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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **NATCO PHARMA LIMITED,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Celgene Corporation ("Celgene"), by its undersigned attorneys, for its Complaint against defendant Natco Pharma Limited ("Natco" or "Defendant"), 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. 5,635,517 (the "'517 patent"), 6,045,501 (the "'501 patent"), 6,281,230 (the "'230 patent"), 6,315,720 (the "'720 patent"), 6,555,554 (the "'554 patent"), 6,561,976 (the "'976 patent"), 6,561,977 (the "'977 patent"), 6,755,784 (the

"'784 patent"), 7,119,106 (the "'106 patent"), and 7,465,800 (the "'800 patent") 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. On information and belief, 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.

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 an unknown generic pharmaceutical company based in the United States ("Natco's Unknown Partner") to market and distribute Natco's generic drug products complained of herein, including in this district. On information and belief, Natco's Unknown Partner regularly conducts business in this judicial district, including marketing and selling pharmaceutical products. Prior to filing suit, Celgene asked counsel for Natco to identify Natco's Unknown Partner. Natco's counsel refused, but did not deny that such partner exists.

Jurisdiction and Venue

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

6. 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. Additionally, on information and belief, Natco's Unknown Partner makes, ships, uses, offers to sell or sells, or causes others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and derives revenue from such activities. On information and belief, Natco's Unknown Partner also has customers in the State of New Jersey.

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

The Patents in Suit

8. On June 3, 1997, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '517 patent, entitled "Method of Reducing TNFα Levels with Amino Substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxo-and 1,3-dioxoisoindolines" to Celgene as assignee of the inventors George W. Muller, David I. Stirling, and Roger Shen-Chu Chen. On June 29, 1999, the USPTO duly and lawfully issued a reexamination certificate for the '517 patent. On March 27, 2008, the USPTO extended the term of the '517 patent under 35 U.S.C. § 156 for a period of 1,167 days. A copy of the '517 patent and its reexamination certificate are attached hereto as Exhibit A.

9. On April 4, 2000, the USPTO duly and lawfully issued the '501 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 '501 patent is attached hereto as Exhibit B.

10. On August 28, 2001, the USPTO duly and lawfully issued the '230 patent, entitled "Isoindolines, Method of Use, and Pharmaceutical Compositions" to Celgene as assignee of the inventors George W. Muller, David I. Stirling, and Roger Shen-Chu Chen. A copy of the '230 patent is attached hereto as Exhibit C.

11. On November 13, 2001, the USPTO duly and lawfully issued the '720 patent, entitled "Methods for Delivering a Drug to a Patient While Avoiding the Occurrence of an Adverse Side Effect Known or Suspected of Being Caused by the Drug" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '720 patent is attached hereto as Exhibit D.

12. On April 29, 2003, the USPTO duly and lawfully issued the '554 patent, entitled "Isoindolines, Method of Use, and Pharmaceutical Compositions" to Celgene as assignee of the inventors George W. Muller, David I. Stirling, and Roger Shen-Chu Chen. A copy of the '554 patent is attached hereto as Exhibit E.

13. On May 13, 2003, the USPTO duly and lawfully issued the '976 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 '976 patent is attached hereto as Exhibit F.

14. On May 13, 2003, the USPTO duly and lawfully issued the '977 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 '977 patent is attached hereto as Exhibit G.

15. On June 29, 2004, the USPTO duly and lawfully issued the '784 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. On May 3, 2005, a certificate of correction was granted by the USPTO to correct a typographical error in claim 29 of the '784 patent. A copy of the '784 patent and its certificate of correction are attached hereto as Exhibit H.

16. On October 10, 2006, the USPTO duly and lawfully issued the '106 patent, entitled "Pharmaceutical Compositions of 1-oxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline" to Celgene as assignee of the inventors George W. Muller, David I. Stirling, and Roger Shen-Chu Chen. A copy of the '106 patent is attached hereto as Exhibit I.

17. On December 16, 2008, the USPTO duly and lawfully issued the '800 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 '800 patent is attached hereto as Exhibit J.

The REVLIMID® Drug Product

18. 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*, lenalidomide, solid forms of lenalidomide, pharmaceutical compositions containing lenalidomide, and methods of use and administration of lenalidomide or pharmaceutical compositions containing lenalidomide.

19. 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®.

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