EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff,	)	
v.	)	05-CV-12237-WGY
F. HOFFMANN-LAROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN LAROCHE INC., a New Jersey Corporation, Defendants.	)	Hon. William G. Young

COMPLAINT IN INTERVENTION

Intervenor-plaintiff Ortho Biotech Products, L.P., for its Complaint in Intervention, alleges as follows:

The Parties

1. Intervenor-plaintiff Ortho Biotech Products, L.P. ("OBP") is a New Jersey limited partnership with its principal pace of business in Raritan, New Jersey. OBP develops, manufactures and markets biotechnology-derived products. OBP is a wholly-owned subsidiary of Johnson & Johnson.

2. Upon information and belief, plaintiff Amgen Inc. ("Amgen") is a corporation existing under the laws of the State of Delaware with its principal place of business in Thousand Oaks, California.

3. Upon information and belief, defendant F. Hoffmann-LaRoche Ltd. ("HLR Ltd.") is a foreign corporation existing under the laws of Switzerland with its principal place of business in Basel, Switzerland.

4. Upon information and belief, defendant Roche Diagnostics GmbH ("Roche GmbH") is a foreign corporation existing under the laws of Germany with its principal places of business in Penzberg, Germany and Mannheim, Germany.

5. Upon information and belief, Defendant Hoffmann LaRoche Inc. ("HLR Inc.") is a corporation existing under the laws of the State of New Jersey with its principal place of business in Nutley, New Jersey.

6. Upon information and belief, HLR Ltd., Roche GmbH and HLR Inc., transact business within the District of Massachusetts and/or are otherwise subject to the jurisdiction of this Court.

7. Defendants HLR Ltd., Roche GmbH, and HLR Inc. are hereinafter referred to individually and collectively as "Roche."

Jurisdiction and Venue

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1338(a), 2201 and 2202, in that the claims arise under the patent laws of the United States, Title 35 of the United States Code.

9. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), (c), and (d), and 1400(b).

Background

10. On September 30, 1985, Amgen and Ortho Pharmaceutical Corp. ("OPC") executed a Product License Agreement ("PLA") concerning the manufacture, use and sale in the United States of recombinant human erythropoietin ("EPO"), a biotechnology-derived copy of a natural protein that treats anemia by stimulating the production of red blood cells. By virtue of a series of internal corporate transfers, OPC has assigned to OBP its rights under the PLA to sell EPO. OPC and OBP are hereinafter referred to individually and collectively as "Ortho."

11. The PLA grants to Ortho an exclusive license under Amgen's EPO-related patents to market and sell EPO in the United States for all human therapeutic uses or "indications" except two: (a) diagnostics and (b) use in patients undergoing kidney dialysis.

12. Amgen currently sells EPO in the United States for use in dialysis patients under the brand name Epogen®. Ortho sells EPO in the United States for use in non-dialysis patients under the brand name Procrit®.

Amgen's Complaint

13. On November 8, 2005, Amgen filed its complaint in this Court against Roche seeking, *inter alia*, a declaratory judgment that Roche is currently infringing, or will soon be infringing, six of Amgen's patents relating to EPO by importing, using, offering for sale, and/or selling in the United States products that contain EPO. Three such patents specifically concern EPO itself (as opposed to processes or products used to manufacture EPO), namely:

a. U.S. Patent No. 5,547,933 (the "'933 patent"), issued on August 20, 1996, claims non-naturally occurring human EPO glycoproteins having specified biological activities that are produced by the process of growing mammalian host cells transformed or transfected with an isolated DNA sequence encoding human EPO, pharmaceutical compositions containing said human EPO glycoproteins, and methods for using such pharmaceutical composition. A true and correct copy of the '933 patent is attached hereto as Exhibit 1.

b. U.S. Patent No. 5,621,080 (the "'080 patent"), issued on April 15, 1997, claims non-naturally occurring EPO glycoproteins having certain *in vivo* biological activity and a specified amino acid sequence, and pharmaceutical compositions containing such EPO glycoproteins. A true and correct copy of the '080 patent is attached hereto as Exhibit 2.

c. U.S. Patent No. 5,955,422 (the "'422 patent"), issued on September 21, 1999, claims pharmaceutical compositions comprising a therapeutically effective amount of human

EPO purified from mammalian cells grown in culture. A true and correct copy of the '422 patent is attached hereto as Exhibit 3.

Roche's Infringing Product

14. Upon information and belief, Roche is currently importing into the United States a pharmaceutical composition containing a recombinant human EPO product that Roche calls "Ro50-3821." Roche also refers to this product "R744" and "Continuous Erythropoiesis Receptor Activator" or "CERA."

15. Upon information and belief, Roche's product contains a glycosylated EPO to which Roche has attached a polyethylene glyclol ("PEG") polymer. Roche's product is hereinafter referred to as "PEG-EPO."

16. Upon information and belief, PEG-EPO contains EPO as claimed in the '933, '080 and '422 patents and licensed exclusively to Ortho for sale in Ortho's exclusive field of use (*i.e.*, all human uses except dialysis and diagnostics).

17. The addition of PEG to glycosylated EPO does not materially change the glycosylated EPO contained within PEG-EPO.

18. But for the glycosylated EPO contained within PEG-EPO, PEG-EPO would not stimulate the production of red blood cells when administered to human patients.

FIRST CAUSE OF ACTION
(Declaratory Judgment Of Infringement)

19. Ortho re-alleges and incorporates by reference the allegations in paragraphs 1 through 18 above.

20. Under the terms of the PLA, Ortho holds an exclusive license under, *inter alia*, the '422, '933 and '080 patents to sell EPO in the United States in a broad field of use: all human uses except dialysis and diagnostics.

21. Upon information and belief, Roche's sale and/or offer to sell PEG-EPO in the United States infringes or will infringe, either literally or under the doctrine of equivalents, one or more claims of the '933, '080, and '422 patents. Upon information and belief, such infringement is occurring, or will occur, within Ortho's exclusive field of use.

22. Roche has announced that it intends shortly to file an application with the United States Food and Drug Administration ("FDA") to sell pharmaceutical compositions containing PEG-EPO, and that it expects to obtain regulatory approval to market and sell PEG-EPO, including in Ortho's exclusive field of use, within the next 12-14 months.

23. For example, on February 1, 2006, Roche made the following announcement in an "Investor Update" available on its website (http://www.roche.com/iruar05e.pdf):

> Clinical development of CERA, the first continuous erythropoietin receptor activator for the treatment of anemia, is progressing on track. **The phase III renal programme for this product includes six trials involving over 2,400 patients with chronic kidney disease (both on dialysis and not on dialysis)**. The first four phase III trials in dialysis patients were successfully completed at the end of 2005. CERA is the only anti-anemia drug ever studied using long dosing intervals (once every four weeks) in all patients for its initial filing. **Roche plans to file marketing applications worldwide for CERA in renal anemia in 2006**. (emphasis added)

24. Similarly, on November 12, 2005, Roche issued a press release that reported on a clinical study finding that Roche's PEG-EPO product "was able to control anemia in patients with chronic kidney disease not on dialysis within a narrow target range . . . ."

25. Ortho is informed and believes that, in anticipation of FDA regulatory approval, Roche has been and is making meaningful preparations to market and sell PEG-EPO in the United States, including:

a. Completing its collection of data from its PEG-EPO phase III clinical trials to file its Biologics License Application with the FDA;

b. Preparing to file or filing an application with FDA for regulatory approval to market and sell PEG-EPO in the United States;

c. Hiring key management, support, and sales personnel to market and sell PEG-EPO upon receipt of regulatory approval to do so in the United States;

d. Retaining outside consultants and vendors to assist in its marketing and sale of PEG-EPO in the United States;

e. Contacting potential customers to solicit interest in purchasing PEG-EPO from Roche upon regulatory approval in the United States; and

f. Completing construction and commencing operations of a new facility in Penzberg, Germany to manufacture the EPO in PEG-EPO for export to the United States, at a reported cost of 182 million Euros.

26. Roche's sale and/or offer to sell PEG-EPO in the United States, including in Ortho's exclusively licensed field of use, will infringe, either literally or under the doctrine of equivalents, one or more claims of the '933, '080, and '422 patents.

27. Upon information and belief, Amgen has taken action that demonstrates its intent to enforce its patents against Roche's imminent marketing and sale of PEG-EPO in the United States, including in Ortho's exclusive field of use, and Roche has demonstrated a refusal to desist from continued and impending infringement of the '933, '080, and '422 patents. As such, a definite and concrete controversy now exists between Ortho and Roche regarding Roche's continued and impending infringement of one or more claims of the '933, '080, and '422 patents by selling, and/or offering for sale, PEG-EPO within Ortho's exclusive field of use.

28. Ortho seeks a judicial determination and declaration that Roche is currently infringing or, upon FDA approval and commercial introduction, will infringe one or more claims of

the ‘933, ‘080, and/or ‘422 patents by selling and/or offering for sale PEG-EPO within Ortho’s exclusive field of use. Such a determination and declaration is necessary and appropriate at this time in order that the parties may ascertain their respective rights and duties.

PRAYER FOR RELIEF

WHEREFORE, Ortho requests that the Court enter judgment in its favor and against Roche as follows:

a. Declaring that the ‘422, ‘933 and/or ‘080 patents are currently infringed or will be infringed by Roche’s sale and/or offer for sale in the United States of products containing EPO, including PEG-EPO, within Ortho’s exclusively licensed field of use;

b. Enjoining Roche from selling or offering to sell in the United States products containing recombinant human EPO, including PEG-EPO, within Ortho’s exclusively licensed field of use;

c. Awarding Ortho its costs and expenses of suit;

d. Awarding Ortho such damages as it may incur on account of Roche’s infringing sales of PEG-EPO in Ortho’s exclusive field of use, in an amount to be determined at trial; and

e. Granting Ortho such other and further relief as the Court deems just and proper.

Dated: _____

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