IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 2:09-cv-05675
	)	
AMGEN INC.,	)	Hon. Stewart Dalzell, U.S.D.J.
	)	
Defendant.	)	
	)	

AMENDED COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT INVALIDITY

Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva"), by and through their undersigned counsel, for their claims for relief against Defendant Amgen Inc. ("Amgen") allege as follows:

NATURE OF THE ACTION

1. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and the United States Patent Law, 35 U.S.C. § 100 *et seq.*

2. Teva brings this action seeking at least the following declarations: (i) each of the claims of U.S. Patent No. 5,580,755 ("the '755 patent") is invalid and (ii) each of the claims of U.S. Patent No. 5,582,823 ("the '823 patent") is invalid. Copies of the '755 and '823 patents are attached hereto as Exhibits 1 and 2, respectively.

THE PARTIES

3. Plaintiff Teva is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

4. Defendant Amgen is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at One Amgen Center Drive, Thousand Oaks, California.

JURISDICTION AND VENUE

5. This action arises under the Declaratory Judgments Act, 28 U.S.C. §§ 2201 and 2202 and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

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

7. This Court has personal jurisdiction over Defendant Amgen because, *inter alia*, Amgen has continuous and systematic contacts with the State of Pennsylvania including conducting substantial and regular business therein through the marketing, distribution and sales of its pharmaceutical products, including on information and belief the products of Amgen that are at issue in this litigation.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) because Defendant Amgen is subject to personal jurisdiction in this Judicial District.

BACKGROUND

9. On February 20, 1991, the U.S. Food & Drug Administration ("FDA") approved Amgen's Biologics License Application ("BLA") No. 103353/0 for subcutaneous injections of a recombinant methionyl human granulocyte colony-stimulating factor ("r-met-hG-CSF" or "Filgrastim") product. Amgen markets its Filgrastim product in the U.S. as a parenteral solution under the trademark Neupogen®.

10. Neupogen® is approved for reducing the duration of fever and the time to neutrophil recovery following induction or consolidation chemotherapy treatment of adults with

acute myeloid leukemia; decreasing the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies that are receiving myelosuppressive anti-cancer drugs; reducing the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies that are treated with myeloablative chemotherapy followed by marrow transplantation; mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; and chronic administration to reduce the incidence and duration of sequelae of neutropenia in symptomatic patients with congenital, cyclic or idiopathic neutropenia.

11. Amgen's Physician Prescribing Information for Neupogen® asserts that Neupogen® and its use are covered by U.S. Patents Nos. 4,810,643 ("the '643 patent"), 4,999,291 ("the '291 patent") and the '755 and '823 patents. The terms of the '643 and '291 patents are expired.

12. The U.S. Patent and Trademark Office ("PTO") issued the '755 patent on December 3, 1996. The '755 patent is titled "Human Pluripotent Granulocyte Colony-Stimulating Factor" and identifies Lawrence M. Souza as the inventor and Amgen as the assignee. The '755 patent contains two claims that are directed to "[a]n isolated human pluripotent granulocyte colony stimulating factor (hpG-CSF) polypeptide". According to the current records of the PTO, the term of the '755 patent is presently set to expire on December 3, 2013.

13. The PTO issued the '823 patent on December 10, 1996. The '823 patent is titled "Methods Of Treating Bacterial Inflammation And Granulocytopoiesis By Administering Human Pluripotent Granulocyte Colony-Stimulating Factor" and identifies Lawrence M. Souza as the inventor and Amgen as the assignee. The '823 patent contains five claims that are directed

to "[a] method of treating a mammal for bacterial inflammation [using] hpG-CSF polypeptide" and "[a] method for providing granulocytopoietic therapy to a mammal [using] hpG-CSF polypeptide". According to the current records of the PTO, the term of the '823 patent is presently set to expire on December 10, 2013.

14. Teva developed its Filgrastim-containing pharmaceutical product for worldwide distribution for the treatment of neutropenia. To date, Teva has invested in excess of two-million dollars to develop, secure regulatory approval for, and market its Filgrastim product. In support of its desire to secure regulatory approval, Teva has led an extensive phase III clinical program, which involved prescribing the Filgrastim product to more than 500 patients for various cancer indications. This clinical program followed a series of phase I studies in which nearly 200 patients received doses of the Filgrastim product.

15. On September 15, 2008, the European Commission's Directorate General for Enterprise and Industry, granted Teva authorization to market and sell its Filgrastim product for the treatment of neutropenia.

16. In November of 2008 Teva began selling its Filgrastim product in Europe under the trademark TevaGrastim®.

17. On November 30, 2009, Teva submitted BLA No. 125,294 to the FDA seeking approval to market its Filgrastim product in the U.S., under the proposed brand name NEUTROVAL™, for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes) and for the reduction in the duration of neutropenia in patients that undergo myeloablative therapy followed by bone

marrow transplantation and, therefore, are considered to be at increased risk of prolonged, severe neutropenia.

18. Teva's BLA was substantially complete as submitted on November 30, 2009, and the FDA formally accepted the filing for review. Teva's filing constitutes its representation to the FDA that it completed sufficient clinical testing and analysis of its Filgrastim product to obtain FDA approval to distribute and sell such product. Based on Prescription Drug User Fee Act guidelines, Teva reasonably believes that approval of Teva's BLA will come well in advance of the expiry of the '755 and '823 patents. Teva possesses a present intent to sell its Filgrastim product upon receipt of such approval.

19. Amgen has exhibited a pattern of consistently asserting its patents to attempt to prevent competing products from entering the market. Gordon Binder, the CEO of Amgen from 1988 to 2000, explained Amgen's belief that "[i]f you don't defend your patents, it's the same as having no patents . . . . Nobody else is going to defend your patents. . . . A company that doesn't defend its patents is on the way to going out of business." *Los Angeles Times*, November 27, 1990, "Patent Ruling Will Be Critical For Drug Maker". Kevin Sharer, the current CEO of Amgen, more recently vowed that Amgen will assert its patents covering its anemia drugs Aranesp® and Epogen® in court or at the International Trade Commission against the launch by a competitor in the U.S. by stating that "[w]ill defend our franchise – we will not cede anything." *Wall Street Journal Online*, January 26, 2007.

20. Consistent with this stated policy, Amgen has exhibited a pattern of asserting its patents and seeking declaratory judgments in situations where others have sought regulatory approval to launch products in competition with Amgen. *See, e.g., Amgen, Inc.* v. *Hoechst Marion Roussel, Inc.*, 579 F. Supp. 2d 199 (D. Mass. 2008); *Amgen, Inc. v. Hoffman-La Roche*

Ltd., 456 F. Supp. 2d 267 (D. Mass. 2006); *Amgen, Inc. v. Ariad Pharm., Inc*., 513 F. Supp. 2d 34 (D. Del. 2007).

21. Once Teva's BLA is approved by the FDA, Teva intends to sell its Filgrastim product in the United States without a license from Amgen and prior to the expiration of Amgen's '755 and '823 patents. It is expected that Teva's product will compete with Amgen's Neupogen®.

22. Amgen's historical actions, combined with the steps taken by Teva, cause Teva reasonable apprehension that Amgen will imminently assert as a result of Teva's filing of Teva's BLA, among other things, that Teva infringes one or more claims of the '755 and '823 patents as a result of Teva's activities related to its Filgrastim product. Teva thus asks this Court to declare that the '755 and '823 patents are invalid.

FIRST CLAIM FOR RELIEF

(Declaratory Judgment of Invalidity of Each Claim of the '755 and '823 Patents)

23. Teva repeats each of the allegations made in paragraphs 1-22 herein.

24. One or more of the claims of the '755 and '823 patents are invalid for failure to comply with one or more of the requisite statutory and/or decisional requirements and/or conditions for patentability under Title 35 of the United States Code, including without limitation sections 101, 102, 103, 112 and 116 and/or for double patenting.

25. A judicial declaration of the invalidity of the claims of the '755 and '823 patent is appropriate and necessary.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests that the Court enter judgment in its favor and against Amgen as follows:

A. Declaring invalid each of the claims of the ’755 and ’823 patents;

B. Enjoining and restraining Amgen, its agents, servants, employees, attorneys and those persons in active concert, participation and privity with Amgen who receive actual notice of the invalidation of the ’755 or ’823 patents by personal service or otherwise, from charging or asserting against Teva, its agents, vendees, suppliers, customers or any others in privity with it, that any of them are infringing any claim of the ’823 or ’755 patent;

C. Adjudging this to be an exceptional case under 35 U.S.C. § 285 and awarding to Teva its attorney fees, costs, and expenses; and

D. Granting to Teva such other and further relief as this Court may deem just and proper.

Respectfully submitted,

Date: May 4, 2009

By: s/ Joseph Wolfson JW383

Joseph Wolfson, Esquire
Attorney ID No. 44431
STEVENS & LEE, P.C.
620 Freedom Business Center
Suite 200
PO Box 62330
King of Prussia, PA 19406
Tel: (610) 205-6019
Fax: (610) 988-0808

Of Counsel:

David M. Hashmall, Esquire
Ira Jay Levy, Esquire
John P. Hanish, Esquire
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405
Tel: (212) 813-8800
Fax: (212) 355-3333

Counsel For Plaintiff
Teva Pharmaceuticals USA, Inc.

CERTIFICATE OF SERVICE

I, JOSEPH WOLFSON, ESQUIRE, certify that on this date the foregoing Amended Complaint for Declaratory Judgment of Patent Invalidity was filed and made available for viewing via the Court's ECF system. I further certify that a true and correct copy was served upon the following counsel of record, via hand delivery:

David J. Wolfsohn, Esquire
Aleksander J. Goranin, Esquire
Woodcock Washburn, LLP
Cira Centre, 12th Floor
2929 Arch Street
Philadelphia, PA 19104

s/ Joseph Wolfson JW383

Date: May 4, 2010