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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, *Plaintiff*, v. CIPLA LIMITED, *Defendant.*	Hon. Susan D. Wigenton Civil Action No. 2:18-cv-8964-SDW-LDW **(Filed Electronically)**

CIPLA'S ANSWER, DEFENSES, AND COUNTERCLAIMS
TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT

Defendant Cipla Limited ("Cipla") hereby answers the Complaint brought by Plaintiff Celgene Corporation ("Celgene"). Additionally, Cipla hereby asserts counterclaims for declaratory judgment of non-infringement and invalidity of U.S. Patent Nos. 7,977,357 ("the '357 patent"); 8,193,219 ("the '219 patent"); and 8,431,598 ("the '598 patent") (collectively,

"the patents-in-suit"). With respect to the allegations made in the Complaint, upon knowledge with respect to Cipla's own acts, and upon information and belief as to other matters, Cipla responds and 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 Cipla's filing of an Abbreviated New Drug Application ("ANDA") No. 210435 ("Cipla's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Celgene's 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg REVLIMID® drug products prior to the expiration of United States Patent Nos. 7,977,357 (the "'357 patent"), 8,193,219 (the "'219 patent"), and 8,431,598 (the "'598 patent"), all owned by Celgene (collectively, "the patents-in-suit").

Cipla's Response: Cipla admits that this purports to be an action for patent infringement of the patents-in-suit, under the patent laws of the United States, Title 35, United States Code. Cipla admits that this action purports to relate to Celgene's 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg REVLIMID® capsules. Cipla admits that it filed ANDA No. 210435 ("Cipla's ANDA") with the FDA seeking approval to market a generic pharmaceutical product. Cipla further admits, based on publicly available information, that the United States Patent and Trademark Office ("PTO") lists Celgene as assignee of the patents-in-suit. Cipla lacks knowledge or information sufficient to form a belief about the truth of Celgene's remaining allegations in paragraph 1 of the Complaint and therefore denies them.

The Parties

2. Plaintiff Celgene is a biopharmaceutical company committed to improving the lives of patients worldwide. Celgene focuses on, and invests heavily in, the discovery and development of products for the treatment of severe and life-threatening conditions. Celgene is a world leader in the treatment of many such diseases. 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.

Cipla's Response: Cipla admits, upon information and belief, that 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. Cipla lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Celgene's allegations in paragraph 2 of the Complaint and on that basis denies them.

3. On information and belief, Defendant Cipla Ltd. is a corporation organized and existing under the laws of India, maintaining its headquarters at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai – 400 013, India.

Cipla's Response: Admitted.

The Patents-in-Suit

4. On July 12, 2011, the United States Patent and Trademark Office (the "USPTO") duly and lawfully issued the '357 patent, entitled, "Polymorphic Forms of 3-(4- amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee of the inventors Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller. A copy of the '357 patent is attached hereto as Exhibit A.

Cipla's Response: Cipla denies that the '357 patent was "duly and lawfully issued." Cipla admits that Exhibit A purports to be a copy of United States Patent No. 7,977,357. Cipla admits that, on its face, the '357 patent is titled "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," bears an issuance date of July 12, 2011, and identifies Celgene as the assignee. Cipla lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Celgene's allegations in paragraph 4 of the Complaint and on that basis denies them.

5. On June 5, 2012, the USPTO duly and lawfully issued the '219 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee of the inventors Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller. A copy of the '219 patent is attached hereto as Exhibit B.

Cipla's Response: Cipla denies that the '219 patent was "duly and lawfully issued." Cipla admits that Exhibit B purports to be a copy of United States Patent No. 8,193,219. Cipla admits that, on its face, the '219 patent is titled "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," bears an issuance date of June 5, 2012, and identifies

Celgene as the assignee. Cipla lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Celgene's allegations in paragraph 5 of the Complaint and on that basis denies them.

6. On April 30, 2013, the USPTO duly and lawfully issued the '598 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione" to Celgene as assignee of the inventors Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller. A copy of the '598 patent is attached hereto as Exhibit C.

Cipla's Response: Cipla denies that the '598 patent was "duly and lawfully issued." Cipla admits that Exhibit C purports to be a copy of United States Patent No. 8,431,598. Cipla admits that, on its face, the '598 patent is titled "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," bears an issuance date of April 30, 2013, and identifies Celgene as the assignee. Cipla lacks knowledge or information sufficient to form a belief as to the truth of the remainder of Celgene's allegations in paragraph 6 of the Complaint and on that basis denies them.

The REVLIMID® Drug Product

7. 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®. REVLIMID® is an FDA-approved medication used for the treatment of certain forms of cancer, including multiple myeloma (MM), in combination with dexamethasone. The claims of the patents-in-suit cover, *inter alia*, solid forms of lenalidomide and pharmaceutical compositions containing those solid forms.

Cipla's Response: Cipla admits that the FDA's website indicates that Celgene holds NDA No. 21-880 for lenalidomide capsules sold in the United States under the brand name Revlimid®. Cipla lacks knowledge or information sufficient to form a belief about the truth of Celgene's remaining allegations in paragraph 7 of the Complaint and therefore denies them.

Jurisdiction and Venue

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Cipla's Response: Cipla admits that this action purports to arise under the patent laws of the United States. The remaining allegations in paragraph 8 of the Complaint constitute conclusions of law to which no answer is required. To the extent an answer is required, Cipla admits that this Court has jurisdiction over the subject matter of this action.

9. This Court has personal jurisdiction over Cipla by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Cipla is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, Cipla has purposefully conducted and continues to conduct business in this Judicial District, including the purposeful sale and distribution of drug products. This Judicial District is a likely destination for the generic drug products described in Cipla's ANDA.

Cipla's Response: The allegations in paragraph 9 of the Complaint constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla does not contest personal jurisdiction in this Court for purposes of this case only. Cipla denies the remaining allegations in paragraph 9 of the Complaint.

10. On information and belief Cipla derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) ("API") used in various generic pharmaceutical products sold throughout the United States, including in this Judicial District.

Cipla's Response: Cipla admits that it directly or indirectly sells generic pharmaceutical products in the United States, including in this Judicial District. Cipla denies the remaining allegations in paragraph 10 of the Complaint.

11. On information and belief, Cipla participated in the preparation and/or filing of ANDA No. 210435, and as described below, provided notice of its ANDA filing in New Jersey.

Cipla's Response: Cipla admits that it prepared and submitted Cipla's ANDA to the FDA. Cipla denies the remaining allegations in paragraph 11 of the Complaint.

12. This Court also has personal jurisdiction over Cipla because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Celgene in the State of New Jersey. On information and belief, Cipla intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have

led and will continue to lead to foreseeable harm and injury to Celgene in New Jersey and in this Judicial District.

Cipla's Response: The allegations in paragraph 12 of the Complaint constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla does not contest personal jurisdiction in this Court for purposes of this case only. Cipla denies the remaining allegations in paragraph 18 of the Complaint.

13. On information and belief, Cipla has previously been sued in this Judicial District and has not challenged personal jurisdiction. *See, e.g., Celgene Corporation v. Cipla Limited*, No. 17-6163 (SDW)(LDW); *AstraZeneca AB, et al. v. Cipla Limited, et al.*, No. 16-9583 (RMB)(JS); *Merck, Sharp & Dohme Corp., et al. v. Cipla USA, Inc., et al.*, No. 13-4017 (JBS)(AMD); *Prometheus Labs., Inc. v. Roxane Labs., Inc., et al.*, No. 11-1241 (KM)(MAH) (Cipla Ltd.); and *AstraZeneca AB v. Ivax Corp., et al.*, No. 08-4993 (JAP)(TJB) (Cipla Ltd.).

Cipla's Response: Cipla admits that it has previously been a party to the civil actions listed in paragraph 13 of the Complaint, and that the filings in those cases speak for themselves. The remaining allegations in paragraph 13 of the Complaint are denied or contain conclusions of law for which no response is required.

14. Cipla has further availed itself of the jurisdiction of this Court by previously asserting counterclaims in this jurisdiction. See, e.g., *Celgene Corporation v. Cipla Limited*, No. 17-6163 (SDW)(LDW); *AstraZeneca AB, et al. v. Cipla Limited, et al.*, No. 16-9583 (RMB)(JS); *Abraxis Bioscience, LLC & Celgene Corp. v. Cipla Ltd.*, No. 16-9074 (JMV)(MF); *Janssen Prods., L.P. v. Cipla Ltd.*, No. 15-2549 (WHW)(CLW); *Merck, Sharp & Dohme Corp., et al. v. Cipla USA, Inc., et al.*, No. 13-4017 (JBS)(AMD); *Prometheus Labs., Inc. v. Roxane Labs., Inc., et al.*, No. 11-1241 (KM)(MAH) (Cipla Ltd.); *Janssen Prods, L.P. v. Lupin Ltd., et al.*, No. 10-5954 (WHW)(CLW); *AstraZeneca AB v. Ivax Corp., et al.*, No. 08-4993 (JAP)(TJB) (Cipla Ltd.); and *AstraZeneca AB v. Ranbaxy Pharm., Inc., et al.*, No. 05-5553 (MLC)(TJB) (Cipla Ltd.).

Cipla's Response: Cipla admits that it has asserted counterclaims in civil actions brought against it in this District, and that the filings of those counterclaims speak for themselves. The remaining allegations in paragraph 14 of the Complaint are denied or contain conclusions of law for which no response is required.

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

Cipla's Response: The allegations in paragraph 15 of the Complaint constitute conclusions of law to which no answer is required. To the extent that a response is required, Cipla does not contest venue in this Court for purposes of this case only. Cipla reserves the right to challenge venue in light of the *TC Heartland LLC v. Kraft Foods Gp. Brands LLC*, 137 S. Ct. 1514 (2017) case for all other actions.

Acts Giving Rise To This Suit

16. Pursuant to Section 505 of the FFDCA, Cipla filed Cipla's ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg lenalidomide capsules ("Cipla's Proposed Products"), before the patents-in-suit expire.

Cipla's Response: Cipla admits that it filed an ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg lenalidomide capsules described in Cipla's ANDA ("Cipla's Proposed Products"). Cipla denies the remaining allegations in paragraph 16 of the Complaint.

17. On information and belief, following FDA approval of Cipla's ANDA, Cipla will make, use, sell, or offer to sell Cipla's Proposed Products throughout the United States, or import such generic products into the United States.

Cipla's Response: Cipla admits that it filed Cipla's ANDA with the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla's Proposed Products. Cipla denies the remaining allegations in paragraph 17 of the Complaint.

18. On information and belief, in connection with the filing of its ANDA as described above, Cipla provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Cipla's Paragraph IV Certification"), alleging that the claims of United States Patent Nos. 7,465,800 (the "'800 patent"), 7,855,217 (the "'217 patent"), 7,968,569 (the "'569 patent"), 8,530,498 (the "'498 patent"), 8,648,095 (the "'095 patent"), 9,101,621 (the "'621 patent"), and 9,101,622 (the "'622 patent") are invalid, unenforceable, and/or will not be infringed by the activities described in Cipla's ANDA.

Cipla's Response: Cipla admits that, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Cipla included with its ANDA certifications that the claims of the patents listed in paragraph 18 of the Complaint and contained in the Orange Book for REVLIMID® are invalid, unenforceable, and/or will not be infringed by the manufacture, sale, or use of Cipla's Proposed Products.

19. No earlier than June 30, 2017, Cipla sent written notice of its Paragraph IV Certification to Celgene ("Cipla's Notice Letter"). Cipla's Notice Letter alleged that the claims of the '800, '217, '569, '498, '095, '621, and '622 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Cipla's ANDA. Cipla's Notice Letter also informed Celgene that Cipla seeks approval to market Cipla's Proposed Products before the '800, '217, '569, '498, '095, '621, and '622 patents expire. Cipla specifically directed Cipla's Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

Cipla's Response: Cipla admits that it sent written notice of its ANDA and its Paragraph IV certifications to Celgene on June 30, 2017. Cipla further admits that it sent the written notice of its ANDA to Celgene's Chief Executive Officer in Summit, NJ; Celgene's Executive Director of Regulatory Affairs in Summit, NJ; and Celgene's office in Warren, NJ. Cipla's notice of its Paragraph IV certification speaks for itself. Cipla denies the remaining allegations in paragraph 19 of the Complaint.

Count I: Infringement of the '357 Patent

20. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

Cipla's Response: In response to paragraph 20 of the Complaint, Cipla incorporates by reference paragraphs 1 through 19 of this Answer as if fully set forth herein.

21. Cipla, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla's Proposed Products, prior to the expiration of the '357 patent.

Cipla's Response: Cipla admits that by submission of its Paragraph IV Certification, Cipla seeks approval to market Cipla's Proposed Products before the '800, '217, '569, '498, '095, '621, and '622 patents expire. Cipla denies the remaining allegations in paragraph 21.

22. Cipla's ANDA has been pending before the FDA since at least June 30, 2017, the date that Cipla sent Cipla's Notice Letter to Celgene.

Cipla's Response: Admitted.

23. Cipla's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla's Proposed Products, prior to the expiration of the '357 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

Cipla's Response: Denied.

24. There is a justiciable controversy between the parties hereto as to the infringement of the '357 patent.

Cipla's Response: The allegations in paragraph 24 of the Complaint contain conclusions of law to which no answer is required. To the extent that a response is required, Cipla admits that there is justiciable controversy between Celgene and Cipla. Cipla denies the remaining allegations in paragraph 24 of the Complaint.

25. Unless enjoined by this Court, upon FDA approval of Cipla's ANDA, Cipla will infringe one or more claims of the '357 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Cipla's Proposed Products in the United States.

Cipla's Response: Denied.

26. Unless enjoined by this Court, upon FDA approval of Cipla's ANDA, Cipla will induce infringement of one or more claims of the '357 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Cipla's Proposed Products in the United States. On information and belief, upon FDA approval of Cipla's ANDA, Cipla will intentionally encourage acts of direct infringement with knowledge of the '357 patent and knowledge that its acts are encouraging infringement.

Cipla's Response: Denied.

27. Unless enjoined by this Court, upon FDA approval of Cipla's ANDA, Cipla will contributorily infringe one or more claims of the '357 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Cipla's Proposed Products in the United States. On information and belief, Cipla has had and continues to have knowledge that Cipla's Proposed Products are especially adapted for a use that infringes one or more claims of the '357 patent and that there is no substantial non-infringing use for Cipla's Proposed Products.

Cipla's Response: Denied.

28. Celgene will be substantially and irreparably damaged and harmed if Cipla's infringement of the '357 patent is not enjoined.

Cipla's Response: Denied.

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

Cipla's Response: Denied.

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

Cipla's Response: Denied.

Count II: Infringement of the '219 Patent

31. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

Cipla's Response: In response to paragraph 31 of the Complaint, Cipla incorporates by reference paragraphs 1 through 30 of this Answer as if fully set forth herein.

32. Cipla, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla's Proposed Products, prior to the expiration of the '219 patent.

Cipla's Response: Cipla admits that by submission of its Paragraph IV Certification, Cipla seeks approval to market Cipla's Proposed Products before the '800, '217, '569, '498, '095, '621, and '622 patents expire. Cipla denies the remaining allegations in paragraph 32.

33. Cipla's ANDA has been pending before the FDA since at least June 30, 2017, the date that Cipla sent Cipla's Notice Letter to Celgene.

Cipla's Response: Admitted.

34. Cipla's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla's Proposed Products, prior to the expiration of the '219 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

Cipla's Response: Denied.

35. There is a justiciable controversy between the parties hereto as to the infringement of the '219 patent.

Cipla's Response: The allegations in paragraph 35 of the Complaint contain conclusions of law to which no answer is required. To the extent that a response is required, Cipla admits that there is justiciable controversy between Celgene and Cipla. Cipla denies the remaining allegations in paragraph 35 of the Complaint.

36. Unless enjoined by this Court, upon FDA approval of Cipla's ANDA, Cipla will infringe one or more claims of the '219 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Cipla's Proposed Products in the United States.

Cipla's Response: Denied.

37. Unless enjoined by this Court, upon FDA approval of Cipla's ANDA, Cipla will induce infringement of one or more claims of the '219 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Cipla's Proposed Products in the United States. On information and belief, upon FDA approval of Cipla's ANDA, Cipla will intentionally encourage acts of direct infringement with knowledge of the '219 patent and knowledge that its acts are encouraging infringement.

Cipla's Response: Denied.

38. Unless enjoined by this Court, upon FDA approval of Cipla's ANDA, Cipla will contributorily infringe one or more claims of the '219 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Cipla's Proposed Products in the United States. On information and belief, Cipla has had and continues to have knowledge that Cipla's Proposed Products are especially adapted for a use that infringes one or more claims of the '219 patent and that there is no substantial non-infringing use for Cipla's Proposed Products.

Cipla's Response: Denied.

39. Celgene will be substantially and irreparably damaged and harmed if Cipla's infringement of the '219 patent is not enjoined.

Cipla's Response: Denied.

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

Cipla's Response: Denied.

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

Cipla's Response: Denied.

Count III: Infringement of the ’598 Patent

42. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

Cipla’s Response: In response to paragraph 42 of the Complaint, Cipla incorporates by reference paragraphs 1 through 41 of this Answer as if fully set forth herein.

43. Cipla, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla’s Proposed Products, prior to the expiration of the ’598 patent.

Cipla’s Response: Cipla admits that by submission of its Paragraph IV Certification, Cipla seeks approval to market Cipla’s Proposed Products before the ’800, ’217, ’569, ’498, ’095, ’621, and ’622 patents expire. Cipla denies the remaining allegations in paragraph 43.

44. Cipla’s ANDA has been pending before the FDA since at least June 30, 2017, the date that Cipla sent Cipla’s Notice Letter to Celgene.

Cipla’s Response: Admitted.

45. Cipla’s submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla’s Proposed Products, prior to the expiration of the ’598 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

Cipla’s Response: Denied.

46. There is a justiciable controversy between the parties hereto as to the infringement of the ’598 patent.

Cipla’s Response: The allegations in paragraph 46 of the Complaint contain conclusions of law to which no answer is required. To the extent that a response is required, Cipla admits that there is justiciable controversy between Celgene and Cipla. Cipla denies the remaining allegations in paragraph 46 of the Complaint.

47. Unless enjoined by this Court, upon FDA approval of Cipla’s ANDA, Cipla will infringe one or more claims of the ’598 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Cipla’s Proposed Products in the United States.

Cipla's Response: Denied.

48. Unless enjoined by this Court, upon FDA approval of Cipla's ANDA, Cipla will induce infringement of one or more claims of the '598 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Cipla's Proposed Products in the United States. On information and belief, upon FDA approval of Cipla's ANDA, Cipla will intentionally encourage acts of direct infringement with knowledge of the '598 patent and knowledge that its acts are encouraging infringement.

Cipla's Response: Denied.

49. Unless enjoined by this Court, upon FDA approval of Cipla's ANDA, Cipla will contributorily infringe one or more claims of the '598 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Cipla's Proposed Products in the United States. On information and belief, Cipla has had and continues to have knowledge that Cipla's Proposed Products are especially adapted for a use that infringes one or more claims of the '598 patent and that there is no substantial non-infringing use for Cipla's Proposed Products.

Cipla's Response: Denied.

50. Celgene will be substantially and irreparably damaged and harmed if Cipla's infringement of the '598 patent is not enjoined.

Cipla's Response: Denied.

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

Cipla's Response: Denied.

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

Cipla's Response: Denied.

Prayer for Relief

Cipla denies that Celgene is entitled to any of the requested relief or any other relief. Each averment and/or allegation contained in Celgene's Complaint that is not specifically admitted herein is hereby denied.

DEFENSES

Cipla alleges the following defenses without prejudice to the denials set forth in the responses to paragraphs 1-52. Without any admissions as to the burden of proof, burden of

persuasion, or the truth of any allegations in Celgene's Complaint, Cipla states the following defenses:

First Defense – Non-infringement of the '357 Patent

Cipla's Proposed Products have not infringed, do not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '357 patent, literally or under the Doctrine of Equivalents.

Second Defense – Invalidity of the '357 Patent

Each claim of the '357 patent is invalid for failure to comply with one or more conditions and requirements for patentability, including without limitations, 35 U.S.C. §§ 101, 102, 103, 112, and/or other judicially created bases for invalidity.

Third Defense – Non-infringement of the '219 Patent

Cipla's Proposed Products have not infringed, do not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '219 patent, literally or under the Doctrine of Equivalents.

Fourth Defense – Invalidity of the '219 Patent

Each claim of the '219 patent is invalid for failure to comply with one or more conditions and requirements for patentability, including without limitations, 35 U.S.C. §§ 101, 102, 103, 112, and/or other judicially created bases for invalidity.

Fifth Defense – Non-infringement of the '598 Patent

Cipla's Proposed Products have not infringed, do not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '598 patent, literally or under the Doctrine of Equivalents.

Sixth Defense – Invalidity of the '598 Patent

Each claim of the '598 patent is invalid for failure to comply with one or more conditions and requirements for patentability, including without limitations, 35 U.S.C. §§ 101, 102, 103, 112, and/or other judicially created bases for invalidity.

Seventh Defense – No Relief Available

Celgene is barred from obtaining relief pursuant to one or more provisions of 35 U.S.C. § 1, *et seq.*, including but not limited to §§ 286 and 287.

Celgene has not suffered any damages.

Celgene is not suffering an irreparable injury.

Eighth Defense – Failure to State a Claim

The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

Ninth Defense – No Exceptional Case

Cipla's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Tenth Defense – No Willful Infringement

Cipla has not willfully infringed any claim of the '357 patent, the '219 patent, or the '598 patent.

Eleventh Defense – Estoppel

Celgene is estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

Twelfth Defense – Waiver

Celgene has waived any alleged defect in the way in which the notice of Paragraph-IV certification was served.

Thirteenth Defense – Damages

Celgene's damages, if any, are limited pursuant to 35 U.S.C. §§ 286-287.

RESERVATION OF DEFENSES

Cipla reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

COUNTERCLAIMS

Defendant and Counterclaim Plaintiff, Cipla Limited ("Cipla"), asserts the following counterclaim against Plaintiff and Counterclaim Defendant, Celgene Corporation.

Nature and Summary of Counterclaim

1. This counterclaim includes claims for a declaratory judgment that U.S. Patent Nos. 7,977,357 ("the '357 patent"); 8,193,219 ("the '219 patent"); and 8,431,598 ("the '598 patent") (collectively, "the patents-in-suit") are invalid and/or not infringed.

2. Cipla submitted ANDA No. 210435 ("Cipla's ANDA") to the FDA seeking approval for the commercial manufacture, use, importation, offer for sale, and sale of generic 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg lenalidomide capsules ("Cipla's ANDA Products"). Celgene Corp.'s REVLIMID® capsules is the Reference Listed Drug ("RLD") relied upon in Cipla's ANDA.

3. Celgene has previously listed several patents in the FDA's Approved Drug Products with Therapeutic Equivalence (commonly referred to as the "Orange Book") as allegedly covering REVLIMID® capsules. An earlier action between the parties, captioned *Celgene Corp. v. Cipla Ltd.*, Civ. No. 17-6163 (SDW) (LDW) ("REVLIMID® ANDA Litigation") involves the patents listed in the Orange Book for REVLIMID®.

4. On May 8, 2018, Celgene Corp. filed a suit for patent infringement of the patents-in-suit. Cipla does not infringe any valid claim of the patents-in-suit.

5. None of the patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book") as allegedly covering REVLIMID® capsules. The patents-in-suit cover a different polymorph of lenalidomide, the active pharmaceutical ingredient in REVLIMID®. By bringing this action against Cipla, Celgene has admitted that Cipla's ANDA Products do not infringe the polymorph patents involved in the REVLIMID® ANDA Litigation.

6. Cipla's declaratory judgment counterclaims are necessary to remove the patents-in-suit as a barrier to Cipla's market entry. Although these patents have no bearing on FDA approval of the accused Cipla's ANDA Products, Celgene may attempt to obtain either an injunction or damages based on these non-Orange Book-listed patents-in-suit.

7. Cipla therefore seeks a declaration that the patents-in-suit are invalid and/or not infringed by Cipla's ANDA Products.

The Parties

8. Cipla Limited is a corporation existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbia-400013, India.

9. On information and belief, Counterclaim Defendant Celgene Corp. 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.

10. Counterclaim Defendant is the entity that filed the Complaint in this action on May 8, 2018.

Jurisdiction and Venue

11. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

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

13. This Court has personal jurisdiction over Counterclaim Defendant because Celgene Corp., upon information and belief, has its headquarters and principal place of business in Summit, New Jersey.

14. Personal jurisdiction over Counterclaim Defendant is also proper because Celgene has availed itself to this forum in this action, and in other lenalidomide-related litigations. *See, e.g.*, REVLIMID® ANDA Litigation ; *Celgene Corp. v. Zydus Pharms. (USA) Inc. et al*, No. 17-cv-02528 (D.N.J. Apr. 12, 2017); *Celgene Corp. v. Dr. Reddy's Labs., Ltd. et al*, No. 16-cv-07704 (D.N.J. Oct. 20, 2016).

15. To the extent that venue is proper in connection with Counterclaim Defendant's Complaint, it is equally proper for these counterclaims under 28 U.S.C. §§ 1391 and 1400. Venue is also proper in this Court because Celgene is subject to personal jurisdiction in this District.

Background

Celgene Corp.'s Patents

16. Counterclaim Defendant Celgene Corp. holds approved NDA No. 021880 for lenalidomide capsules under the name REVLIMID®.

17. On its face, the '357 patent, entitled "Polymorphic Forms Of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6,-dione," issued on July 12, 2011.

18. On its face, the '219 patent, entitled "Polymorphic Forms Of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6,-dione," issued on June 5, 2012.

19. On its face, the '598 patent, entitled "Polymorphic Forms Of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6,-dione," issued on April 30, 2013.

20. On information and belief, Celgene Corp. is the assignee of the '357 patent, the '219 patent, and the '598 patent.

21. None of these patents are listed in the Orange Book for REVLIMID®.

Cipla's ANDA Products

22. Cipla filed ANDA No. 210435 seeking FDA approval to market a generic version of Celgene's REVLIMID®-branded lenalidomide product. The REVLIMID® ANDA Litigation is the Hatch-Waxman Act litigation based on Cipla's ANDA. Cipla's ANDA Products do not, and will not, infringe any of Celgene's Orange Book-listed patents.

23. This litigation involves patents that are not listed in the Orange Book. The patents-in-suit are all directed to a polymorph of lenalidomide that is different than the one used in REVLIMID® and claimed by the Orange Book patents. By bringing this case against Cipla, Celgene has conceded that Cipla's ANDA Products do not infringe any valid claim of the Orange Book-listed polymorph patents.

Count I: Declaratory Judgment of Invalidity of the '357 Patent

24. Cipla realleges and incorporates herein by reference the allegations of Counterclaim paragraphs 1-23.

25. The '357 patent is invalid for failure to comply with one or more conditions and requirements for patentability, including without limitations, 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

26. Accordingly, there is an actual, immediate, and justiciable controversy between the parties.

27. Cipla is entitled to a declaration by the Court that one or more claims of the '357 patent is invalid.

28. Cipla is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

Count II: Declaratory Judgment of Non-infringement of the '357 Patent

29. Cipla realleges and incorporates herein by reference the allegations of Counterclaim paragraphs 1-28.

30. Counterclaim Defendant has alleged in this action that Cipla has infringed, or will infringe, the '357 patent under 35 U.S.C. § 271(a)-(c) by selling Cipla's ANDA Products.

31. There is an actual, immediate, and justiciable controversy between the parties regarding whether Cipla's ANDA Products, described in Cipla's ANDA, will infringe any valid and enforceable claim of the '357 patent.

32. Cipla is entitled to a declaration by the Court that it has not, and will not, infringe, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the '357 patent and is not liable for such infringement.

33. Cipla is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

Count III: Declaratory Judgment of Invalidity of the '219 Patent

34. Cipla realleges and incorporates herein by reference the allegations of Counterclaim paragraphs 1-33.

35. The '219 patent is invalid for failure to comply with one or more conditions and requirements for patentability, including without limitations, 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

36. Accordingly, there is an actual, immediate, and justiciable controversy between the parties.

37. Cipla is entitled to a declaration by the Court that one or more claims of the '219 patent is invalid.

38. Cipla is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

Count IV: Declaratory Judgment of Noninfringement of the '219 Patent

39. Cipla realleges and incorporates herein by reference the allegations of Counterclaim paragraphs 1-38.

40. Counterclaim Defendant has alleged in this action that Cipla has infringed, or will infringe, the '219 patent under 35 U.S.C. § 271(a)-(c) by selling Cipla's ANDA Products.

41. There is an actual, immediate, and justiciable controversy between the parties regarding whether Cipla's ANDA Products, described in Cipla's ANDA, will infringe any valid and enforceable claim of the '219 patent.

42. Cipla is entitled to a declaration by the Court that it has not, and will not, infringe, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the '219 patent and is not liable for such infringement.

43. Cipla is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

Count V: Declaratory Judgment of Invalidity of the '598 Patent

44. Cipla realleges and incorporates herein by reference the allegations of Counterclaim paragraphs 1-43.

45. The '598 patent is invalid for failure to comply with one or more conditions and requirements for patentability, including without limitations, 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

46. Accordingly, there is an actual, immediate, and justiciable controversy between the parties.

47. Cipla is entitled to a declaration by the Court that one or more claims of the ’598 patent is invalid.

48. Cipla is entitled to further necessary or proper relief based on the Court’s declaratory judgment or decree.

Count VI: Declaratory Judgment of Noninfringement of the ’598 Patent

49. Cipla realleges and incorporates herein by reference the allegations of Counterclaim paragraphs 1-48.

50. Counterclaim Defendant has alleged in this action that Cipla has infringed, or will infringe, the ’598 patent under 35 U.S.C. § 271(a)-(c) by selling Cipla’s ANDA Products.

51. There is an actual, immediate, and justiciable controversy between the parties regarding whether Cipla’s ANDA Products, described in Cipla’s ANDA, will infringe any valid and enforceable claim of the ’598 patent.

52. Cipla is entitled to a declaration by the Court that it has not, and will not, infringe, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the ’598 patent and is not liable for such infringement.

53. Cipla is entitled to further necessary or proper relief based on the Court’s declaratory judgment or decree.

PRAYER FOR RELIEF

WHEREFORE, Cipla requests that the Court enter judgment in its favor and against Celgene Corp. as follows:

(a) Declaring that Cipla's ANDA Products have not, do not, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '357 patent;

(b) Declaring that Cipla's ANDA Products have not, do not, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '219 patent;

(c) Declaring that Cipla's ANDA Products have not, do not, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '598 patent;

(d) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Cipla's ANDA Products does not, and will not, infringe any valid and enforceable claim of the '357 patent;

(e) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Cipla's ANDA Products does not, and will not, infringe any valid and enforceable claim of the '219 patent;

(f) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Cipla's ANDA Products does not, and will not, infringe any valid and enforceable claim of the '598 patent;

(g) Declaring that the claims of the '357 patent are invalid and/or unenforceable;

(h) Declaring that the claims of the '219 patent are invalid and/or unenforceable;

(i) Declaring that the claims of the '598 patent are invalid and/or unenforceable;

(j) Awarding Cipla its costs and expenses in this action;

(k) If the facts demonstrate that the case is exceptional within the meaning of 35 U.S.C. § 285, awarding Cipla reasonable attorney fees and costs reasonably incurred in prosecuting this action;

(l) Granting Cipla such other and further relief as the Court deems just and appropriate; and

(m) Ordering that the Counterclaim Defendant's Complaint be dismissed with prejudice and judgment be entered in favor of Cipla.

Dated: July 16, 2018

Respectfully submitted,

s/ Lisa J. Rodriguez

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter captioned *Celgene Corporation v. Cipla Limited*, Civil Action No. 17-6163 (SDW)(LDW) (D.N.J.) is related to the matter in controversy because the matter in controversy involves the same plaintiff, the same patents, and the same NDA.

I further certify that the matter captioned *Celgene Corporation v. Zydus Pharmaceuticals (USA) Inc., et al.*, Civil Action No. 18-8519 (SDW)(LDW) (D.N.J.) is related to the matter in controversy because the matter in controversy involves the same plaintiff, the same patents, and the same NDA.

I further certify that the matters captioned *Celgene Corporation v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 16-7704 (SDW)(LDW) (D.N.J.), *Celgene Corporation v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 17-5314 (SDW)(LDW) (D.N.J.), *Celgene Corporation v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 18-6378 (SDW)(LDW) (D.N.J.), *Celgene Corporation v. Zydus Pharmaceuticals (USA) Inc., et al.*, Civil Action No. 17-2528 (SDW)(LDW) (D.N.J.), *Celgene Corporation v. Lotus Pharm. Co., et al.*, Civil Action No. 17-6842 (SDW)(LDW) (D.N.J.), and *Celgene Corporation v. Apotex Inc., Civil Action No. 18-461 (SDW)(LDW) (D.N.J.)* are related to the matter in controversy because the matter in controversy involves the same plaintiff and the same NDA.

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: July 16, 2018

s/ Lisa J. Rodriguez

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CERTIFICATION OF SERVICE

This is to certify that on this sixteenth day of July, 2018, a true and correct copy of the foregoing **CIPLA LIMITED'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT** was caused to be served by e-mail and/or Federal Express on the following counsel of record:

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Dated: July 16, 2018

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