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

MALLINCKRODT LLC and MALLINCKRODT INC., *Plaintiffs,* v. ACTAVIS LABORATORIES FL, INC., *Defendant.*	)	Civil Action No. 2:15-cv-03800-KSH-CLW

SECOND AMENDED COMPLAINT

Plaintiffs Mallinckrodt LLC and Mallinckrodt Inc. (collectively and individually, "Mallinckrodt" or "Plaintiffs"), by their undersigned attorneys, for their Amended Complaint against Defendant Actavis Laboratories FL, Inc. ("Actavis" or "Defendant"), herein allege:

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Actavis filing an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of Plaintiffs' pharmaceutical product XARTEMIS® XR prior to the expiration of United States Patent Nos. 8,658,631 ("the '631 patent"); 8,741,885

("the '885 patent"); 8,992,975 ("the '975 patent); and 9,050,335 ("the '335 patent") and 9,468,636 ("the '636 patent").[1]

PARTIES

2. Plaintiff Mallinckrodt LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

3. Plaintiff Mallinckrodt Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

4. On information and belief, Defendant Actavis Laboratories FL, Inc., is a company organized and existing under the laws of the State of Florida with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On information and belief, Actavis is in the business of selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

5. On information and belief, Actavis has previously submitted to the jurisdiction of this Court and has purposefully availed itself of the jurisdiction of this Court by filing lawsuits and/or asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

[1] In the first Amended Complaint, Plaintiffs also asserted United States Patent Nos. 8,597,681 ("the '681 patent"); 8,980,319 ("the '319 patent"); 7,976,870 ("the '870 patent"); 8,668,929 ("the '929 patent"); 8,372,432 ("the '432 patent"); 8,377,453 ("the '453 patent"); and 8,394,408 ("the '408 patent"). On May 25, 2016 the Court entered a stipulated Order dismissing all claims and counterclaims relating to those patents. (D.E. 66.) On June 22, 2016 the Court entered a stipulated Order dismissing original plaintiff, Depomed, Inc. (Depomed"), from the action as none of the patents owned by Depomed remained at issue in the case. (D.E. 71.)

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Actavis by virtue of, inter alia, it having corporate presence in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law, previously consenting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of New Jersey.

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

XARTEMIS® XR

9. XARTEMIS® XR is an extended release tablet for oral administration. XARTEMIS® XR contains the active ingredients oxycodone hydrochloride and acetaminophen. The recommended dose of XARTEMIS® XR is one dose every 12 hours without regard to the patients' fed state. XARTEMIS® XR is indicated for the management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate.

10. XARTEMIS® XR combines an opioid analgesic agent with a non-opioid analgesic agent. XARTEMIS® XR provides the advantage of additive and synergistic analgesic effects allowing for a lower dose of opioid, a lower dose of the non-opioid analgesic, fewer side effects, and the ability to treat a broader spectrum of pain or pain states due to the different mechanisms of actions.

11. Previously marketed drug products delivered the combination drugs as an immediate release product.

12. This limitation required the drug product to be administered frequently and/or continuously throughout the day (or night) for continuous pain management. This frequent and/or continuous dosing is often inconvenient and difficult to maintain. Regular dosing is, therefore, inconvenient and frequently leads to poor patient compliance – potentially resulting in a dose being taken after pain break through events, causing unnecessary pain and suffering.

13. During drug development, it was surprisingly discovered that a pharmaceutically acceptable gastric retentive dosage form can be formulated to provide release in the stomach of a combination of a sparingly soluble drug and a highly soluble drug at rates proportional to one another over an extended period of time.

14. In 2008, Mallinckrodt licensed from Depomed patents, a patent application, and know-how. Subsequent to completion of drug product development, Mallinckrodt sought approval from the FDA to market XARTEMIS® XR in the United States. The FDA approved Mallinckrodt's New Drug Application No. 204031 ("the XARTEMIS® XR NDA") for oxycodone hydrochloride and acetaminophen extended-release tablets, under the trade name XARTEMIS® XR, on March 11, 2014.

15. As a part of the regulatory process for obtaining approval of the XARTEMIS® XR NDA, Mallinckrodt was required by the FDA to submit a proposed label for the drug. See 21 C.F.R. § 201.56(b). The label for XARTEMIS® XR instructs physicians and patients, inter alia, about the proper dosage and administration of XARTEMIS® XR.

16. The label for XARTEMIS® XR indicates, inter alia, that one dose of XARTEMIS® XR is recommended twice daily.

17. A physician familiar with the use of extended-release tablets for the management of acute pain such as XARTEMIS® XR would therefore understand that

administration of an opioid analgesic combined with a non-opioid analgesic agent would be subject to the label's instruction to administer a dose twice daily.

18. Plaintiffs have educated prescribing physicians regarding the use of XARTEMIS® XR. Physicians are informed that the recommended dose of XARTEMIS® XR is one dose every 12 hours. Physicians are told that the second dose may be administered as early as 8 hours after the initial dose if patients require analgesia at that time. Subsequent doses are to be administered every 12 hours. Further, on information and belief, it is the standard of care for physicians to treat acute pain in a manner that prevents break through pain. One or more claims of the patents in suit cover the method of treating pain by administering oxycodone hydrochloride and acetaminophen extended-release every 8-12 hours or twice daily.

THE PATENTS-IN-SUIT

19. On February 25, 2014, the United States Patent and Trademark Office issued the '631 patent, entitled "Combination composition comprising oxycodone and acetaminophen for rapid onset and extended duration of analgesia." The '631 patent was assigned to Mallinckrodt by inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. A copy of the '631 patent is attached hereto as Exhibit A.

20. On June 3, 2014, the United States Patent and Trademark Office issued the '885 patent, entitled "Gastric retentive extended release pharmaceutical compositions." The '885 patent was assigned to Mallinckrodt by inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. A copy of the '885 patent is attached hereto as Exhibit B.

21. On December 3, 2013, the United States Patent and Trademark Office issued the '975 patent, entitled "Methods of producing stabilized solid dosage pharmaceutical

compositions containing morphinans." The '975 patent was assigned to Mallinckrodt by inventors Jae Han Park, Tiffani Eisenhauer, Anish Dhanarajan, Vishal K. Gupta, and Stephen Overholt. A copy of the '975 patent is attached hereto as Exhibit C.

22. On June 9, 2015, the United States Patent and Trademark Office issued the '335 patent, entitled "Pharmaceutical compositions for extended release of oxycodone and acetaminophen resulting in a quick onset and prolonged period of analgesia." The '335 patent was assigned to Mallinckrodt by inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. A copy of the '335 patent is attached hereto as Exhibit D.

23. On October 18, 2016, the United States Patent and Trademark Office issued the '636 patent, entitled "Combination composition comprising oxycodone and acetaminophen for rapid onset and extended duration of analgesia." The '636 patent was assigned to Mallinckrodt by inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. A copy of the '636 patent is attached hereto as Exhibit E.

24. Each of the foregoing patents are listed for XARTEMIS® XR in the Patent and Exclusivity Information Addendum of the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"). The Patent Use Codes listed in the Orange Book for the XARTEMIS® XR product are "Method of Treating Patients with Gastric Retentive Dosage Form" and "Management of Acute Pain in Patients Requiring Opioid Analgesia."

ACTAVIS'S ANDA

25. On information and belief, Actavis submitted ANDA No. 207113 ("the Actavis ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market

oxycodone hydrochloride and acetaminophen extended-release tablets before the expiration of the patents in suit. The oxycodone hydrochloride and acetaminophen extended-release tablets described in the Actavis ANDA are herein referred to as the "Actavis Product."

26. The Actavis ANDA refers to and relies upon the XARTEMIS® XR NDA and contains data that, according to Actavis, demonstrates the bioequivalence of the Actavis Product and XARTEMIS® XR.

27. On or about April 24, 2015, Plaintiffs received Defendant's letter notifying Plaintiffs that Actavis had included a certification in the Actavis ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '631, '885, and '975 patents in suit are invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis Product. On or about September 3, 2015, Actavis sent Plaintiffs a second notice letter stating that Actavis had included a certification in the Actavis ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '335 patent is invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis Product. On or about March 20, 2017, Actavis sent Plaintiffs a third notice letter stating that Actavis had included a certification in the Actavis ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '636 patent is invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis Product.

COUNT I
ACTAVIS'S INFRINGEMENT OF U.S. PATENT NO. 8,658,631 UNDER
35 U.S.C. § 271(e)(2)(A)

28. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-27 of this Complaint.

29. Actavis has infringed the '631 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the

commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the '631 patent.

30. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '631 patent.

31. Plaintiffs have no adequate remedy at law.

COUNT II
ACTAVIS'S INFRINGEMENT OF U.S. PATENT NO. 8,741,885 UNDER 35 U.S.C. § 271(e)(2)(A)

32. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-31 of this Complaint.

33. Actavis has infringed the '885 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the '885 patent.

34. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '885 patent.

35. Plaintiffs have no adequate remedy at law.

COUNT III
ACTAVIS'S INFRINGEMENT OF U.S. PATENT NO. 8,992,975 UNDER 35 U.S.C. § 271(e)(2)(A)

36. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-35 of this Complaint.

37. Actavis has infringed the '975 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the

commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the '975 patent.

38. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '975 patent.

39. Plaintiffs have no adequate remedy at law.

COUNT IV
ACTAVIS'S INFRINGEMENT OF U.S. PATENT NO. 9,050,335 UNDER 35 U.S.C. § 271(e)(2)(A)

40. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-39 of this Complaint.

41. Actavis has infringed the '335 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the '335 patent.

42. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '335 patent.

43. Plaintiffs have no adequate remedy at law.

COUNT V
ACTAVIS'S INFRINGEMENT OF U.S. PATENT NO. 9,468,636 UNDER 35 U.S.C. § 271(e)(2)(A)

44. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-43 of this Complaint.

45. Actavis has infringed the '636 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in

the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the '335 patent.

46. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '636 patent.

47. Plaintiffs have no adequate remedy at law.

COUNT VI
EXCEPTIONAL CASE WITH RESPECT TO ACTAVIS UNDER 35 U.S.C. § 285

48. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-47 of this Complaint.

49. Actavis alleges that five different patents duly examined by the U.S. Patent & Trademark Office are invalid or not infringed. This case is exceptional, and Plaintiffs should be granted award of attorneys' fees under 35 U.S.C. § 285 in light of Actavis's conduct.

PRAYER FOR RELIEF

WHEREFORE, Mallinckrodt Inc. and Mallinckrodt LLC pray for a judgment in their favor and against Defendant Actavis Laboratories FL, Inc., and respectfully request the following relief:

A. A judgment declaring that Actavis has infringed U.S. Patent No. 8,658,631;

B. A judgment declaring that Actavis has infringed U.S. Patent No. 8,741,885;

C. A judgment declaring that Actavis has infringed U.S. Patent No. 8,992,975;

D. A judgment declaring that Actavis has infringed U.S. Patent No. 9,050,335;

E. A judgment declaring that Actavis has infringed U.S. Patent No. 9,468,636;

F. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling

the Actavis Product within the United States, or importing the Actavis Product into the United States, prior to the expiration date of the patents in suit;

G. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 207113 under § 505(j) of the Federal Food, Drug and Cosmetic Act 21 U.S.C. § 355(j) shall not be earlier than the expiration date of the patents in suit, including any exclusivities and extensions;

H. If Actavis commercially manufactures, uses, offers to sell, or sells the Actavis Product within the United States, or imports the Actavis Product into the United States, prior to the expiration of the patents in suit, including any exclusivities and extensions, a judgment awarding Plaintiffs monetary relief together with interest;

I. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285.

J. Costs and expenses in this action; and

K. Such other relief as the Court deems just and proper.

Date: May 23, 2017.

/s/ Michael E. Patunas

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Attorneys for Mallinckrodt LLC and Mallinckrodt Inc.

CERTIFICATE OF SERVICE

I hereby certify that on **May 23, 2017**, the foregoing Second Amended Complaint was served via ECF and email on all counsel of record in this matter.

Date: May 23, 2017

/s/ Michael E. Patunas
Michael E. Patunas