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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **BIOCON PHARMA LIMITED, BIOCON LIMITED, and BIOCON PHARMA, INC.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Celgene Corporation ("Celgene"), by its undersigned attorneys, for its Complaint against Defendants Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc. (collectively, "Biocon" or "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 Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc.'s submission of Abbreviated New Drug Application ("ANDA") No. 215759 ("Biocon's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell generic versions of Celgene's Revlimid® drug products prior to the expiration of United States Patent Nos.

7,189,740 ("the '740 patent"), 7,465,800 ("the '800 patent"), 7,855,217 ("the '217 patent"), 7,968,569 ("the '569 patent"), 8,404,717 ("the '717 patent"), 8,530,498 ("the '498 patent"), 8,648,095 ("the '095 patent"), 9,056,120 ("the '120 patent"), 9,101,621 ("the '621 patent"), and 9,101,622 ("the '622 patent") (collectively, "the patents-in-suit"), all owned by Celgene.

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, including cancer. 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 Biocon Pharma Limited ("BPL") is a corporation organized and existing under the laws of India having a principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560100, Karnataka, India.

4. On information and belief, Defendant Biocon Limited is a corporation organized and existing under the laws of India, having a principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560100, Karnataka, India.

5. On information and belief, Defendant Biocon Pharma, Inc. ("BPI") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 485 US Highway 1 S Ste B305, Iselin, New Jersey 08830.

6. On information and belief, BPI is a wholly owned subsidiary of BPL.

7. On information and belief, BPL is a wholly owned subsidiary of Biocon Limited.

8. On information and belief, Biocon Limited is the parent company of BPL.

The Patents-in-Suit

9. On December 16, 2008, the United States Patent and Trademark Office ("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. A copy of the '800 patent is attached hereto as Exhibit A.

10. On December 21, 2010, the USPTO duly and lawfully issued the '217 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee. A copy of the '217 patent is attached hereto as Exhibit B.

11. On June 28, 2011, the USPTO duly and lawfully issued the '569 patent, entitled, "Methods For Treatment of Multiple Myeloma Using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee. A copy of the '569 patent is attached hereto as Exhibit C.

12. On September 10, 2013, the 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. A copy of the '498 patent is attached hereto as Exhibit D.

13. 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. A copy of the '095 patent is attached hereto as Exhibit E.

14. On August 11, 2015, the USPTO duly and lawfully issued the '621 patent, entitled, "Methods For Treating Multiple Myeloma With 3-(4-amino-1-oxo-1,3-dihydro-

isoindol-2-yl)-piperidine-2,6-dione After Stem Cell Transplantation," to Celgene as assignee. A copy of the '621 patent is attached hereto as Exhibit F.

15. On August 11, 2015, the USPTO duly and lawfully issued the '622 patent, entitled, "Methods For Treating Newly Diagnosed Multiple Myeloma 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione In Combination With Dexamethasone," to Celgene as assignee. A copy of the '622 patent is attached hereto as Exhibit G.

16. On March 13, 2007, the USPTO duly and lawfully issued the '740 patent, entitled, "Methods of Using 3-(4-amino-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for the Treatment and Management of Myelodysplastic Syndromes," to Celgene as assignee. A copy of the '740 patent is attached hereto as Exhibit H.

17. On March 26, 2013, the USPTO duly and lawfully issued the '717 patent, entitled, "Methods of Treating Myelodysplastic Syndromes Using Lenalidomide," to Celgene as assignee. A copy of the '717 patent is attached hereto as Exhibit I.

18. On June 16, 2015, the USPTO duly and lawfully issued the '120 patent, entitled, "Methods of Treating Myelodysplastic Syndromes with a Combination Therapy Using Lenalidomide and Azacitidine," to Celgene as assignee. A copy of the '120 patent is attached hereto as Exhibit J.

The Revlimid® Drug Product

19. 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. 021880), which it sells under the trade name Revlimid®. The claims of the patents-in-suit cover, *inter alia*, solid forms of lenalidomide, pharmaceutical compositions

containing lenalidomide, and methods of use and administration of lenalidomide or pharmaceutical compositions containing lenalidomide.

20. 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®.

21. The labeling for Revlimid® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Revlimid® for the treatment of, *inter alia*, adult patients with multiple myeloma (MM), in combination with dexamethasone.

22. The labeling for Revlimid® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Revlimid® for the treatment of, *inter alia*, adult patients with MM, as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT).

23. The labeling for Revlimid® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Revlimid® for the treatment of, *inter alia*, adult patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities.

24. The labeling for Revlimid® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Revlimid® according to one or more of the methods claimed in the patents-in-suit.

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