IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and MALLINCKRODT LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 14-1381 (RGA)
ACTAVIS LLC (f/k/a ACTAVIS INC.), ACTAVIS SOUTH ATLANTIC LLC, ACTAVIS PHARMA, INC., ACTAVIS ELIZABETH LLC, ACTAVIS HOLDCO U.S., INC., and TEVA PHARMACEUTICALS USA, INC.	)	
Defendants.	)	

AMENDED COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Mallinckrodt LLC ("Mallinckrodt"), for their Amended Complaint against Defendants Actavis LLC (f/k/a Actavis Inc.), Actavis South Atlantic LLC, Actavis Pharma, Inc., Actavis Elizabeth LLC, Actavis Holdco U.S., Inc., and Teva Pharmaceuticals USA, Inc., (collectively "Defendants"), allege as follows:

PARTIES

1. 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 opioid painkiller designed to be crush-resistant (alternatively referred to herein as "Opana ER CRF").

2. Plaintiff Mallinckrodt is a Delaware company, having its principal place of business at 675 McDonnell Blvd., St. Louis, Missouri 63042. Mallinckrodt manufactures and

distributes products used in diagnostic procedures and in the treatment of pain and related conditions.

3. Upon information and belief, Defendant Actavis LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Actavis LLC 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. Actavis LLC was formerly known as Actavis Inc.

4. Upon information and belief, Defendant 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, Florida 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 Actavis Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Interpace Parkway Morris Corporate Center III, Parsippany, NJ 07054. Actavis Pharma, 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.

6. Upon information and belief, Defendant Actavis Elizabeth LLC is a limited liability company, organized and existing under the laws of the State of Delaware, having its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey, 07202. Actavis

Elizabeth LLC 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.

7. Upon information and belief, ASA, Actavis Pharma, Inc., and Actavis Elizabeth LLC are wholly-owned subsidiaries of Actavis LLC.

8. Upon information and belief, Actavis LLC controls and directs the operations of ASA, Actavis Pharma, Inc., and Actavis Elizabeth LLC. Upon information and belief, Actavis LLC, ASA, Actavis Pharma, Inc., and Actavis Elizabeth LLC have acted as each other's alter ego, agent, and partner in the development, manufacturing, distribution, offer for sale, and sale in this judicial district of the infringing products at issue. Upon information and belief, Actavis LLC, ASA, Actavis Pharma, Inc., and Actavis Elizabeth LLC have at least one officer and/or director in common.

9. Upon information and belief, prior to August 2, 2016, Allergan plc ("Allergan") was the corporate parent of Actavis Inc. and/or Actavis LLC, ASA, Actavis Pharma, Inc., and Actavis Elizabeth LLC (collectively, the "Actavis Generics Business").

10. Upon information and belief, in 2016, Allergan assigned certain of the Actavis Generics Business's assets, including Abbreviated New Drug Application ("ANDA") Nos. 79-046 and 20-3930, to Defendant Actavis Holdco U.S., Inc. ("Actavis Holdco"), a newly-formed subsidiary. Upon information and belief, Actavis Holdco is a company organized and existing under the laws of the State of Delaware and maintains its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054.

11. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a corporation organized and existing under the laws of the State of Delaware and

maintains its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Teva 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.

12. Upon information and belief, on August 2, 2016, Teva wholly acquired Actavis Holdco and the Actavis Generics Business.

13. Upon information and belief, Teva now controls and directs the operations of Actavis Holdco and the Actavis Generics Business, including the above-captioned litigation as well as the development, manufacturing, distribution, potential offer for sale, and potential sale in this judicial district of the infringing products at issue. Upon information and belief, all generic pharmaceutical products previously held by Actavis Holdco and/or the Actavis Generics Business are now marketed as Teva's generic pharmaceutical products. Upon information and belief, Teva, Actavis Holdco, and the Actavis Generics Business have at least one officer and/or director in common.

NATURE OF ACTION

14. 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

15. 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).

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

17. Defendants Actavis LLC, ASA, Actavis Pharma, Inc., Actavis Elizabeth LLC, Actavis Holdco, and Teva are Delaware corporations and, therefore, are subject to personal jurisdiction in Delaware.

18. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, they have committed — or aided, abetted, planned, contributed to, or participated in the commission of — tortious conduct which will lead to foreseeable harm and injury to Endo and Mallinckrodt in the State of Delaware. One of the infringing products at issue—Actavis Generic Oxymorphone ER Tablets (described in ANDA No. 79-046)—has been sold in this judicial district.

19. Upon information and belief, ASA has submitted to FDA paperwork purporting to constitute an ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) ("ANDA No. 20-3930"), 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 Supplemental New Drug Application ("sNDA") 201655.

20. Upon information and belief, Defendants intend to distribute and sell Teva's ANDA Products in this judicial district should ANDA No. 20-3930 be approved by FDA.

21. Defendants maintain continuous and systematic contacts with the State of Delaware. Defendants market and sell pharmaceutical products through the United States, including the State of Delaware, and regularly, systematically, and currently transact business in the District of Delaware, 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.

22. Upon information and belief, Defendants currently sell significant quantities of many different generic drug products in the District of Delaware. Those products include, for example, generic versions of Wellbutrin SR®, Xanax®, Ambien®, Prozac®, and Zocor®. A list of generic products manufactured and sold by Defendants in the United States is provided by Teva at http://www.tevagenerics.com.

23. Furthermore, nearly every Defendant has been sued as a patent infringer in this Court and declined to contest that this Court has personal jurisdiction over it. *See, e.g.*, *Avanir Pharmaceuticals, Inc. v. Actavis S. Atl., LLC*, 12-cv-1122-LPS; *Alkermes Pharma Ireland Ltd. v. Actavis, Inc.*, 12-cv-323-SLR; *Novartis Pharms. Corp. v. Actavis S. Atl., LLC*, 11-cv-1077-RGA.; *Bayer Pharma AG v. Watson Labs., Inc.*, 14-cv-760-GMS; *Orexo AB v. Actavis Elizabeth LLC*, 14-cv-829-SLR-SRF; *Acorda Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, 14-cv-941-LPS; *Merck Sharp & Dohme Corp. v. Teva Pharms. USA, Inc.*, 14-cv-874-SLR.

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

FACTUAL BACKGROUND

The Drug Approval Process

25. 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).

26. 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 "reference listed drug" or "branded drug").

Endo's Opana ER CRF NDA

27. On December 12, 2011, FDA approved Endo's Supplemental New Drug Application ("sNDA") 201655, under § 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), for Opana ER CRF, which is designed to be a crush-resistant tablet that contains oxymorphone hydrochloride for the relief of pain.

28. Opana ER CRF is distributed and sold throughout the United States for relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.

THE '737 PATENT

29. On August 19, 2014, the PTO duly and legally issued 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" to Endo Pharmaceuticals Inc. as assignee. Harry Ahdieh is named as the inventor. A true and correct copy of the '737 Patent is attached as Exhibit A.

30. Endo is the sole owner and assignee of the '737 Patent.

31. Opana ER CRF is covered by one or more claims of the '737 Patent.

32. Endo has submitted patent information regarding the '737 Patent for listing by the FDA in the Orange Book. Upon information and belief, the FDA has or will list the '737 Patent in the Orange Book for Opana ER CRF.

THE '779 PATENT

33. On October 28, 2014, the PTO duly and legally issued U.S. Patent No. 8,871,779 ("the '779 Patent"), entitled "Process for Preparing Morphinan-6-One Products with Low Levels of α,β-Unsaturated Ketone Compounds" to Mallinckrodt as assignee. Henry J. Buehler, William E. Dummitt, Anthony Mannino, Dennis C. Aubuchon, and Hong Gu are named as inventors. A true and correct copy of the '779 Patent is attached as Exhibit B.

34. Mallinckrodt is the assignee and owner of the '779 Patent.

35. Endo has an exclusive license to the '779 Patent from Mallinckrodt in the appropriate field of use, including the exclusive right to enforce the '779 Patent in that field.

36. Opana ER CRF is covered by one or more claims of the '779 Patent.

37. On October 30, 2014, Endo submitted patent information regarding the '779 Patent for listing by the FDA in the Orange Book. Upon information and belief, the FDA has or will list the '779 Patent in the Orange Book for Opana ER CRF.

RELATED TEVA LITIGATION

38. On November 7, 2014, Plaintiffs filed related suit, C.A. No. 14-1389, against Teva, *et al.*, alleging that the extended-release oxymorphone tablets described in Teva's ANDA No. 20-4324 infringe claims 1-6 of the '779 Patent. C.A. No. 14-1389, D.I. 1 ("Related Litigation"). In February 2016, Teva stipulated that its proposed tablets met all limitations of asserted claims 1-6 of the '779 Patent. C.A. No. 14-1389, D.I. 118. This Court tried the case on July 11-13, 2016.

39. Validity of the '779 Patent was fully litigated in the Related Litigation, and in its October 7, 2016 Trial Opinion, the Court found that "[Teva] failed to prove by clear and convincing evidence that any of the asserted claims of the '779 patent are invalid." C.A. No. 14-1389, D.I. 192 at 30. The Court's November 30, 2016 Final Judgment states: "IT IS HEREBY

ORDERED, ADJUDGED AND DECREED that: 1. Final judgment is entered in favor of Plaintiffs Endo Pharmaceuticals Inc. and Mallinckrodt LLC ('Plaintiffs') and against Defendants Teva Pharmaceuticals USA, Inc. ('Teva') and Barr Laboratories, Inc. (collectively, 'Defendants') that claims 1-6 of the '779 patent are not invalid." C.A. No. 14-1389, D.I. 203.

ACTAVIS'S FIRST ANDA FILING

40. In or about February 2008, ASA filed ANDA No. 79-046 seeking approval to engage in the commercial manufacturing, use and sale of the Actavis Generic Oxymorphone ER Tablets as a generic version of the original, non-crush-resistant formulation of Opana® ER (the "Discontinued Formulation").

41. In response, Endo filed suit against ASA for infringement of U.S. Patent No. 5,958,456 ("'456 Patent"). *See Endo Pharms. Inc. v. Actavis S. Atl., LLC*, 08-cv-03482-KSH-PS and 2:08-cv-01563-KSH-PS (D.N.J.). Endo and ASA settled their infringement dispute in February 2009.

42. Although the parties' settlement agreement granted Actavis a license under the '456 Patent to make and sell its Generic Oxymorphone ER Tablets, nothing in the agreement grants Defendants any license or other rights under the '737 or '779 Patents.

43. Until approximately May 2016, the Actavis Generics Business made and sold 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg strengths of the Actavis Generic Oxymorphone ER Tablets.

44. Defendants' manufacture and sale of the Actavis Generic Oxymorphone ER Tablets has caused Endo to suffer harm, including without limitation, irreparable injury to its business reputation and goodwill, lost sales of Opana® ER CRF, the loss of the benefit of its investment in developing the reformulated crush-resistant version of Opana® ER, and price erosion for Opana® ER CRF.

ACTAVIS'S SECOND ANDA FILING

45. Upon information and belief, some time before December 5, 2012, ASA submitted to FDA paperwork purporting to constitute an Abbreviated New Drug Application (ANDA No. 20-3930) 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 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 products described in sNDA 201655.

46. Pursuant to ANDA No. 20-3930, Defendants are seeking FDA approval to make, use, and sell Teva's ANDA Products prior to expiration of the '737 and '779 Patents.

ENDO'S COUNT I: INFRINGEMENT OF THE '737 PATENT

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

48. This 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. 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.

49. Defendants' commercial manufacture, offer for sale, or sale of the Actavis Generic Oxymorphone ER Tablets has infringed, and if permitted to resume such sales will infringe, the '737 Patent under 35 U.S.C. § 271(a)-(c), including without limitation that it induces physicians and patients to infringe the '737 Patent by performing all of the recited steps of one or more of claims 1–6 of the '737 Patent.

ENDO AND MALLINCKRODT'S COUNT II: INFRINGEMENT OF THE '779 PATENT

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

51. Defendants' commercial manufacture, offer for sale, or sale of the Actavis Generic Oxymorphone ER Tablets have infringed, and if permitted to resume such sales will infringe, the '779 Patent under 35 U.S.C. § 271(a)-(c).

52. Upon information and belief, Defendants have been aware of the existence of the '779 Patent since before Plaintiffs filed suit, and were aware at that time that the commercial manufacture, sale, and offer for sale of the Actavis Generic Oxymorphone ER Tablets constitutes infringement of the '779 Patent.

53. On May 16, 2016, Defendants stipulated that the tablets described in ANDA Nos. 79-046 and 20-3930 meet all limitations of the asserted claims of the '779 patent. D.I. 120.

54. Defendants are precluded by this Court's judgment in the Related Litigation from challenging the validity or enforceability of the '779 patent.

ENDO'S COUNT III: INFRINGEMENT OF THE '737 PATENT

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

56. This 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. 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.

57. The submission of ANDA No. 20-3930 to FDA constitutes infringement of the '737 Patent under 35 U.S.C. § 271(e)(2)(A).

58. Defendants are seeking FDA approval to engage in the commercial manufacture, use, or sale of the Teva ANDA Products before expiration of the '737 Patent. On information and belief, if granted approval, Defendants intend to launch the Teva ANDA Products before expiration of the '737 Patent.

59. Any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products before expiration of the '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '737 Patent under 35 U.S.C. § 271(a)-(c), including without limitation that it will induce physicians and patients to infringe the '737 Patent by performing all of the recited steps of one or more of claims 1–6 of the '737 Patent.

60. Any such launch by Defendants of the Teva ANDA Products before expiration of the '737 Patent would cause Endo to suffer immediate and irreparable harm.

ENDO'S COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '737 PATENT

61. Endo incorporates each of paragraphs 1-46 and 55-60 above as if set forth fully herein.

62. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

63. There is an actual case or controversy such that the Court may entertain Endo's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

64. Defendants have made and will continue to make substantial preparation in the United States to manufacture, offer to sell, sell and/or import Teva's ANDA Products before expiration of the '737 Patent.

65. Defendants' actions indicate their intention to manufacture, offer to sell, and sell Teva's ANDA Products before expiration of the '737 Patent, and further indicate a refusal to change the course of its action in the face of acts by Endo.

66. Any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products before expiration of '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '737 Patent under 35 U.S.C. § 271(a)-(c), including without limitation that it will induce physicians and patients to infringe the '737 Patent by performing all of the recited steps of one or more of claims 1–6 of the '737 Patent.

67. Endo is entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products by Defendants before expiration of the '737 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '737 Patent.

ENDO AND MALLINCKRODT'S COUNT V:
INFRINGEMENT OF THE '779 PATENT

68. Endo and Mallinckrodt incorporate each of paragraphs 1-46 above as if set forth fully herein.

69. The submission of ANDA No. 20-3930 to FDA constitutes infringement of the '779 Patent under 35 U.S.C. § 271(e)(2)(A).

70. Defendants are seeking FDA approval to engage in the commercial manufacture, use, or sale of the Teva ANDA Products before expiration of the '779 Patent. On information and belief, if granted approval, Defendants intend to launch Teva's ANDA Products before expiration of the '779 Patent.

71. Any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products before expiration of the '779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '779 Patent under 35 U.S.C. § 271(a)-(c).

72. Any launch by Defendants of Teva's ANDA Products before expiration of the '779 Patent would cause Endo and Mallinckrodt to suffer immediate and irreparable harm.

73. Upon information and belief, Defendants are aware of the existence of the '779 Patent, and are aware that the commercial manufacture, sale, and offer for sale of Teva's ANDA Products constitutes infringement of the '779 Patent.

74. On May 16, 2016, Defendants stipulated that the tablets described in ANDA Nos. 79-046 and 20-3930 meet all limitations of the asserted claims of the '779 patent. D.I. 120.

75. Defendants are precluded by this Court's judgment in the Related Litigation from challenging the validity or enforceability of the '779 patent.

ENDO AND MALLINCKRODT'S COUNT VI:
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '779 PATENT

76. Endo and Mallinckrodt incorporate each of paragraphs 1-46 and 68-75 above as if set forth fully herein.

77. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

78. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

79. Defendants have made and will continue to make substantial preparation in the United States to manufacture, offer to sell, and sell Teva's ANDA Products before expiration of the '779 Patent.

80. Defendants' actions indicate its intention to manufacture, offer to sell, sell and/or import Teva's ANDA Products before expiration of the '779 Patent.

81. Any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products before expiration of the '779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '779 Patent under 35 U.S.C. § 271(a)-(c).

82. Defendants stipulated that the tablets described in ANDA Nos. 79-046 and 20-3930 meet all limitations of the asserted claims of the '779 patent. D.I. 120.

83. Defendants are precluded by this Court's judgment in the Related Litigation from challenging the validity or enforceability of the '779 patent.

84. Any launch by Defendants of Teva's ANDA Products before expiration of the '779 Patent would cause Endo and Mallinckrodt to suffer immediate and irreparable harm.

85. Plaintiffs are entitled to a declaratory judgment that any commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Products by Defendants before expiration of the '779 Patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '779 Patent.

ENDO AND MALLINCKRODT'S COUNT VII:
DECLARATORY JUDGMENT THAT DEFENDANTS ARE PRECLUDED FROM CHALLENGING THE VALIDITY OR ENFORCEABILITY OF THE '779 PATENT

86. Endo and Mallinckrodt incorporate each of paragraphs 1-85 above as if set forth fully herein.

87. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

88. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

89. Teva fully litigated validity of the '779 Patent in related action C.A. No. 14-1389, and the Court ruled: "Final judgment is entered in favor of Plaintiffs Endo Pharmaceuticals Inc. and Mallinckrodt LLC ('Plaintiffs') and against Defendants Teva Pharmaceuticals USA, Inc. ('Teva') and Barr Laboratories, Inc. (collectively, 'Defendants') that claims 1-6 of the '779 patent are not invalid." C.A. No. 14-1389, D.I. 203.

90. Following the August 2, 2016 acquisition, Teva assumed full control over the operations of Actavis Holdco and the Actavis Generics Business, including the above-captioned litigation as well as the development, manufacturing, distribution, potential offer for sale, and potential sale in this judicial district of the infringing products at issue.

91. On August 17, 2016, counsel for Actavis represented to Endo that, going forward, Teva would make all decisions relating to ANDA Nos. 20-3930 and 79-046 and that Teva would handle all associated litigation.

92. In an October 14, 2016 memorandum of law filed in a separate action between Actavis and the Federal Trade Commission ("FTC"), Actavis stated that "[t]he generics business of Actavis . . . is now owned and operated by Teva" and conceded that an FTC injunction against Teva bound Actavis as a subsidiary or affiliate "[c]ontrolled currently or in the future by Teva." Memorandum of Law in Support of Defendant Actavis Holdco U.S. Inc.'s Motion for Summary Judgment at 3, 7, 13-14, FTC v. Actavis Inc., C.A. No. 1:09-cv-955-TWT, D.I. 541.

93. All generic pharmaceutical products previously held by Actavis Holdco and/or the Actavis Generics Business are now marketed as Teva's generic pharmaceutical products. Specifically, as of November 8, 2016, the Teva website listed the tablets described in Actavis ANDA No. 79-046 as Teva's "Generic of Opana® Extended Release" product. See

https://www.tevagenerics.com/product/oxymorphone-hydrochloride-extended-release-tablets-usp-cii.

94. Plaintiffs are entitled to a declaratory judgment that, pursuant to the doctrines of res judicata and/or collateral estoppel, Teva and its affiliates (including all other Defendants in this action) are precluded, by virtue of this Court's judgement in the Related Litigation, from challenging the validity or enforceability of the '779 Patent in this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Endo respectfully requests the following relief:

A. A judgment that Defendants have infringed and are infringing the '737 Patent, and a declaration that Defendants' commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the '737 Patent;

B. A declaration that the '737 Patent is valid and enforceable;

C. A judgment that Defendants have infringed and are infringing the '779 Patent, and a declaration that Defendants' commercial manufacture, distribution, use, and sale of its ANDA Products would infringe the '779 Patent;

D. A declaration that the '779 Patent is valid and enforceable;

E. A declaration that Defendants are precluded from challenging the validity or enforceability of the '779 Patent in this action;

F. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of 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 '737 and '779 Patents, including any extensions;

G. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283, restraining and enjoining Defendants, their officers, agents, servants and employees, and

those persons in active concert or participation with any of them, from infringement of the '737 and '779 Patents, for the full terms thereof, including any extensions;

H. An order that damages or other monetary relief be awarded to Endo because of Defendants' engaging in the commercial manufacture, use, offer to sell, sale, distribution or importation of the Actavis Generic Oxymorphone ER Tablets, or in inducing such conduct by others, prior to the expiration of the '737 and '779 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 Plaintiffs with prejudgment interest;

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

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

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December 12, 2016

CERTIFICATE OF SERVICE

I hereby certify that on December 12, 2016, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused to be served copies of the foregoing document on December 12, 2016, upon the following in the manner indicated:

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