UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
CASE NO.:

MERCK SHARP & DOHME CORP.,
CUBIST PHARMACEUTICALS LLC,
OPTIMER PHARMACEUTICALS LLC,
MSD INVESTMENT HOLDINGS (IRELAND), and
MSD INTERNATIONAL GMBH,

Plaintiffs,

v.

ACTAVIS LABORATORIES FL, INC.,
ACTAVIS PHARMA, INC., and
TEVA PHARMACEUTICALS USA, INC.,

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck Sharp & Dohme Corp. ("Merck"), Cubist Pharmaceuticals LLC ("Cubist"), Optimer Pharmaceuticals LLC ("Optimer"), MSD Investment Holdings (Ireland) ("MSD Investment Ireland"), and MSD International GmbH ("MSD International") (collectively, "Plaintiffs") for their Complaint against Defendants Actavis Laboratories FL, Inc., Actavis Pharma, Inc., and Teva Pharmaceuticals USA, Inc. (collectively, "Actavis " or "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.* This action relates to Abbreviated New Drug Application ("ANDA") No. 208443, and amendments made to the ANDA ("Amended ANDA" or "Actavis's Amended ANDA"), which Defendants filed or caused to be filed with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial

manufacture, use, sale, offer for sale, and/or importation of generic copies of Plaintiffs' DIFICID® (fidaxomicin) Tablets prior to the expiration of U.S. Patent No. 7,906,489 ("the '489 Patent"), U.S. Patent No. 8,586,551 ("the '551 Patent"), U.S. Patent No. 7,378,508 ("the '508 Patent"), U.S. Patent No. 7,863,249 ("the '249 Patent"), and U.S. Patent No. 8,859,510 ("the '510 Patent").

2. Plaintiffs previously filed Case No. 1:15-cv-61858-KMWin this District in response to the original submission of ANDA No. 208443 to the FDA. That case was dismissed without prejudice pursuant to a stipulation entered in parallel litigation in the District of New Jersey. Plaintiffs now file the instant action in response to Defendants' submission to the FDA of Amended ANDA No. 208443.

PARTIES

3. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 1 Merck Drive, Whitehouse Station, New Jersey, 08889. Merck is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve health.

4. Plaintiff Cubist is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Cubist is a wholly owned subsidiary of Merck & Co., Inc. Plaintiff Cubist was formerly known as Cubist Pharmaceuticals, Inc.

5. Plaintiff Optimer is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Optimer is a wholly owned subsidiary of Merck & Co., Inc. Plaintiff Optimer was formerly known as Optimer Pharmaceuticals, Inc.

6. Plaintiff MSD Investment Ireland is an unlimited liability company incorporated under the laws of Ireland with registered number 463181 and having its registered office at Ballydine, Kilsheelan, Clonmel, Co Tipperary, Ireland and its principal place of business at Weystrasse 20, 6000 Lucerne 6, Switzerland. MSD Investment Ireland is a wholly owned subsidiary of Merck & Co., Inc.

7. Plaintiff MSD International is a Swiss limited liability company having its registered office at Weystrasse 20, 6000 Lucerne 6, Switzerland. MSD International is a wholly owned subsidiary of Merck & Co., Inc.

8. Defendant Actavis Laboratories FL, Inc. ("Actavis Labs. FL") is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at 4955 Orange Drive, Davie, Florida 33314. Actavis Labs. FL is an indirect wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc., which itself is an indirect wholly-owned subsidiary of Teva Pharmaceuticals Industries Ltd. Actavis Labs. FL is registered with the Florida Department of State Divisions of Corporations, under Document No. P02000124617, as a business operating in Florida, and has appointed Corporate Creations Network Inc., 11380 Prosperity Farms Road, No. 221E, Palm Beach Gardens, FL 33410 as its registered agent for service of process in Florida. On information and belief, Actavis Labs. FL is registered with the State of Florida Department of Business and Professional Regulation as a Prescription Drug Manufacturer under License Nos. 20205, 20206, 20207, and 20208; as an Over the Counter Drug Manufacturer under License Nos. 21681, 21682, 21683, and 21684; and holds Product Registration Permits License Nos. RXD1654, RXD1888, RXD1897, OTC2439. On information and belief, Actavis Labs. FL is in the business of, among other things, developing and

manufacturing generic pharmaceutical products and obtaining regulatory approval for generic pharmaceutical products that it distributes in Florida and throughout the United States.

9. Defendant Actavis Pharma, Inc. ("Actavis Pharma") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Actavis Pharma is a wholly-owned subsidiary of Teva Pharmaceuticals Industries Ltd. Actavis Pharma is registered with the Florida Department of State Division of Corporations, under Document No. F01000003775, as a business operating in Florida and has appointed Corporate Creations Network, Inc., 11380 Prosperity Farms Road #221E, Palm Beach Gardens, FL 33410 as its registered agent for service of process in Florida. On information and belief, Actavis Pharma is in the business of, among other things, distributing and/or selling generic pharmaceutical products, including those that are manufactured by Actavis Labs. FL, in Florida and throughout the United States.

10. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, PA 19454. Teva USA is a wholly-owned subsidiary of Teva Pharmaceuticals Industries Ltd. Teva USA is registered with the Florida Department of State Division of Corporations, under Document No. F08000004247, as a business operating in Florida and has appointed Corporate Creations Network, Inc., 11380 Prosperity Farms Road #221E, Palm Beach Gardens, FL 33410 as its registered agent for service of process in Florida. On information and belief, Teva is registered with the State of Florida Department of Business and Professional Regulation as a Non-Resident Prescription Drug Manufacturer under License Nos. 26447 and 26713; as a Complimentary Drug Distributor under

License Nos. 40136 and 40360; and as an Out-of-State Prescription Drug Wholesale Distributor under License Nos. 232172 and 232194. On information and belief, Teva USA, at least through the actions of its subsidiaries, including Actavis Labs. FL, is in the business of, among other things, developing, manufacturing, obtaining regulatory approval for, marketing, distributing, and selling generic pharmaceutical products, including those that are manufactured by Actavis Labs. FL, in Florida and throughout the United States.

JURISDICTION AND VENUE

11. This action for patent infringement arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq.*

12. This Court has subject-matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

14. This Court has personal jurisdiction over Defendants by virtue of their specific acts in, and their continuous and systematic contacts with, the State of Florida.

15. This Court has personal jurisdiction over Actavis Labs. FL by virtue of, among other things: (1) its continuous and systematic contacts with Florida, including its principal place of business in Davie, Florida; (2) its acts of patent infringement that will result in foreseeable harm to Plaintiffs in Florida; (3) its sale of a substantial volume of pharmaceutical products in Florida; (4) its consent to jurisdiction in Florida by its registration to do business in Florida and appointment of a registered agent in Florida for the receipt of service of process; and (5) its conduct by, through, and in concert with Actavis Pharma and Teva USA.

16. This Court has personal jurisdiction over Actavis Pharma by virtue of, among other things: (1) its continuous and systematic contacts with Florida; (2) its acts of patent

infringement that will result in foreseeable harm to Plaintiffs in Florida; (3) its sale of a substantial volume of pharmaceutical products in Florida; (4) its consent to jurisdiction in Florida by its registration to do business in Florida and appointment of a registered agent in Florida for the receipt of service of process; and (5) its conduct by, through, and in concert with Actavis Labs. FL and Teva USA.

17. This Court has personal jurisdiction over Teva USA by virtue of, among other things: (1) its continuous and systematic contacts with Florida; (2) its acts of patent infringement that will result in foreseeable harm to Plaintiffs in Florida; (3) its sale of a substantial volume of pharmaceutical products in Florida; (4) its consent to jurisdiction in Florida by its registration to do business in Florida and appointment of a registered agent in Florida for the receipt of service of process; and (5) its conduct by, through, and in concert with Actavis Labs. FL and Actavis Pharma.

18. As noted above, on information and belief, Actavis Labs. FL has substantial, continuous and systematic contacts with Florida, including, *inter alia*, having a principal place of business in Florida.

19. Further, Actavis Labs. FL has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in Florida. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including harm and injury in Florida. For example, on information and belief, Actavis Labs. FL is actively preparing to make generic copies of DIFICID® (fidaxomicin) Tablets that are the subject of Actavis's Amended ANDA No. 208443, and is preparing to commercially manufacture, use, sell, offer to sell, and/or import such generic copies in this State and this Judicial District immediately upon approval of Actavis's Amended ANDA.

20. As noted above, on information and belief, Actavis Pharma has substantial, continuous and systematic contacts with Florida, including, *inter alia*, being registered with the Florida Department of State Division of Corporations as a business operating in Florida and having a registered agent for service of process in Florida.

21. Further, Actavis Pharma, at least through the actions of its affiliates Actavis Labs. FL and Teva USA, has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in Florida. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including harm and injury in Florida. For example, on information and belief, Actavis Pharma is actively preparing to commercially manufacture, use, sell, offer to sell, and/or import generic copies of DIFICID® (fidaxomicin) Tablets that are the subject of Actavis's Amended ANDA No. 208443, and is preparing to commercially manufacture, use, sell, offer to sell, and/or import such generic copies in this State and this Judicial District immediately upon approval of Actavis's Amended ANDA.

22. As noted above, on information and belief, Teva USA also has substantial, continuous and systematic contacts with Florida, including, *inter alia*, being registered with the Florida Department of State Division of Corporations as a business operating in Florida and having a registered agent for service of process in Florida.

23. Further, Teva USA, at least through the actions of its affiliates Actavis Labs. FL, and Actavis Pharma, has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in Florida. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including harm and injury in Florida. For example, on information and belief, Teva USA is actively preparing to

commercially manufacture, use, sell, offer to sell, and/or import generic copies of DIFICID® (fidaxomicin) Tablets that are the subject of Actavis's Amended ANDA No. 208443, and is preparing to commercially manufacture, use, sell, offer to sell, and/or import such generic copies in this State and this Judicial District immediately upon approval of Actavis's Amended ANDA.

24. On information and belief, Actavis Labs. FL, Actavis Pharma, and Teva USA hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distributing, and importing generic drug products in Florida and throughout the United States.

25. More specifically, Defendants, on information and belief, collectively share common directors, officers, principals and/or facilities, operate as agents of each other and act in concert with each other in the design, formulation, development, manufacture, packaging, distribution, marketing and/or sale of pharmaceutical products throughout the United States, including Florida, and will do the same with respect to Actavis's product for which they have sought approval from the FDA in Amended ANDA No. 208443.

26. On information and belief, Actavis Labs. FL, Actavis Pharma, and Teva USA operate as an integrated business ultimately owned and controlled by Teva Pharmaceuticals Industries Ltd.

27. On information and belief, Defendants have sold a substantial volume of generic pharmaceutical products in Florida.

28. On information and belief, Defendants conduct marketing and sales activities in the State of Florida, including, but not limited to, the systemic and continuous distribution, marketing and sales of generic pharmaceutical products to Florida residents.

29. On information and belief, Defendants acted in concert to develop a generic copy of DIFICID® (fidaxomicin) Tablets and to seek approval from the FDA to sell generic copies of DIFICID® (fidaxomicin) Tablets in Florida and throughout the United States.

30. On information and belief, Actavis Pharma and Teva USA, together with and/or through their affiliate and/or agent, Actavis Labs. FL, filed the Amended ANDA No. 208443, which is at issue in this patent-infringement suit, with the FDA.

31. Plaintiffs' claim for patent infringement arose as a result of Actavis Labs. FL sending the required notice of its Amended ANDA. The notice was sent on behalf of Actavis Labs. FL by Teva USA and stated that Actavis Labs. FL is an indirect, wholly owned subsidiary of Teva USA.

32. On information and belief, Actavis Pharma and Teva USA, together with their affiliate and/or agent, Actavis Labs. FL, have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including harm and injury in Florida.

33. On January 16, 2020, Plaintiffs filed a Complaint against Defendants Actavis Labs. FL, Actavis Pharma, and Teva USA for patent infringement in the United States District Court for the District of New Jersey. The resulting action, Civ. Action. No. 2:20-cv-00534 ("the New Jersey DIFICID® Action"), is currently pending. A copy of the Complaint in the New Jersey DIFICID® Action, excluding exhibits, is attached hereto as Exhibit 6. The New Jersey Complaint alleges essentially the same acts of infringement as the present Complaint.

34. Based on Actavis Labs. FL, Actavis Pharma, and Teva USA's continuous and systematic business contacts with New Jersey, each of the Defendants is subject to personal

jurisdiction in the District of New Jersey and venue is proper in the District of New Jersey. However, Actavis Labs. FL, Actavis Pharma, and Teva USA may assert that they are not subject to such jurisdiction or they may contest venue.

35. Plaintiffs are therefore filing the instant Complaint, which has identical infringement claims against Actavis Labs. FL, Actavis Pharma, and Teva USA as the New Jersey DIFICID® Action, as a so-called Hatch-Waxman "protective suit," to preserve their right for a 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii). If Actavis Labs. FL, Actavis Pharma, and Teva USA challenge jurisdiction or venue in the New Jersey DIFICID® Action, then Plaintiffs intend to move to stay the instant action pending resolution of any jurisdictional challenge in the New Jersey DIFICID® Action, or alternatively, to transfer this action to the district of New Jersey.

PLAINTIFFS' DIFICID® (FIDAXOMICIN) TABLETS

36. Plaintiff Cubist is the holder of New Drug Application ("NDA") No. 201699 that has been approved by the FDA for the manufacture and sale of DIFICID® (fidaxomicin) Tablets for oral use ("DIFICID®" or the "DIFICID® drug product"). Plaintiff Cubist was formerly known as Cubist Pharmaceuticals, Inc. On October 24, 2013, Cubist Pharmaceuticals, Inc. acquired Optimer Pharmaceuticals, Inc., which is the entity that originally filed NDA No. 201699. Optimer Pharmaceuticals, Inc. subsequently became Optimer Pharmaceuticals LLC.

37. DIFICID® is approved by the FDA for the treatment of *Clostridium difficile*-associated diarrhea in adults 18 years of age or older. Under NDA No. 201699, DIFICID® is marketed in 200 mg tablets. The drug is marketed under the registered trade name and trademark DIFICID®.

THE PATENTS-IN-SUIT

The '489 Patent

38. The '489 Patent, entitled "18-Membered Macrocycles and Analogs Thereof," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on March 15, 2011, naming Youe-Kong Shue, Chan-Kou Hwang, Yu-Hung Chiu, Alex Romero, Farah Babakhani, Pamela Sears, and Franklin Okumu as the inventors. A copy of the '489 Patent is attached hereto as Exhibit 1.

39. Plaintiff Merck is the owner, by assignment, of the '489 Patent and has the full right to sue and to recover for infringement thereof. Plaintiff Optimer previously owned the '489 Patent and retains certain interests in the '489 Patent. And Plaintiffs MSD Investment Ireland and MSD International have certain rights in the '489 Patent by license.

40. The '489 Patent is listed in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering the drug DIFICID®, at the dosage of 200 mg, which is the subject of approved NDA No. 201699. In accordance with 21 U.S.C. § 355(b)(1), the '489 Patent is listed in connection with DIFICID® and NDA No. 201699 in the Orange Book as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" DIFICID®.

The '551 Patent

41. The '551 Patent, entitled "18-Membered Macrocycles and Analogs Thereof," was duly and legally issued by the USPTO on November 19, 2013, naming Youe-Kong Shue, Chan-Kou Hwang, Yu-Hung Chiu, Alex Romero, Farah Babakhani, Pamela Sears, and Franklin Okumu as the inventors. A copy of the '551 Patent is attached hereto as Exhibit 2.

42. Plaintiff Merck is the owner, by assignment, of the '551 Patent and has the full right to sue and to recover for infringement thereof. Plaintiff Optimer previously owned the '551 Patent and retains certain interests in the '551 Patent. And Plaintiffs MSD Investment Ireland and MSD International have certain rights in the '551 Patent by license.

43. The '551 Patent is listed in the Orange Book as covering the drug DIFICID®, at the dosage of 200 mg, which is the subject of approved NDA No. 201699. In accordance with 21 U.S.C. § 355(b)(1), the '551 Patent is listed in connection with DIFICID® and NDA No. 201699 in the Orange Book as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" DIFICID®.

The '508 Patent

44. The '508 Patent, entitled "Polymorphic Crystalline Forms of Tiacumicin B," was duly and legally issued by the USPTO on May 27, 2008, naming Yu-Hung Chiu, Tessie Mary Che, Alex Romero, Yoshi Ichikawa, and Youe-Kong Shue as the inventors. A copy of the '508 Patent is attached hereto as Exhibit 3.

45. Plaintiff Merck is the owner, by assignment, of the '508 Patent and has the full right to sue and to recover for infringement thereof. Plaintiff Optimer previously owned the '508 Patent and retains certain interests in the '508 Patent. And Plaintiffs MSD Investment Ireland and MSD International have certain rights in the '508 Patent by license.

46. The '508 Patent is listed in the Orange Book as covering the drug DIFICID®, at the dosage of 200 mg, which is the subject of approved NDA No. 201699. In accordance with 21 U.S.C. § 355(b)(1), the '508 Patent is listed in connection with DIFICID® and NDA No. 201699 in the Orange Book as a patent "with respect to which a claim of patent infringement

could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" DIFICID®.

The '249 Patent

47. The '249 Patent, entitled "Macrolide Polymorphs, Compositions Comprising Such Polymorphs, and Methods of Use and Manufacture Thereof," was duly and legally issued by the USPTO on January 4, 2011, naming Yu-Hung Chiu, Tessie Mary Che, Alex Romero, Yoshi Ichikawa, and Youe-Kong Shue as the inventors. A copy of the '249 Patent is attached hereto as Exhibit 4.

48. Plaintiff Merck is the owner, by assignment, of the '249 Patent and has the full right to sue and to recover for infringement thereof. Plaintiff Optimer previously owned the '249 Patent and retains certain interests in the '249 Patent. And Plaintiffs MSD Investment Ireland and MSD International have certain rights in the '249 Patent by license.

49. The '249 Patent is listed in the Orange Book as covering the drug DIFICID®, at the dosage of 200 mg, which is the subject of approved NDA No. 201699. In accordance with 21 U.S.C. § 355(b)(1), the '249 Patent is listed in connection with DIFICID® and NDA No. 201699 in the Orange Book as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" DIFICID®.

The '510 Patent

50. The '510 Patent, entitled "Macrocyclic Polymoprhs, Compositions Comprising Such Polymorphs, and Methods of Use and Manufacture Thereof," was duly and legally issued by the USPTO on October 14, 2014, naming Yu-Hung Chiu, Tessie Mary Che, Alex Romero,

Yoshi Ichikawa, and Youe-Kong Shue as the inventors. A copy of the '510 Patent is attached hereto as Exhibit 5.

51. Plaintiff Merck is the owner, by assignment, of the '510 Patent and has the full right to sue and to recover for infringement thereof. Plaintiff Optimer previously owned the '510 Patent and retains certain interests in the '510 Patent. And Plaintiffs MSD Investment Ireland and MSD International have certain rights in the '510 Patent by license.

52. The '510 Patent is listed in the Orange Book as covering the drug DIFICID®, at the dosage of 200 mg, which is the subject of approved NDA No. 201699. In accordance with 21 U.S.C. § 355(b)(1), the '510 Patent is listed in connection with DIFICID® and NDA No. 201699 in the Orange Book as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" DIFICID®.

ACTAVIS'S AMENDED ANDA SUBMISSION

53. By letter dated July 23, 2015 (the "Actavis Notice Letter"), Actavis Labs. FL notified Plaintiffs that it had submitted to the FDA ANDA No. 208443 ("Actavis's ANDA") for Actavis's Fidaxomicin Tablets, a drug product that is a generic copy of DIFICID® (fidaxomicin) Tablets (the "ANDA Product" or "Actavis's ANDA Product").

54. On information and belief, Defendants filed or caused to be filed Actavis's ANDA with the FDA, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's ANDA Product prior to the expirations of the '489, the '551, the '508, the '249, and the '510 Patents.

55. In the Actavis Notice Letter, Actavis Labs. FL notified Plaintiffs that, as part of its ANDA No. 208443, Actavis had filed certifications of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '489, the '551, the

‘508, the ‘249, and the ‘510 Patents. On information and belief, ANDA No. 208443 contains certification(s) pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ‘489, the ‘551, the ‘508, the ‘249, and the ‘510 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation of Actavis’s ANDA Product.

56. By filing or causing to be filed Actavis’s ANDA, Defendants necessarily represented to the FDA that the ANDA Product has the same active ingredient, the same method of administration, the same dosage form, and the same strength as DIFICID® and is bioequivalent to DIFICID®.

57. By letter dated December 6, 2019 (the “Second Actavis Notice Letter”), Actavis Labs. FL notified Plaintiffs that it had submitted to the FDA an amendment to its previously submitted ANDA No. 208443.

58. On information and belief, Defendants filed or caused to be filed Amended ANDA No. 208443 with the FDA, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Actavis’s Fidaxomicin Tablets, a drug product that is a generic copy of DIFICID® (fidaxomicin) Tablets (the “Amended ANDA Product” or “Actavis’s Amended ANDA Product”) prior to the expirations of the ‘489, the ‘551, the ‘508, the ‘249, and the ‘510 Patents.

59. In the Second Actavis Notice Letter, Actavis Labs. FL notified Plaintiffs that, as part of its amendment to ANDA No. 208443, Actavis had filed certifications in accordance with 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) with respect to the ‘489, the ‘551, the ‘508, the ‘249, and the ‘510 Patents. On information and belief, Amended ANDA No. 208443 contains certification(s) pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ‘489, the ‘551, the ‘508, the ‘249, and the ‘510 Patents are invalid, unenforceable and/or will

not be infringed by the commercial manufacture, use, sale, offer for sale, or importation of Actavis's Amended ANDA Product.

60. Upon information and belief, Actavis's Paragraph IV Certification in the Amended ANDA is a required "recertification for a previously submitted paragraph IV certification" pursuant to FDA's regulations because Amended ANDA No. 208443 seeks to "add a new indication or other condition of use"; "add a new strength"; "make other than minor changes in product formulation"; and/or seeks to "change the physical form or crystalline structure of the active ingredient." *See* 21 C.F.R. 314.96(d)(1).

61. By filing or causing to be filed the Amended ANDA No. 208443, Defendants necessarily represented to the FDA that the Amended ANDA Product has the same active ingredient, the same method of administration, the same dosage form, and the same strength as DIFICID® and is bioequivalent to DIFICID®. The Second Actavis Notice Letter did not identify any non-infringement basis for claims 1–2, 4–10, and 12–14 of the '489 Patent, claims 1–6 of the '551 Patent, claims 1–2, 8–9, 11–12, and 15–20 of the '508 Patent, claims 1–3, 6, and 10–12 of the '249 Patent, and claims 1–13 of the '510 Patent.

62. On information and belief, if Actavis's Amended ANDA is approved by the FDA, the Defendants will, prior to the expiration of the '489, the '551, the '508, the '249, and the '510 Patents, begin commercially manufacturing, using, selling, offering to sell, and/or importing Actavis's Amended ANDA Product.

63. On information and belief, if Actavis's Amended ANDA is approved by the FDA, the Defendants will, prior to the expiration of the '489, the '551, the '508, the '249, and the '510 Patents, begin marketing Actavis's Amended ANDA Product for the treatment of *Clostridium*

difficile-associated diarrhea in adults 18 years or older, and doctors and patients will use Actavis's Amended ANDA Product for the indications marketed by the Defendants.

64. Defendants had knowledge of the '489, the '551, the '508, the '249, and the '510 Patents at least as of the date when Actavis's original ANDA No. 208443 was submitted to the FDA containing the Paragraph IV Certification with respect to the '489, the '551, the '508, the '249, and the '510 Patents.

65. Defendants' submission to the FDA of Amended ANDA No. 208443, with the Paragraph IV Certification seeking approval to market Actavis's ANDA Product, is an act of infringement by the Defendants of one or more claims of each of the '489, the '551, the '508, the '249, and the '510 Patents under 35 U.S.C. § 271(e)(2). This infringement entitles Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for Amended ANDA No. 208443 be a date which is not earlier than the expiration date of the last expiring of the '489, the '551, the '508, the '249, and the '510 Patents, including any extensions of that date.

66. Defendants' anticipated commercial manufacture, use, sale, offer for sale and/or importation of Actavis's Amended ANDA Product will infringe one or more claims of the '489, the '551, the '508, the '249, and the '510 Patents under 35 U.S.C. §§ 271(a), (b), and/or (c).

67. Defendants concede that the submission of the Amended ANDA (and the Amended ANDA Product described therein) infringes one or more claims of each of the '489, the '551, the '508, the '249, and the '510 Patents. The Second Actavis Notice Letter includes a section that purports to provide the factual and legal basis for "Non-Infringement," but Defendants did not identify any non-infringement basis for claims 1–2, 4–10, and 12–14 of the

‘489 Patent, claims 1–6 of the ‘551 Patent, claims 1–2, 8–9, 11–12, and 15–20 of the ‘508 Patent, claims 1–3, 6, and 10–12 of the ‘249 Patent, and claims 1–13 of the ‘510 Patent.

68. This action is being commenced within forty-five days from the date Plaintiffs received the Second Actavis Notice Letter. The Second Actavis Notice Letter was dated December 6, 2019 and was received by Plaintiffs after December 6, 2019.

COUNT I: INFRINGEMENT OF THE ‘489 PATENT

69. Plaintiffs incorporate by reference each of the preceding paragraphs of this Complaint as if fully set forth herein.

70. The use and/or administration of Actavis’s Amended ANDA Product is covered by one or more claims of the ‘489 Patent.

71. By filing or causing to be filed Amended ANDA No. 208443 under 21 U.S.C. § 355(j) with a Paragraph IV Certification regarding the ‘489 Patent in order to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Actavis’s Amended ANDA Product before the expiration of the ‘489 Patent, Defendants committed an act of infringement of one or more claims of the ‘489 Patent under 35 U.S.C. § 271(e)(2)(A).

72. If Defendants commercially manufacture, use, sell, offer to sell, and/or import the Amended ANDA Product in the United States or import the Amended ANDA Product into the United States, or induce or contribute to any such conduct during the term of the ‘489 Patent, Defendants would further infringe the ‘489 Patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

73. The use and/or administration of Actavis’s Amended ANDA Product, on information and belief in accordance with and as directed by the proposed labeling for that product, before the expiration of the ‘489 Patent would infringe one or more claims of the ‘489 Patent under 35 U.S.C. § 271(a).

74. By seeking approval to distribute the Amended ANDA Product with, on information and belief, its proposed labeling, Defendants intend to cause others, specifically medical professionals, to perform acts that Defendants know will infringe the '489 Patent.

75. Unless enjoined by this Court, Defendants intend to, and will, engage in the infringing commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's Amended ANDA Product immediately and imminently upon approval of Actavis's Amended ANDA.

76. Unless enjoined by this Court, Defendants intend to, and will, actively induce infringement of the '489 Patent when Actavis's Amended ANDA is approved, and intend to, and will do so, immediately and imminently upon approval of Actavis's Amended ANDA.

77. Defendants know that Actavis's Amended ANDA Product and, on information and belief, its proposed labeling are especially made or adapted for use in infringing the '489 Patent, and that Actavis's Amended ANDA Product and, on information and belief, its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Defendants intend to, and will, contribute to the infringement of the '489 Patent immediately and imminently upon approval of Actavis's Amended ANDA.

78. Defendants had knowledge of the '489 Patent at least as of the date Actavis's original ANDA No. 208443 was submitted and are knowingly infringing the '489 Patent.

79. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '489 Patent, actively inducing infringement of the '489 Patent, and/or contributing to the infringement of the '489 Patent.

80. Unless Defendants are enjoined from infringing the '489 Patent, actively inducing infringement of the '489 Patent, and/or contributing to the infringement of the '489 Patent,

Plaintiffs will suffer irreparable harm for which they have no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

81. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Amended ANDA No. 208443 to be a date which is not earlier than the expiration date of the '489 Patent, including any extensions of that date.

82. This case is "exceptional," as that term is used in 35 U.S.C. § 285, and Plaintiffs are entitled to an award of their reasonable attorneys' fees and expenses.

COUNT II: INFRINGEMENT OF THE '551 PATENT

83. Plaintiffs incorporate by reference each of the preceding paragraphs of this Complaint as if fully set forth herein.

84. Actavis's Amended ANDA Product is covered by one or more claims of the '551 Patent.

85. By filing or causing to be filed Amended ANDA No. 208443 under 21 U.S.C. § 355(j) with a Paragraph IV Certification regarding the '551 Patent in order to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's Amended ANDA Product before the expiration of the '551 Patent, Defendants committed an act of infringement of one or more claims of the '551 Patent under 35 U.S.C. § 271(e)(2)(A).

86. If Defendants commercially manufacture, use, sell, offer to sell, and/or import the Amended ANDA Product in the United States or induce or contribute to any such conduct during the term of the '551 Patent, Defendants would further infringe the '551 Patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

87. The commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's Amended ANDA Product before the expiration of the '551 Patent would infringe one or more claims of the '551 Patent under 35 U.S.C. § 271(a).

88. By seeking approval to distribute the Amended ANDA Product, Defendants intend to cause others, specifically medical professionals and patients, to perform acts that Defendants know will infringe the '551 Patent.

89. Unless enjoined by this Court, Defendants intend to, and will, engage in the infringing commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's Amended ANDA Product immediately and imminently upon approval of Actavis's Amended ANDA.

90. Unless enjoined by this Court, Defendants intend to, and will, actively induce infringement of the '551 Patent when Actavis's Amended ANDA is approved, and intend to, and will do so, immediately and imminently upon approval of Actavis's Amended ANDA.

91. Defendants know that Actavis's Amended ANDA Product is especially made or adapted for use in infringing the '551 Patent, and that Actavis's Amended ANDA Product is not suitable for substantial noninfringing use. Unless enjoined by this Court, Defendants intend to, and will, contribute to the infringement of the '551 Patent immediately and imminently upon approval of Actavis's Amended ANDA.

92. Defendants had knowledge of the '551 Patent at least as of the date Actavis's original ANDA No. 208443 was submitted and are knowingly infringing the '551 Patent.

93. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '551 Patent, actively inducing infringement of the '551 Patent, and/or contributing to the infringement of the '551 Patent.

94. Unless Defendants are enjoined from infringing the '551 Patent, actively inducing infringement of the '551 Patent, and/or contributing to the infringement of the '551 Patent, Plaintiffs will suffer irreparable harm for which they have no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

95. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Amended ANDA No. 208443 to be a date which is not earlier than the expiration date of the '551 Patent, including any extensions of that date.

96. This case is "exceptional," as that term is used in 35 U.S.C. § 285, and Plaintiffs are entitled to an award of their reasonable attorneys' fees and expenses.

COUNT III: INFRINGEMENT OF THE '508 PATENT

97. Plaintiffs incorporate by reference each of the preceding paragraphs of this Complaint as if fully set forth herein.

98. Actavis's Amended ANDA Product is covered by one or more claims of the '508 Patent.

99. By filing or causing to be filed Amended ANDA No. 208443 under 21 U.S.C. § 355(j) with a Paragraph IV Certification regarding the '508 Patent in order to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's Amended ANDA Product before the expiration of the '508 Patent, Defendants committed an act of infringement of one or more claims of the '508 Patent under 35 U.S.C. § 271(e)(2)(A).

100. If Defendants commercially manufacture, use, sell, offer to sell, and/or import the Amended ANDA Product in the United States or import the Amended ANDA Product into the

United States, or induce or contribute to any such conduct during the term of the '508 Patent, Defendants would further infringe the '508 Patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

101. The commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's Amended ANDA Product before the expiration of the '508 Patent would infringe one or more claims of the '508 Patent under 35 U.S.C. § 271(a).

102. By seeking approval to distribute the Amended ANDA Product, Defendants intend to cause others, specifically medical professionals and patients, to perform acts that Defendants know will infringe the '508 Patent.

103. Unless enjoined by this Court, Defendants intend to, and will, engage in the infringing commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's Amended ANDA Product immediately and imminently upon approval of Actavis's Amended ANDA.

104. Unless enjoined by this Court, Defendants intend to, and will, actively induce infringement of the '508 Patent when Actavis's Amended ANDA is approved, and intend to, and will do so, immediately and imminently upon approval of Actavis's Amended ANDA.

105. Defendants know that Actavis's Amended ANDA Product is especially made or adapted for use in infringing the '508 Patent, and that Actavis's Amended ANDA Product is not suitable for substantial noninfringing use. Unless enjoined by this Court, Defendants intend to, and will, contribute to the infringement of the '508 Patent immediately and imminently upon approval of Actavis's Amended ANDA.

106. Defendants had knowledge of the '508 Patent at least as of the date Actavis's original ANDA No. 208443 was submitted and are knowingly infringing the '508 Patent.

107. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '508 Patent, actively inducing infringement of the '508 Patent, and/or contributing to the infringement of the '508 Patent.

108. Unless Defendants are enjoined from infringing the '508 Patent, actively inducing infringement of the '508 Patent, and/or contributing to the infringement of the '508 Patent, Plaintiffs will suffer irreparable harm for which they have no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

109. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Amended ANDA No. 208443 to be a date which is not earlier than the expiration date of the '508 Patent, including any extensions of that date.

110. This case is "exceptional," as that term is used in 35 U.S.C. § 285, and Plaintiffs are entitled to an award of their reasonable attorneys' fees and expenses.

COUNT IV: INFRINGEMENT OF THE '249 PATENT

111. Plaintiffs incorporate by reference each of the preceding paragraphs of this Complaint as if fully set forth herein.

112. Actavis's Amended ANDA Product is covered by one or more claims of the '249 Patent.

113. By filing or causing to be filed Amended ANDA No. 208443 under 21 U.S.C. § 355(j) with a Paragraph IV Certification regarding the '249 Patent in order to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's Amended ANDA Product before the expiration of the '249 Patent, Defendants committed an act of infringement of one or more claims of the '249 Patent under 35 U.S.C. § 271(e)(2)(A).

114. If Defendants commercially manufacture, use, sell, offer to sell, and/or import the Amended ANDA Product in the United States or import the Amended ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '249 Patent, Defendants would further infringe the '249 Patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

115. The commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's Amended ANDA Product before the expiration of the '249 Patent would infringe one or more claims of the '249 Patent under 35 U.S.C. § 271(a).

116. By seeking approval to distribute the Amended ANDA Product, Defendants intend to cause others, specifically medical professionals and patients, to perform acts that Defendants know will infringe the '249 Patent.

117. Unless enjoined by this Court, Defendants intend to, and will, engage in the infringing commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's Amended ANDA Product immediately and imminently upon approval of Actavis's Amended ANDA.

118. Unless enjoined by this Court, Defendants intend to, and will, actively induce infringement of the '249 Patent when Actavis's Amended ANDA is approved, and intend to, and will do so, immediately and imminently upon approval of Actavis's Amended ANDA.

119. Defendants know that Actavis's Amended ANDA Product is especially made or adapted for use in infringing the '249 Patent, and that Actavis's Amended ANDA Product is not suitable for substantial noninfringing use. Unless enjoined by this Court, Defendants intend to, and will, contribute to the infringement of the '249 Patent immediately and imminently upon approval of Actavis's Amended ANDA.

120. Defendants had knowledge of the '249 Patent at least as of the date Actavis's original ANDA No. 208443 was submitted and are knowingly infringing the '249 Patent.

121. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '249 Patent, actively inducing infringement of the '249 Patent, and/or contributing to the infringement of the '249 Patent.

122. Unless Defendants are enjoined from infringing the '249 Patent, actively inducing infringement of the '249 Patent, and/or contributing to the infringement of the '249 Patent, Plaintiffs will suffer irreparable harm for which they have no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

123. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Amended ANDA No. 208443 to be a date which is not earlier than the expiration date of the '249 Patent, including any extensions of that date.

124. This case is "exceptional," as that term is used in 35 U.S.C. § 285, and Plaintiffs are entitled to an award of their reasonable attorneys' fees and expenses.

COUNT V: INFRINGEMENT OF THE '510 PATENT

125. Plaintiffs incorporate by reference each of the preceding paragraphs of this Complaint as if fully set forth herein.

126. The use and/or administration of Actavis's Amended ANDA Product is covered by one or more claims of the '510 Patent.

127. By filing or causing to be filed Amended ANDA No. 208443 under 21 U.S.C. § 355(j) with a Paragraph IV Certification regarding the '510 Patent in order to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's Amended

ANDA Product before the expiration of the '510 Patent, Defendants committed an act of infringement of one or more claims of the '510 Patent under 35 U.S.C. § 271(e)(2)(A).

128. If Defendants commercially manufacture, use, sell, offer to sell, and/or import the Amended ANDA Product in the United States or import the Amended ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '510 Patent, Defendants would further infringe the '510 Patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

129. The use and/or administration of Actavis's Amended ANDA Product, on information and belief in accordance with and as directed by the proposed labeling for that product, before the expiration of the '510 Patent would infringe one or more claims of the '510 Patent under 35 U.S.C. § 271(a).

130. By seeking approval to distribute the Amended ANDA Product with, on information and belief, its proposed labeling, Defendants intend to cause others, specifically medical professionals, to perform acts that Defendants know will infringe the '510 Patent.

131. Unless enjoined by this Court, Defendants intend to, and will, engage in the infringing commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's Amended ANDA Product immediately and imminently upon approval of Actavis's Amended ANDA.

132. Unless enjoined by this Court, Defendants intend to, and will, actively induce infringement of the '510 Patent when Actavis's Amended ANDA is approved, and intend to, and will do so, immediately and imminently upon approval of Actavis's Amended ANDA.

133. Defendants know that Actavis's Amended ANDA Product and, on information and belief, its proposed labeling are especially made or adapted for use in infringing the '510 Patent, and that Actavis's Amended ANDA Product and, on information and belief, its proposed

labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Defendants intend to, and will, contribute to the infringement of the '510 Patent immediately and imminently upon approval of Actavis's Amended ANDA.

134. Defendants had knowledge of the '510 Patent at least as of the date Actavis's original ANDA No. 208443 was submitted and are knowingly infringing the '510 Patent.

135. Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '510 Patent, actively inducing infringement of the '510 Patent, and/or contributing to the infringement of the '510 Patent.

136. Unless Defendants are enjoined from infringing the '510 Patent, actively inducing infringement of the '510 Patent, and/or contributing to the infringement of the '510 Patent, Plaintiffs will suffer irreparable harm for which they have no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

137. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Amended ANDA No. 208443 to be a date which is not earlier than the expiration date of the '510 Patent, including any extensions of that date.

138. This case is "exceptional," as that term is used in 35 U.S.C. § 285, and Plaintiffs are entitled to an award of their reasonable attorneys' fees and expenses.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment in favor of Plaintiffs and against Defendants;

B. Judgment that the '489, the '551, the '508, the '249, and the '510 Patents have not been proven invalid or unenforceable.

C. Judgment that the Defendants have infringed, literally or by the doctrine of equivalents, the ‘489, the ‘551, the ‘508, the ‘249, and the ‘510 Patents under 35 U.S.C. § 271(e)(2) by the submission of Amended ANDA No. 208443;

D. Judgment declaring that commercial manufacturing, using, selling, offering to sell, and/or importing Actavis’s Amended ANDA Product, or inducing or contributing to such conduct, will constitute infringement, active inducement of infringement and/or contributory infringement of the ‘489, the ‘551, the ‘508, the ‘249, and the ‘510 Patents by Defendants under 35 U.S.C. §§ 271(a), (b) and/or (c);

E. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Amended ANDA No. 208443 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date no earlier than the date of expiration of the last expiring of the ‘489, the ‘551, the ‘508, the ‘249, and the ‘510 Patents plus any additional periods of exclusivity to which the Patents are or become entitled;

F. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65 enjoining Defendants, and their officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, sale, offer to sell, and/or importation within the United States of any drug product described in Amended ANDA No. 208443, and any product that is similar to or only colorably different from those products, before the date of expiration of the last expiring of the ‘489, the ‘551, the ‘508, the ‘249, and the ‘510 Patents plus any additional periods of exclusivity to which the Patents are or become entitled;

G. Damages or other monetary relief, including prejudgment and postjudgment interest, if Defendants engage in the commercial manufacture, use, sale, offer to sell, or importation of Actavis's Amended ANDA Product, or any other products that infringe the '489, the '551, the '508, the '249, and the '510 Patents, or that induce or contribute to the infringement of the '489, the '551, the '508, the '249, and the '510 Patents, prior to the expiration of the last expiring of the '489, the '551, the '508, the '249, and the '510 Patents plus any additional periods of exclusivity to which the Patents are or become entitled;

H. A declaration that this an exceptional case and an award to Plaintiffs of their reasonable attorneys' fees and expenses, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

I. Such other and further relief as this Court may deem just and proper.

Dated: January 17, 2020

Respectfully submitted,

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(pro hac vice applications to be submitted)*

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