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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

CELGENE CORPORATION,

Plaintiff,

v.

**NATCO PHARMA LIMITED,
ARROW INTERNATIONAL LIMITED,
ACTAVIS, INC., WATSON
LABORATORIES, INC., WATSON
PHARMA, INC., and ANDA, INC.,**

Defendants.

Civil Action No. _____

**COMPLAINT FOR
PATENT INFRINGEMENT**

(Filed Electronically)

Plaintiff Celgene Corporation (“Celgene”), by its undersigned attorneys, for its Complaint against defendants Natco Pharma Limited (“Natco”), Arrow International Limited (“Arrow”), Actavis, Inc. (“Actavis”), Watson Laboratories, Inc. (“Watson”), Watson Pharma, Inc. (“Watson Pharma”), and Anda, Inc. (“Anda”) (collectively, “Defendants”), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Natco’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market a generic version of Celgene’s REVLIMID[®] drug product prior

to the expiration of United States Patent Nos. 8,530,498 (the “498 patent”), 8,589,188 (the “188 patent”), 8,626,531 (the “531 patent”), and 8,648,095 (the “095 patent”), all owned by Celgene (collectively, “the patents-in-suit”).

The Parties

2. Plaintiff Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. Defendant Natco is a corporation organized and existing under the laws of India, having a principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad 500 033 India. Natco is in the business of, among other things, manufacturing and marketing of pharmaceutical substances and finished dosage forms for Indian, U.S. and other international markets.

4. On information and belief, Natco is registered to do business in the State of New Jersey. On information and belief, Natco also regularly transacts business within this judicial District. Further, on information and belief, Natco develops numerous generic drugs for sale and use throughout the United States, including in this judicial District. On information and belief, Natco also prepares and/or aids in the preparation and submission of ANDAs to the FDA. Additionally, on information and belief, Natco has partnered with other Defendants to market and distribute Natco’s generic drug products complained of herein, including in this District.

5. Defendant Arrow is a corporation organized and existing under the laws of Malta, having a principal place of business at 57 St. Christopher St., Valletta VLT 08 Malta. Arrow is in the business of, among other things, distributing and selling pharmaceutical products through various directly and indirectly owned subsidiaries and affiliates.

6. On information and belief, Arrow is registered to do business in the State of New Jersey. Further, on information and belief, Arrow also regularly transacts business within this judicial District. Further, on information and belief, Arrow develops numerous generic drugs for sale and use throughout the United States, including in this judicial District. On information and belief, Arrow also prepares and/or aids in the preparation and submission of ANDAs to the FDA. Additionally, on information and belief, Arrow has partnered with Natco to market and distribute Natco's generic drug products complained of herein, including in this District. On information and belief, Arrow is a wholly owned subsidiary of Actavis, which was formerly known as Watson Pharmaceuticals, Inc.

7. Defendant Actavis is a corporation organized and existing under the laws of Nevada, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Actavis is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market through various directly or indirectly owned operating subsidiaries, including, but not limited to, Arrow, Watson, Watson Pharma, and Anda.

8. On information and belief, Actavis regularly conducts business in this judicial District, including marketing and selling pharmaceutical products.

9. Defendant Watson is a corporation organized and existing under the laws of Nevada, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

10. On information and belief, Watson regularly conducts business in this judicial District, including marketing and selling pharmaceutical products. On information and belief,

Watson is a wholly owned subsidiary of Actavis, which was formerly known as Watson Pharmaceuticals, Inc.

11. Defendant Watson Pharma is a corporation organized and existing under the laws of Delaware, having a principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962. Watson Pharma is in the business of, among other things, distributing and selling generic versions of branded pharmaceutical products for the U.S. market.

12. On information and belief, Watson Pharma regularly conducts business in this judicial District, including marketing and selling pharmaceutical products. On information and belief, Watson Pharma is a wholly owned subsidiary of Actavis, which was formerly known as Watson Pharmaceuticals, Inc.

13. Defendant Anda is a corporation organized and existing under the laws of Florida, having a principal place of business at 2915 Weston Road, Weston, Florida 33331-3627. Anda is in the business of, among other things, distributing and supplying generic, brand and specialty pharmaceutical products for the U.S. market.

14. On information and belief, Anda regularly conducts business in this judicial District, including marketing and selling pharmaceutical products. On information and belief, Anda is a wholly owned subsidiary of Actavis, which was formerly known as Watson Pharmaceuticals, Inc.

Jurisdiction and Venue

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a).

16. This Court has personal jurisdiction over Natco by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Natco has purposefully availed itself of this forum by, among other things, making, shipping,

using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. On information and belief, Natco also has purchased retail pharmacies in the State of New Jersey. Further, on information and belief, Natco has customers in the State of New Jersey. Natco also failed to contest jurisdiction and has availed itself of this forum by filing counterclaims in a related litigation in this jurisdiction. *See Celgene Corp. v. Natco Pharma Limited, et al.*, No. 10-5197 (D.N.J.).

17. This Court has personal jurisdiction over Arrow by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Arrow has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. On information and belief, Arrow has customers in the State of New Jersey. Further, Arrow is a wholly owned subsidiary of Actavis, (formerly known as Watson Pharmaceuticals, Inc.), which has substantial contacts with the State of New Jersey. Arrow also failed to contest jurisdiction, and has availed itself of this forum by filing counterclaims, in a related litigation in this jurisdiction. *See Celgene Corp. v. Natco Pharma Ltd, et al.*, No. 10-5197 (D.N.J.).

18. This Court has personal jurisdiction over Actavis, Watson, and Watson Pharma by virtue of their maintaining “Executive Offices” and “Commercial Headquarters” in this judicial District. Additionally, on information and belief, Actavis, Watson, and Watson Pharma make, ship, use, offer to sell or sell, or cause others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and derive revenue from such activities. On information and belief, Actavis, Watson, and Watson Pharma also have customers in the State of New Jersey.

Watson also failed to contest jurisdiction, and has availed itself of this forum by filing counterclaims, in a related litigation in this jurisdiction. *See Celgene Corp. v. Natco Pharma Ltd., et al.*, No. 10-5197 (D.N.J.) (D.I. 208). Watson Pharma has also availed itself of this forum by filing counterclaims in that related litigation. *See id.* at D.I. 18.

19. This Court has personal jurisdiction over Anda by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Anda has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell, or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. On information and belief, Anda has customers in the State of New Jersey. Further, Anda is a wholly owned subsidiary of Actavis, Inc. (formerly known as Watson Pharmaceuticals, Inc.), which has substantial contacts with the State of New Jersey. Anda has availed itself of this forum by filing counterclaims in a related litigation in this jurisdiction. *See Celgene Corp. v. Natco Pharma Ltd., et al.*, No. 10-5197 (D.N.J.) (D.I. 18).

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

The Patents-in-Suit

21. On September 10, 2013, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’498 patent, entitled “Methods For Treating Multiple Myeloma With 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl) Piperidine-2,6-Dione” to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the ’498 patent is attached hereto as Exhibit A.

22. On November 19, 2013, the USPTO duly and lawfully issued the ’188 patent, entitled “Methods for Delivering a Drug to a Patient While Preventing the Exposure of a Foetus

or Other Contraindicated Individual to the Drug” to Celgene as assignee of the inventors Marc Elsayed and Bruce Williams. A copy of the ’188 patent is attached hereto as Exhibit B.

23. On January 7, 2014, the USPTO duly and lawfully issued the ’531 patent, entitled “Methods for Delivering a Drug to a Patient While Restricting Access to the Drug By Patients For Whom the Drug May Be Contraindicated” to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the ’531 patent is attached hereto as Exhibit C.

24. On February 11, 2014, the USPTO duly and lawfully issued the ’095 patent, entitled “Methods For Treating Multiple Myeloma Using 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl) piperidine-2,6-Dione In Combination With Proteasome Inhibitor” to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the ’095 patent is attached hereto as Exhibit D.

The REVLIMID[®] Drug Product

25. Celgene holds an approved New Drug Application (“NDA”) under Section 505(a) of the Federal Food Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 355(a), for lenalidomide capsules (NDA No. 21-880), which it sells under the trade name REVLIMID[®]. The claims of the patents-in-suit cover, *inter alia*, systems and methods of use and administration of lenalidomide or pharmaceutical compositions containing lenalidomide.

26. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to REVLIMID[®].

Acts Giving Rise to this Suit

27. Pursuant to Section 505 of the FFDCA, Natco filed ANDA No. 201-452 (“Natco’s ANDA”) seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation into the United States of lenalidomide capsules 5 mg, 10 mg, 15 mg, and

25 mg (“Natco’s Proposed Products”), before the patents-in-suit expire. Arrow assisted Natco in preparing and filing that ANDA. On information and belief, Watson is now prosecuting ANDA No. 201452 before the FDA.

28. In connection with the filing of its ANDA as described in the preceding paragraph, Natco has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Natco’s ANDA.

29. No earlier than April 3, 2014, Natco sent written notice of its ANDA certification to Celgene (“Natco’s Notice Letter”). Natco’s Notice Letter alleged that the claims of the ’498, ’188, ’531, and ’095 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Natco’s ANDA. Natco’s Notice Letter also informed Celgene that Natco seeks approval to market Natco’s Proposed Products before the ’498, ’188, ’531, and ’095 patents expire.

30. Natco and Arrow entered into a “Product Supply Agreement” in November of 2009, amended in December 2009, under which Arrow, among other things, will market and distribute Natco’s Proposed Products upon FDA approval of Natco’s ANDA throughout the United States, including within the State of New Jersey. That agreement defined Arrow as including its successors-in-interest and assigns.

31. On information and belief, Watson Pharmaceuticals, Inc. (now known as Actavis, Inc.) subsequently acquired Arrow. On information and belief, as a result of that acquisition, Watson took over prosecution of Natco’s ANDA at the FDA, and presently manages prosecution of that application. Further, on information and belief, Watson, Watson Pharma, Anda, and/or Arrow will, among other things, market and distribute Natco’s Proposed Products

upon FDA approval of Natco's ANDA throughout the United States, including within the State of New Jersey. On information and belief, besides the "Product Supply Agreement" discussed in the preceding paragraph, Natco has not signed any written agreement with Arrow, Watson, or any other entity (including, but not limited to, any other defendant and/or Watson Pharmaceuticals, Inc.) detailing the precise relationship between the parties with respect to Natco's ANDA and Natco's Proposed Products.

Count I: Infringement of the '498 Patent

32. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

33. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules into the United States, prior to the expiration of the '498 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

34. There is a justiciable controversy between the parties hereto as to the infringement of the '498 patent.

35. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will infringe the '498 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States.

36. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will induce infringement of the '498 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA,

Defendants will intentionally encourage acts of direct infringement with knowledge of the '498 patent and knowledge that their acts are encouraging infringement.

37. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will contributorily infringe the '498 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '498 patent and that there is no substantial noninfringing use for Natco's Proposed Products.

38. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '498 patent is not enjoined.

39. Celgene does not have an adequate remedy at law.

40. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '188 Patent

41. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

42. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules into the United States, prior to the expiration of the '188 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

43. There is a justiciable controversy between the parties hereto as to the infringement of the '188 patent.

44. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will infringe the '188 patent under 35 U.S.C. § 271(a) by making, using, offering to

sell, importing into the United States, and/or selling Natco's Proposed Products in the United States.

45. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will induce infringement of the '188 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '188 patent and knowledge that their acts are encouraging infringement.

46. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will contributorily infringe the '188 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '188 patent and that there is no substantial noninfringing use for Natco's Proposed Products.

47. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '188 patent is not enjoined.

48. Celgene does not have an adequate remedy at law.

49. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '531 Patent

50. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

51. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules into

the United States, prior to the expiration of the '531 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

52. There is a justiciable controversy between the parties hereto as to the infringement of the '531 patent.

53. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will infringe the '531 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States.

54. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will induce infringement of the '531 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '531 patent and knowledge that their acts are encouraging infringement.

55. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will contributorily infringe the '531 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '531 patent and that there is no substantial noninfringing use for Natco's Proposed Products.

56. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '531 patent is not enjoined.

57. Celgene does not have an adequate remedy at law.

58. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '095 Patent

59. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

60. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules into the United States, prior to the expiration of the '095 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

61. There is a justiciable controversy between the parties hereto as to the infringement of the '095 patent.

62. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will infringe the '095 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States.

63. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will induce infringement of the '095 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '095 patent and knowledge that their acts are encouraging infringement.

64. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Defendants will contributorily infringe the '095 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling Natco's Proposed Products

in the United States. On information and belief, Defendants have had and continue to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '095 patent and that there is no substantial noninfringing use for Natco's Proposed Products.

65. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '095 patent is not enjoined.

66. Celgene does not have an adequate remedy at law.

67. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

(A) A Judgment be entered that Defendants have infringed the '498, '188, '531, and '095 patents by submitting ANDA No. 201-452;

(B) A Judgment be entered that Defendants have infringed, and that Defendants', making, using, selling, offering to sell, or importing into the United States Natco's Proposed Products will infringe one or more claims of the '498, '188, '531, and '095 patents;

(C) An Order that the effective date of FDA approval of ANDA No. 201-452 be a date which is not earlier than the later of the expiration of the '498, '188, '531, and '095 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing into the United States Natco's Proposed Products until after the expiration of the '498, '188, '531, and '095 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any systems or methods as claimed in the '498, '188, '531, and '095 patents, or from actively inducing or contributing to the infringement of any claim of any of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Natco's Proposed Products will directly infringe, induce, and/or contribute to infringement of the '498, '188, '531, and '095 patents;

(G) To the extent that Defendants have committed any acts with respect to the systems or methods claimed in the '498, '188, '531, and '095 patents, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiff be awarded damages for such acts;

(H) If Defendants engage in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Natco's Proposed Products prior to the expiration of the '498, '188, '531, and '095 patents, a Judgment awarding damages to Plaintiff resulting from such infringement, together with interest;

(I) A Judgment declaring that the '498, '188, '531, and '095 patents remain valid and enforceable;

(J) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(K) Costs and expenses in this action; and

(L) Such further and other relief as this Court may deem just and proper.

Dated: May 15, 2014

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

I hereby certify that the matter in controversy involves the same plaintiff, three of the same defendants, and the same Abbreviated New Drug Application that are at issue in the matter captioned *Celgene Corporation v. Natco Pharma Limited, et al.*, Civil Action No. 10-5197 (SDW)(MCA), which is currently pending in this judicial District.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: May 15, 2014

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