IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

AMGEN INC. and AMGEN MANUFACTURING LIMITED, Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendant.	Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Amgen Inc. and Amgen Manufacturing Ltd. (together, "Amgen") for its Complaint against Defendants Apotex Inc. and Apotex Corp. (together, "Apotex") allege as follows:

THE PARTIES

1. Amgen Inc. is a corporation existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen Inc. discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry.

2. Amgen Manufacturing Limited ("AML") is a corporation existing under the laws of Bermuda with its principal place of business in Juncos, Puerto Rico. AML manufactures and sells biologic medicines for treating particular diseases in humans.

3. Apotex Inc. is a corporation existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. Upon information and belief, acting in concert with Defendant Apotex Corp., Apotex Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and

sold throughout the United States and in the State of Florida. *See Amgen Inc. & Amgen Mfg. Ltd. v. Apotex Inc. & Apotex Corp.*, No. 0:15-cv-61631-JIC (consolidated with No. 0:15-cv-62081-JIC), D.E. 47 at 2, 5 (S.D. Fla. Oct. 23, 2015).

4. Apotex Corp. is a corporation existing under the laws of Delaware, with its principle place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, acting in concert with Defendant Apotex Inc., Apotex Corp. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold throughout the United States and in the State of Florida. Upon information and belief, Apotex Corp. is also the United States agent for Apotex Inc. for purposes including, but not limited to, filing regulatory submissions to and corresponding with the U.S. Food and Drug Administration ("FDA"). *See* No. 0:15-cv-61631-JIC, D.E. 47 at 2 (S.D. Fla. Oct. 23, 2015).

5. Upon information and belief, Apotex Corp. is a wholly owned affiliate of Apotex Inc. Upon information and belief, Apotex Corp. acts at the direction of, under the control of, and for the direct benefit of Apotex Inc. and is controlled and/or dominated by Apotex Inc.

NATURE OF THE ACTION

6. This is an action for patent infringement involving United States Patent No. 9,856,287 ("the '287 Patent"), attached hereto as Exhibit 1, arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. § 271(e)(2)(C)(i), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act of 2009 ("the BPCIA"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (amending, *inter alia*, 35 U.S.C. § 271 and 42 U.S.C. § 262).

BACKGROUND

A. Amgen's Innovative NEUPOGEN® and NEULASTA® Products

7. Amgen is one of the world's leading biopharmaceutical companies and is dedicated to using discoveries in human biology to invent, develop, manufacture, and sell new therapeutic products for the benefit of patients suffering from serious illnesses. Developing a new therapeutic product from scratch is extremely expensive: studies estimate the cost of obtaining FDA approval of a new biologic product at more than $2.5 billion. *See* DiMasi J.A. *et al*., Innovation in the pharmaceutical industry: New estimates of R&D costs, 47 J. Health Econ. 20, 25-26 (2016), attached hereto as Exhibit 2. Toward that end, Amgen has invested billions of dollars into its research and development efforts.

8. In 1991, after conducting extensive clinical trials and submitting the results of those trials to FDA to prove that NEUPOGEN® is safe, pure, and potent, Amgen first received FDA approval for NEUPOGEN® to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever. The FDA later approved several additional indications for the therapeutic use of NEUPOGEN®, including the treatment of patients with severe chronic neutropenia, patients with acute myeloid leukemia receiving induction or consolidation chemotherapy, patients receiving bone marrow transplant, and patients undergoing peripheral blood progenitor cell collection and therapy.

9. Neutropenia is a deficiency in neutrophils, a condition which makes the individual highly susceptible to infection. Neutrophils are the most abundant type of white blood cell and form a vital part of the human immune system. Neutropenia can result from a number of causes; it is a common side effect of chemotherapeutic drugs used to treat certain forms of cancer.

10. The active ingredient in NEUPOGEN® is filgrastim, a recombinantly expressed, 175-amino acid form of a protein known as human granulocyte-colony stimulating factor or "G-CSF." NEUPOGEN® is also known as recombinant methionyl human granulocyte-colony stimulating factor. NEUPOGEN® works by binding to specific receptors on the surface of certain types of cells to stimulate the production of neutrophils. NEUPOGEN® thus counteracts neutropenia.

11. In 2002, Amgen received FDA approval for NEULASTA®. As it did for NEUPOGEN®, Amgen conducted extensive clinical trials and submitted the results of those trials to FDA to prove that NEULASTA® is safe, pure, and potent. NEULASTA® is also indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever.

12. The active ingredient in NEULASTA® is pegfilgrastim, a form of the G-CSF protein conjugated to a 20 kD monomethoxypolyethylene glycol ("m-PEG" or simply, "PEG"). NEULASTA® counteracts neutropenia by the same mechanism of action as NEUPOGEN®. NEULASTA®, by virtue of the conjugated PEG moiety, has a longer serum half-life than NEUPOGEN® and therefore requires less frequent administration compared to NEUPOGEN®.

13. NEUPOGEN® and NEULASTA® represent major advances in cancer treatment by protecting chemotherapy patients from the harmful effects of neutropenia and by thus facilitating more effective chemotherapy regimes.

B. The BPCIA and the Prior Actions

14. Under the traditional pathway for FDA approval, an innovator must demonstrate that its biologic drug is safe, pure, and potent through clinical trials. *See* 42 U.S.C. § 262(a).

The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. 42 U.S.C. § 262(k). The abbreviated pathway (also known as "the subsection (k) pathway") allows a biosimilar applicant (or "subsection (k) applicant") to rely on the prior licensure and approval status of an innovative biological product (a "reference product") that the biosimilar purports to copy. Under the subsection (k) pathway, the biosimilar applicant may rely on its reference product's data rather than demonstrating that the biosimilar product is safe, pure, and potent, as the reference product sponsor ("RPS") did when it filed its Biologics License Application ("BLA") under the traditional 42 U.S.C. § 262(a) pathway.

15. The BPCIA provides for the subsection (k) applicant and the RPS to engage in a series of information exchanges and good-faith negotiations between parties prior to the filing of a patent infringement lawsuit, as set forth in 42 U.S.C. § 262(*l*)(2)-(*l*)(5). This process culminates in an "immediate patent infringement action" pursuant to 42 U.S.C. § 262(*l*)(6).

16. Additionally, under 42 U.S.C. § 262(*l*)(7), if a patent is issued to, or exclusively licensed by, the RPS after the date that the RPS provided the list to the subsection (k) applicant under 42 U.S.C. § 262(*l*)(3)(A), and the RPS reasonably believes that, due to the issuance of such a patent, a claim of patent infringement could reasonably be asserted by the RPS if a person not licensed by the RPS engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application, not later than 30 days after such issuance or licensing, the RPS shall provide to the subsection (k) applicant a supplement to the list provided by the RPS under 42 U.S.C. § 262(*l*)(3)(A) that includes such patent. Not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the RPS in accordance with 42 U.S.C. § 262(*l*)(3)(B), and such patent shall be subject to 42 U.S.C. § 262(*l*)(8).

DOCKET ALARM

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