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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **QILU PHARMACEUTICAL CO. LTD.,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Celgene Corporation ("Celgene"), by its undersigned attorneys, for its Complaint against Defendant Qilu Pharmaceutical Co. Ltd. ("Qilu"), 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 Qilu's submission of Abbreviated New Drug Application ("ANDA") No. 217265 ("Qilu'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. 7,465,800 (the "'800 patent") and 7,855,217 (the "'217 patent") (together, "the patents-in-suit"), both 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 Qilu Pharmaceutical Co. Ltd. is a corporation organized and existing under the laws of China, having a principal place of business at 8888 Lvyou Road, High-tech Zone, Jinan, 250104, China.

The Patents-in-Suit

4. 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." A copy of the '800 patent is attached hereto as Exhibit A.

5. 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." A copy of the '217 patent is attached hereto as Exhibit B.

The Revlimid® Drug Product

6. 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 and pharmaceutical compositions containing lenalidomide.

7. 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®.

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.

9. This Court has personal jurisdiction over Qilu by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Qilu's subsidiary, Qilu Healthcare Inc., maintains a regular and established, physical place of business in Princeton, New Jersey.

10. On information and belief, Qilu Healthcare Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 101042575. On information and belief, Qilu Healthcare Inc. is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5005245.

11. On information and belief, Qilu purposefully has conducted and continues to conduct business in this Judicial District.

12. On information and belief, Qilu 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, Qilu also prepares and/or aids in the preparation and submission of ANDAs to the FDA, including Qilu's ANDA.

13. On information and belief, this Judicial District is a likely destination for the generic drug products described in Qilu's ANDA.

14. This Court has personal jurisdiction over Qilu because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter egos, including Qilu Healthcare, Inc., a company with its principal place of business in New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey, including through, directly or indirectly, Qilu Healthcare, Inc.

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

16. In the alternative, this Court has personal jurisdiction over Qilu because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Celgene's claims arise under federal law; (b) Qilu is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Qilu has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Qilu satisfies due process.

17. On information and belief, Qilu works in privity and/or concert either directly or indirectly through one or more of its wholly owned subsidiaries with respect to the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

18. On information and belief, Qilu submitted and/or actively participated in the submission of its ANDA. On information and belief, Qilu will work in privity and/or concert with Qilu Healthcare, Inc., and/or other related entities towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including the 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg lenalidomide capsules that are the subject of Qilu's ANDA ("Qilu's Proposed Products"), throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

19. On information and belief, Qilu intends to benefit directly if its ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Qilu's ANDA.

20. Venue is proper in this Judicial District for Qilu pursuant to 28 U.S.C. §§ 1391 and/or 1400(b), including, for example, because Qilu is a company organized and existing under the laws of China and may be sued in any judicial district.

Acts Giving Rise To This Suit

21. Pursuant to Section 505 of the FFDCA, Qilu submitted its ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Qilu's Proposed Products before the patents-in-suit expire.

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