreement;

C. A declaration and judgment that Impax has infringed each of the New Patents;

D. Compensatory damages, as well as any other appropriate relief, arising out of Impax's breach of the Settlement and License Agreement and breach of its duty of good faith and fair dealing arising thereunder;

E. Compensatory damages, and such other relief as is appropriate for Impax's infringement of the New Patents;

F. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285 and all other relevant statutes;

G. An order that Impax's infringement of the '122 and '216 patents has been willful, and an award of enhanced damages pursuant to 35 U.S.C. § 284;

H. An award of attorneys' fees against Impax;

I. Costs and expenses in this action against Impax; and

J. Such other and further legal and equitable relief as the Court may deem just and proper.

Dechert LLP

Dated: May 4, 2016

/s/ *Robert D. Rhoad*

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ATTORNEYS FOR PLAINTIFF ENDO PHARMACEUTICALS INC.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for plaintiff Endo Pharmaceuticals Inc. certifies that to the best of his knowledge, the matter in controversy is not the subject of another action pending in any court or of any pending arbitration or administrative proceeding.

Dated: May 4, 2016

/s/ *Robert D. Rhoad*
Robert D. Rhoad