UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC., Defendants.	)	Civil Action No.: 05-CV-12237 WGY **DEFENDANTS' ANSWER AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT** **DEMAND FOR JURY TRIAL**

In response to the Complaint For Declaratory Judgment Of Infringement ("Complaint") filed in this action by Amgen, Inc. ("Amgen"), F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche"), by their attorneys, herein answer the allegations of the Complaint and assert counterclaims against Amgen. This pleading contains: Roche's answer and affirmative defenses to the claims and allegations of Amgen's Complaint (Part I); and Roche's counterclaims against Amgen (Part II).

PART I: ROCHE'S ANSWER AND AFFIRMATIVE DEFENSES

In response to the Complaint of Amgen, defendants Roche, by their attorneys, state as follows:

1. Roche admits that Amgen is a corporation existing under the laws of the State of Delaware with its principal place of business in Thousand Oaks, California. Roche lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 1 of the Complaint.

2. Admitted.

3. Admitted.

4. Admitted.

5. Roche denies the allegations contained in paragraph 5 of the Complaint.

6. The statement in paragraph 6 of the Complaint is neither an averment nor allegation to which a response is required.

7. Admitted.

8. Roche denies that venue and personal jurisdiction are proper in this Court.

9. Roche denies the allegations contained in paragraph 9 of the Complaint.

10. The statements in paragraph 10 of the Complaint are neither averments nor allegations to which a response is required, and Roche otherwise denies these allegations.

11. Roche lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in the statements of paragraph 11 of the Complaint, and denies those allegations.

12. Roche denies the allegations contained in paragraph 12 of the Complaint.

13. Roche denies the allegations contained in paragraph 13 of the Complaint.

14. Roche denies the allegations contained in paragraph 14 of the Complaint, except Roche admits that U.S. Patents Nos. 5,441,868 ("the '868 patent"), 5,547,933 ("the '933 patent"), 5,618,698 ("the '698 patent"), 5,621,080 ("the '080 patent"), 5,756,349 ("the '349 patent") and 5,955,422 ("the '422 patent") (collectively "the patents-in-suit") were issued on the dates alleged.

15. The statements in paragraph 15 of the Complaint are neither averments nor allegations to which a response is required, and Roche otherwise denies these allegations.

16. The statements in paragraph 16 of the Complaint are neither averments nor allegations to which a response is required, except Roche admits that this Court has previously issued certain rulings in other litigations concerning certain of the patents-in-suit, and

Roche refers Amgen to the actual decisions and orders of this Court, and any appellate court for the holdings therein, and Roche otherwise denies these allegations.

17. Roche lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in the statements of paragraph 17 of the Complaint, and denies those allegations.

18. Roche denies the allegations contained in paragraph 18 of the Complaint.

19. Roche denies the allegations contained in paragraph 19 of the Complaint.

20. Roche denies the allegations contained in paragraph 20 of the Complaint.

21. Roche denies the allegations contained in paragraph 21 of the Complaint.

22. Roche denies the allegations contained in paragraph 22 of the Complaint.

23. Roche denies the allegations contained in paragraph 23 of the Complaint.

24. Roche denies the allegations contained in paragraph 24 of the Complaint.

25. Roche repeats and reasserts its responses to and denials of the allegations contained in paragraphs 1- 24 of the Complaint.

26. Roche denies the allegations contained in paragraph 26 of the Complaint, and states that CERA (short for Continuous Erythropoiesis Receptor Activator) was created by Roche and is a unique molecule and has been recognized by the FDA as a new chemical entity containing "no active moiety that [previously] has been approved by the FDA." *See* 21 C.F.R. § 314.108 (April 1, 2005); *see also* 21 C.F.R. § 314.50.

27. Roche denies the allegations contained in paragraph 27 of the Complaint.

28. Roche denies the allegations contained in paragraph 28 of the Complaint.

29. Roche denies the allegations contained in paragraph 29 of the Complaint.

30. Roche denies the allegations contained in paragraph 30 of the Complaint.

31. The statement of paragraph 31 of the Complaint is neither an averment nor allegation to which a response is required, and Roche otherwise denies these allegations.

AFFIRMATIVE DEFENSES

FIRST DEFENSE - FAILURE TO STATE A CLAIM

32. The allegations of the Complaint fail to state a claim upon which relief can be granted and should be dismissed under Fed. R. Civ. P. 12(b)(6).

SECOND DEFENSE - PATENT MISUSE

33. The patents-in-suit are not enforceable, in whole or in part, due to the wrongful and improper conduct by Amgen which constitutes patent misuse.

THIRD DEFENSE - NON-INFRINGEMENT

34. Roche has not infringed and is not infringing any of the claims of the '868, '933, '698, '080, '349 and '422 patents, either directly or indirectly, or literally or under the doctrine of equivalents or due to the reverse doctrine of equivalents.

FOURTH DEFENSE - SAFE HARBOR

35. Roche's allegedly infringing activities do not constitute infringement as a matter of law under 35 U.S.C. § 271(e)(1).

FIFTH DEFENSE - INVALIDITY

36. The claims of the '868, '933, '698, '080, '349 and '422 patents are invalid because they fail to satisfy the conditions for patentability, including as specified in 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or 282.

SIXTH DEFENSE - DOUBLE PATENTING

37. The claims of the '868, '933, '698, '080, '349 and '422 patents are invalid for double patenting over claims of Amgen's earlier issued and now expired U.S. Patent No. 4,703,008 ("the '008 patent").

SEVENTH DEFENSE – INEQUITABLE CONDUCT BEFORE THE PATENT OFFICE

38. The patents-in-suit are unenforceable because individuals substantively involved with the filing and prosecution of these patents, acting as agents or with the knowledge of plaintiff Amgen, misrepresented and/or withheld material information from the United States Patent and Trademark Office ("PTO") with the intent to deceive the PTO for purposes of overcoming patentability issues raised by the PTO.

39. The six patents-in-suit all share the same specification and all claim priority to the parent application of the '008 patent. These patents demonstrate that Amgen essentially possessed only a single invention with minor obvious variations. Through repeated instances of inequitable conduct, Amgen, acting through those substantively involved in the prosecution of these patents, intentionally and willfully misled the PTO and withheld material information, which if known by the PTO would have prevented the patents-in-suit from being issued.

40. Amgen's fraud on the PTO was motivated by Amgen's recognition that expiration of the '008 patent would endanger its long-standing dominance over the sale of Erythropoietin Stimulating Agent ("ESA") products, including ESAs used for the treatment of End Stage Renal Disease and Chronic Kidney Disease as described below, and that Amgen could effectively (albeit unlawfully) seek to extend that dominance by committing inequitable conduct that garnered improperly issued further patents.

41. Among the acts of inequitable conduct that Amgen, and those substantively involved in the prosecution of the patents-in-suit acting on its behalf, made misleading and erroneous statements to the PTO regarding the differences between recombinant

erythropoietin ("r-EPO") and urinary erythropoietin ("u-EPO"), while in other arenas Amgen employees made statements that were inconsistent with the statements made to the PTO.

42. Amgen and its employees, including the named inventor of the patents-in-suit, also made numerous statements that directly contradicted statements made to the PTO during the prosecution of the patents-in-suit relating to r-EPO.

43. The acts of inequitable conduct include that material references and information were not listed as a reference in Amgen's Information Disclosure Statement ("IDS") filings nor submitted to, nor considered by, the Examiner in connection with the prosecution of the patents-in-suit.

44. In addition, Amgen and its representatives, in the course of foreign patent proceedings and before the FDA, relied on statements and information regarding the molecular weights and carbohydrate compositions of r-EPO and u-EPO FDA that were inconsistent, and refuted the positions Amgen took during prosecution of its patents before the PTO, and in the *Fritsch et al. v. Lin* patent interference No. 102,334. For example, Amgen submitted arguments and supporting declarations during European opposition proceedings involving EP 411 678 and EP 209 539 indicating that r-EPO had the same molecular weight and carbohydrate composition as u-EPO. In contrast, to argue that its r-EPO was patentable, Amgen represented to the PTO that r-EPO differed from u-EPO in molecular weight and carbohydrate composition.

45. Amgen, and those acting on its behalf who were substantively involved in the prosecution of the patents-in-suit, misled the PTO through misstatements and omissions of material information with the intent to deceive and mislead the PTO to obtain the patents-in-suit, thereby tainting all patents sharing the common specification. Accordingly, the patents-in-suit should be held unenforceable for inequitable conduct before the PTO.

EIGHTH DEFENSE - UNCLEAN HANDS

46. The asserted patents are unenforceable due to Amgen's unclean hands.

NINTH DEFENSE - PUBLIC HEALTH AND WELFARE

47. Amgen's request for an injunction precluding Roche from importing into, making, using, or selling CERA in the U.S. is contrary to the public health and welfare.

TENTH DEFENSE - AMGEN IS ESTOPPED FROM SEEKING DAMAGES

48. Amgen has taken the position that it is not seeking damages against Roche related to the accused product in this action.

49. Amgen contends that it is only seeking declaratory and injunctive relief against Roche's alleged acts of infringement.

50. Amgen has alleged that there are current acts of infringement in the United States in connection with the accused product.

51. Based on its decision to forgo damages, Amgen has argued to the Court that Roche is not entitled to a jury trial on Amgen's claims.

52. At the conclusion of the litigation, in the event that Amgen is successful in its claims against Roche and the asserted claims are found to be infringed, valid and enforceable, the Court must undertake an analysis mandated by the United States Supreme Court's decision in *eBay, Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006), to determine if a permanent injunction would be appropriate.

53. Based on Amgen's decision to waive any damages, compensatory or otherwise, as a tactic to deprive Roche of its constitutional right to a jury trial on Amgen's claims (even though Roche contends that they are entitled to a trial by jury), Amgen is estopped and precluded from seeking, asserting or maintaining a claim for damages, compensatory or otherwise, for any damages, whether past, current or future, in the event that Amgen is

successful on its claims and the Court determines that a permanent injunction is not warranted in this case.

ELEVENTH DEFENSE - FILE WRAPPER ESTOPPEL

54. Amgen's claims for infringement of the '868, '933, '698, '080, '349 and '422 patents are barred by file wrapper estoppel.

TWELFTH DEFENSE - EQUITABLE ESTOPPEL

55. Amgen's claims for infringement of the '868, '933, '698, '080, '349 and '422 patents are barred by equitable estoppel.

THIRTEENTH DEFENSE - PROSECUTION LACHES ESTOPPEL

56. Amgen's claims for infringement of the '868, '933, '698, '080, '349 and '422 patents are barred by prosecution laches and estoppel.

PART II: ROCHE'S COUNTERCLAIMS

F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche"), as Counterclaim-Plaintiffs, by their attorneys, allege the following counterclaims on information and belief:

SUMMARY OF COUNTERCLAIMS

1. Roche counterclaims against Amgen under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, for violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, by reason of Amgen's actions to unreasonably restrain trade in, and monopolize, and/or attempt to monopolize a number of relevant markets, including markets for the sale of ESA drugs sold for particular indications. Roche also counterclaims against Amgen for a declaratory judgment of patent invalidity, non-infringement, and unenforceability pursuant to 28 U.S.C. §§ 2201 and 2202.

2. Amgen's patent case against Roche is part of a broad, anticompetitive scheme by Amgen to unlawfully maintain or secure monopoly power in violation of the antitrust laws. Amgen possesses monopoly or substantial market power over the sales of ESA drugs sold for particular indications. Amgen's Epogen® and Aranesp® products have been, and today remain, the only such drugs available for patients suffering from End Stage Renal Disease who are on dialysis ("ESRD"). Similarly, Amgen's Aranesp® is the leading ESA medicine administered to patients with non-dialysis Chronic Kidney Disease ("CKD"). Ortho Biotech Products, L.P. ("Ortho") offers the only other ESA drug available to CKD patients, Procrit®, which Ortho sells only because of a license from Amgen and that has the same active ingredient as Epogen®.

3. Roche's CERA drug (to be marketed under the trade name MIRCERA®) presents the first credible challenge to Amgen's dominance over ESAs sold for ESRD and CKD, the two relevant markets here. Recognizing that its patents are not likely to block Roche's eventual entry with CERA, Amgen has embarked on a course of anticompetitive conduct designed to hinder Roche's ability to enter or compete effectively in these markets. Among other conduct, Amgen has: (a) engaged in sham litigation before this Court by, including but not limited to, seeking to enforce patents that were knowingly obtained through willful fraud on the United States Patent and Trademark Office ("PTO"); (b) engaged in sham litigation before the International Trade Commission ("ITC") in a failed effort to hinder CERA's entry; and (c) blocked Roche's access to customers for CERA by (i) recently cementing a long-term exclusive dealing arrangement with the largest single ESA customer, (ii) engaging in other exclusionary contracting practices, and by (iii) threatening customers that purchasing CERA will result in

Amgen's retaliating by raising prices, denying those customers access to Amgen's ESA products or denying those customers critical discounts on those products.

4. Amgen's anticompetitive scheme, if not invalidated by this Court, will hinder or eliminate the competition that Roche's CERA is poised to create, limit the ability of patients and physicians to choose an alternative medicine that would provide benefits to patients not currently available, and saddle consumers, patients and those who pay for their medicines with supracompetitive prices and the American public health system with greater expenses. Accordingly, Roche seeks under the antitrust laws monetary damages, a declaration that Amgen's conduct is unlawful, and other appropriate relief, including attorneys' fees and costs.

THE PARTIES

5. Counterclaim-Plaintiff F. Hoffmann-La Roche Ltd is a foreign corporation existing under the laws of Switzerland with a principal place of business in Basel, Switzerland.

6. Counterclaim-Plaintiff Roche Diagnostics GmbH is a foreign corporation existing under the laws of Germany with principal places of business in Penzberg, Germany and Mannheim, Germany.

7. Counterclaim-Plaintiff Hoffmann-La Roche Inc. is a New Jersey corporation with a principal place of business at 340 Kingsland Street, Nutley, NJ 07110-1199.

8. Roche is a leading healthcare organization that has been active in the discovery, development, manufacture and marketing of novel healthcare solutions for over 100 years. Using innovative technologies, Roche develops medications and other products to prevent, diagnose and treat life-threatening diseases.

9. Counterclaim-Defendant Amgen is a Delaware corporation with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the counterclaims asserted herein under 28 U.S.C. §§ 1331, 1337(a), 1338(a), 1367 and 2201.

11. This Court has personal jurisdiction over Amgen by virtue of its appearance as a plaintiff in this action.

12. Venue is proper in this district under Sections 4 and 12 of the Clayton Act, 15 U.S.C. §§ 15 and 22, as Amgen is subject to personal jurisdiction in this district. Venue is also proper in this district pursuant to the provisions of 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

FACTUAL ALLEGATIONS

I. ERYTHROPOIETIN STIMULATING AGENTS USED IN THE TREATMENT OF ANEMIA

13. Erythropoietin ("EPO") is a naturally occurring hormone found in human blood. EPO is produced in the kidneys and stimulates red blood cell production in the bone marrow.

14. ESAs are drugs that are used to treat anemia patients by promoting the production of red blood cells. Anemia is the condition of having less than the normal number of red blood cells or less than the normal quantity of hemoglobin in the blood, which decreases the oxygen-carrying capacity of the blood.

15. The principal uses of ESAs are in the treatment of anemia associated with ESRD (*i.e.*, dialysis patients), CKD, and cancer (oncology). ESAs are also used for the treatment of anemia associated with HIV, pediatric renal disease, surgery, hepatitis C and stroke.

II. AMGEN'S MONOPOLY OR MARKET POWER IN THE MARKET FOR THE SALE OF ESA DRUGS FOR THE TREATMENT OF ESRD

16. Part of the interstate trade and commerce adversely affected and restrained by the unlawful Amgen acts described herein, and one of the relevant markets in this case, is the sale in the United States of ESAs for the treatment of ESRD ("ESRD ESA").

17. Approximately 400,000 patients have ESRD in the United States. Patients with ESRD receive regular treatments at dialysis centers to filter their blood through hemodialysis machines to remove toxins. The vast majority of ESRD patients have been diagnosed with anemia and require treatment with an ESA to achieve normal hemoglobin levels.

18. No drug other than an ESA is safe and effective for the treatment of anemia in ESRD patients, and no ESA may be marketed for the treatment of anemia in ESRD patients in the United States unless the FDA has approved it for use as a treatment for (*i.e.*, is "indicated for") anemia in dialysis patients (that is, for treating ESRD anemia).

19. Accordingly, the sale in the United States of ESA drugs for the treatment of ESRD is a relevant market.

20. Since 1989, Amgen has sold an ESA under the brand name Epogen® which is indicated for the treatment of anemia in ESRD patients (that is, patients with chronic renal failure on dialysis). Amgen sold more than $2.4 billion worth of Epogen® in 2005.

21. In 2001, Amgen introduced a different ESA under the brand name Aranesp®, which is also indicated for the treatment of anemia in ESRD patients (that is, patients with chronic renal failure on dialysis). Amgen sold more than $2.1 billion worth of Aranesp® in 2005, although on information and belief only a relatively small proportion of sales are for ESRD use.

22. Epogen® and Aranesp®, both Amgen products, are the only ESAs that have been approved by the FDA for the treatment of anemia in ESRD patients and that are currently sold for such treatment in the United States. Although Procrit®, a product sold by Ortho Biotech Products, L.P. ("Ortho") which has the same active ingredient as Epogen®, is also indicated for the treatment of anemia in ESRD patients, Amgen's long-term license with Ortho prevents Ortho from marketing Procrit® for that purpose.

23. Amgen, as the supplier of the only two ESRD ESA products approved for and available for sale in the United States, has 100% market share and monopoly power in the ESRD ESA market.

24. Approximately sixty-five percent (65%) of ESAs used to treat ESRD patients in the United States are purchased directly from Amgen by two Large Dialysis Organizations ("LDOs"). These two LDOs operate numerous facilities throughout the United States at which ESRD patients receive their dialysis treatment and, when necessary, are administered their ESA medications. ESRD patients receive ESA medications during their dialysis visits. The two LDOs historically have purchased ESA medications under centralized contracts with Amgen.

25. Beyond the two LDOs, the remaining thirty-five percent (35%) of ESRD ESA customers consist of small and medium chain dialysis centers, independent dialysis centers and hospitals.

26. Because of Amgen's monopoly power, each and every dialysis center and other ESRD ESA customer in the United States must purchase ESRD ESA drugs from Amgen. There are no products currently on the market that can be substituted for Amgen's ESRD ESA products. Evidencing Amgen's monopoly power, Amgen has steadily raised the prices of

Epogen® over time. Also evidencing Amgen's monopoly power, to bolster sales of the distinctly-priced Epogen®, Amgen has refused to make Aranesp® available to many customers for ESRD use at an attractive price.

27. Amgen's monopoly power is protected by high barriers to entry. Amgen alone owns at least twenty-eight U.S. patents with claims related to erythropoietin, and owns many more concerning related technologies. Although Roche now plans to enter the market through a product, CERA, that is not blocked or covered by those patents, Amgen has vigorously enforced its patent portfolio against other companies for the past twenty years. In addition to the numerous patents owned by Amgen and others, barriers to entry include the rigorous FDA approval process to test the safety and efficacy of drug products. Other entry barriers include dialysis centers' long-standing agreements and relationships with Amgen. A new entrant faces these and other significant switching costs, which include convincing personnel to learn new methods for administering different ESA products and convincing formularies to place new medications on their approved drug lists. The preference for some customers to contract with a single ESA provider, and the providers' consequent need to compete "for the contract," also constitutes a substantial entry barrier, as do Amgen's contracting practices and other factors.

28. In light of the foregoing, Amgen has monopoly power — that is, the power to raise prices or exclude competition — in the ESRD ESA market.

III. AMGEN'S SUBSTANTIAL AND EXPANDING MARKET POWER IN THE MARKET FOR THE SALE OF ESA DRUGS FOR THE TREATMENT OF CKD

29. Another part of the interstate trade and commerce adversely affected and restrained by the unlawful Amgen acts described herein, and the second relevant market in this case, is the sale in the United States of ESA drugs for the treatment of CKD ("CKD ESA").

30. In addition to patients whose kidney disease is so severe that they require dialysis (that is, ESRD patients), millions more suffer from a less severe although serious condition known as CKD. CKD patients do not receive dialysis. Instead, they have been diagnosed with some level of reduced kidney function by their personal care physician or nephrologist.

31. CKD patients, too, are treated with ESAs because CKD patients commonly also suffer anemia. There is no substitute for ESAs in the safe and effective treatment of anemia associated with CKD. Moreover, no ESA may be marketed for the treatment of anemia in CKD patients in the United States unless the FDA approves its use to treat (is "indicated for") anemia associated with CKD.

32. Accordingly, the sale of ESAs for the treatment of anemia in CKD patients in the United States is a relevant market.

33. Amgen's Aranesp® is indicated for the treatment of anemia in CKD patients. The only other product available for the treatment of anemia in CKD patients in the United States is Procrit®, which is sold by Ortho under a license from Amgen. Procrit® is a branded version of epoetin alfa which is chemically identical to Amgen's Epogen® product. Although Amgen's Epogen® is also indicated for the treatment of anemia in CKD patients, Amgen's license with Ortho precludes Amgen from marketing Epogen® for such use. No other ESA is currently approved by the FDA for use in treating anemia in CKD patients.

34. Procrit® and Aranesp® are distributed for use in the CKD market through traditional channels including specialty distributors, hospitals and their general purchasing organizations and retail pharmacies. In contrast to the ESRD ESA market, the customers for CKD ESA drugs are highly diffuse. These drugs are administered at doctors' offices, hospitals

and at patients' homes. Accordingly, individual doctors and patients make the decisions concerning the purchase of particular ESA products to treat anemia in patients with CKD, and purchasers of CKD ESA drugs include hospitals, individual medical practices, and specialized clinics.

35. Since Aranesp® was introduced in 2001, Amgen has steadily increased Aranesp® sales to the point where it is, or soon will be, the leading product sold in the CKD ESA market. On information and belief, Aranesp®'s share of the CKD market has skyrocketed to approximately 50% of CKD ESA sales since it was first introduced in 2001. On information and belief, Aranesp® has obtained its now leading and near-dominant position not exclusively on the merits, but rather in part through anticompetitive Amgen contracting practices with hospitals, an important ESA customer class.

36. Amgen's substantial and expanding market power in the CKD ESA market is protected by high entry barriers. As discussed above, Amgen has a substantial patent portfolio that it has enforced against competitors for the past 20 years. The need for new entrants to obtain FDA approval for indications related to the safe and effective treatment of CKD is also a substantial entry barrier. There are also substantial barriers to switching. Entrants must convince doctors and nephrologists to switch from Aranesp® or Procrit® to their new product. Hospitals must also be persuaded to add a new product to their formularies. Entrants must also overcome Amgen's anticompetitive contracting practices, which include (as described below) conditioning discounts to hospitals on Amgen's blockbuster oncology drugs on taking certain volumes of Amgen's ESA drugs across indications.

37. Amgen accordingly possesses substantial, increasing market power in the CKD ESA market. Amgen's conduct directed against Roche, as described herein, dangerously

threatens to expand that power into monopoly power by hindering a new product, CERA, that is poised to derail Amgen's march to monopoly.

IV. CERA'S THREAT TO AMGEN'S ESA DOMINANCE

38. Roche is seeking FDA approval to introduce CERA into the United States. CERA is the result of years of research aimed at developing a unique anemia medication that could provide better patient outcomes. Amgen confronts in Roche's CERA a major threat to its dominance in the ESRD ESA and CKD ESA markets.

39. During ESA development work, Roche experimented to create an entirely new molecule. The result was CERA — a chemical entity different from recombinant human EPO (rHuEPO) in both its chemical and biological activity.

40. Because of the differences between CERA on the one hand, and all other ESAs currently on the market, CERA promises to offer physicians and patients the first true alternative that, for at least a significant portion of patients, would prove more appropriate either medically or as a matter of convenience and compliance.

41. CERA's introduction threatens to end the 17-year monopoly that Amgen has enjoyed in the ESRD ESA market. Similarly, it threatens to end Amgen's and its licensee Ortho's control over the CKD ESA market, and endangers the monopoly power that Amgen otherwise threatens to achieve in that market. CERA offers customers for the first time a legitimate choice of an alternative type of ESA for the treatment of anemia. This will likely lead to enhanced competition where there has been limited (CKD ESA) or no (ESRD ESA) such competition.

42. After years of research and development, Roche started the FDA approval process for CERA. That process included, among other activities, engaging LDOs and other

ESA customers to obtain access to anemia patients in order to conduct clinical trials. Roche's CERA product is currently undergoing FDA review for approval.

V. AMGEN'S ANTICOMPETITIVE SCHEME TO UNLAWFULLY MAINTAIN ITS ESA DOMINANCE

43. Amgen recognizes and has asserted that FDA approval of CERA is likely; Amgen itself has alleged that approval of CERA is imminent. Amgen is also well aware that CERA will provide an alternative product choice for customers and providers, and will affect Amgen's monopoly and near-monopoly over the ESRD and CKD ESA markets, respectively. As described below, Amgen has taken, and continues to take, numerous steps to hinder, delay or completely stop the sale of CERA in the United States.

44. Amgen's anticompetitive scheme to impede or block CERA's entry is multifaceted. Among other conduct, Amgen has (a) engaged in unlawful and anticompetitive litigation before this Court, including but not limited to, by seeking to enforce patents that were knowingly obtained through willful fraud on the PTO; (b) engaged in sham litigation by filing an objectively baseless ITC suit for no reason other than to hinder CERA's entry; and (c) sought to block Roche's access to customers for CERA through, among other conduct, (i) exclusive dealing or higher restrictive arrangements, (ii) other anticompetitive contracting practices, and (iii) threats to customers that purchasing CERA will lead to higher prices, lost Amgen discounts or no Amgen ESA products. Absent action by this Court, Amgen's anticompetitive course of conduct may well achieve its objective of thwarting CERA's entry, thereby harming Roche, competition, patients and those who pay for their treatment (consumers), and American taxpayers.

A. Sham Litigation

45. Amgen has prosecuted a sham litigation to hinder CERA's entry. Amgen in April 2006 requested an investigation by the International Trade Commission, contending that Roche was actively importing products that infringed various Amgen patents. The patent laws provide a safe harbor exempting uses related to the FDA approval process from infringement. Amgen requested this baseless investigation even though it had no evidence that Roche had actually imported CERA for any purpose other than those related to seeking FDA approval. Amgen's sole purpose of bringing the ITC action was to increase Roche's costs and delay CERA's entry, regardless of whether Amgen won or lost.

46. For example, Amgen used discovery available in the baseless ITC action to interfere with Roche's clinical trials. Amgen employed third-party subpoenas and other litigation tactics in the ITC case in an effort to intimidate potential clinical investigators and hinder Roche's efforts to obtain FDA approval.

47. Amgen's scorched-earth tactics in its baseless ITC action also distracted key Roche employees from company business, including business related to the FDA approval and launch of CERA. Amgen's baseless ITC action also improperly imposed additional costs on Roche to enter with CERA.

48. Amgen's Complaint of infringement at the ITC was dismissed by a summary judgment order of the Administrative Law Judge after a period of thorough discovery. The Administrative Law Judge held that there was no question of law or fact on Roche's non-infringement. Amgen appealed to the full ITC. The full Commission rejected the appeal and adopted the Administrative Law Judge's decision as the final decision in the case. Accordingly, the ITC terminated the investigation. Amgen has appealed the ITC's decision to the Court of Appeals for the Federal Circuit in yet another attempt to raise Roche's costs of entry with CERA.

B. Attempted Enforcement of Fraudulently Obtained Patents

49. Amgen not only engaged in sham litigation before the ITC, but also persists in doing so before this Court. Counterclaim-Defendant Amgen asserts that it is the assignee and owner of record of the '698, '868, '349, '933, '080, and '422 patents. As alleged above with particularity in Paragraphs 38-45 of Roche's Answer above, these patents were obtained through knowing and willful fraud on the PTO by Amgen and/or its agents, and are invalid and unenforceable. The present patent infringement suit to enforce these patents against Roche was brought by Amgen with knowledge that these patents were obtained by fraud on the PTO and/or not infringed, and with the intent to injure Roche, and impair competition, by delaying or preventing Roche's entry with CERA.

C. Interference With, and Locking Up of, Customers

50. Anticipating FDA approval for CERA, Roche has begun to develop relationships with potential customers for its CERA product through its clinical trials and through other means.

51. As the dominant seller of ESA products, Amgen knows the identity of Roche's potential customers for CERA.

52. On information and belief, Amgen has engaged in a pattern of threats and intimidation designed to deny Roche customers for CERA and to foreclose CERA from the ESRD ESA and CKD ESA markets. Amgen has intentionally and maliciously interfered with potential business relationships of Roche and has damaged Roche's prospective business relationships by causing ESA providers to not consider entering business relationships with Roche.

53. On information and belief, Amgen has offered potential customers research grants and other financial incentives solely for the purpose of intentionally and

maliciously interfering with potential business relationships of Roche and has damaged Roche's prospective business relationships by causing ESA providers to not consider entering business relationships with Roche.

54. On information and belief, Amgen has also threatened numerous ESA customers that, if they order CERA, Amgen may raise the price of, or refuse to sell them, Amgen ESA products, or just as importantly deny those customers discounts on those products that otherwise would be made available, if Amgen prevails in its patent infringement claims against Roche. A provider's inability to receive rebates and/or favorable pricing on the purchase of ESA drugs will likely have severe, detrimental economic consequences. A reduced discount means a higher effective price, and thus fewer funds available to cover ever-increasing provider expenses. The loss of discounts, or the threatened withholding of discounts, is accordingly a credible threat to many ESA customers.

55. On information and belief, Amgen has also entered long-term sole source and supply agreements with key ESA customers to foreclose those customers from contracting with Roche for CERA. Prior to the threat posed by CERA's entry, Amgen had no need for exclusive dealing arrangements. Amgen recently entered into one or more long-term sole sourcing arrangements solely to block CERA from obtaining economies of scale critical to eroding Amgen's ESA dominance.

56. On information and belief, Amgen has also engaged in anticompetitive contracting with hospital purchasers in the ESA markets. These contracts conditioned discounts on Amgen's blockbuster oncology medications, Neulasta® and Neupogen®, on the hospitals' purchases of Amgen's ESA drugs. The importance of obtaining discounts on Amgen's monopoly oncology medications leaves hospitals with little choice but to take Amgen's ESA

drugs across indications, including for CKD and ESRD, thereby (i) impeding competition on the merits in the CKD ESA and ESRD CKD markets for those hospitals' ESA requirements and (ii) making successful entry into those markets for entrants, and effective competition by incumbents, more difficult.

D. Amgen's Anticompetitive Purpose and Lack of Legitimate Business Justification

57. Amgen has engaged in the above-described conduct with the specific intent to maintain or obtain monopoly power in the ESRD ESA and CKD ESA markets, with the specific purpose to hinder Roche's ability to enter those markets successfully with CERA, and without any legitimate business purpose or justifiable cause.

VI. HARM TO PATIENTS, CUSTOMERS, ROCHE AND COMPETITION

58. As Amgen has anticipated and intended, its actions have caused, and absent action by this Court will continue to cause, substantial anticompetitive effects.

59. Amgen's sham litigation and attempted enforcement in this Court of patents obtained through fraud on the PTO harm competition in the relevant ESA markets by improperly raising already high barriers to entry into those markets and anticompetitively imposing higher costs on a new entrant, Roche.

60. Amgen's denial to Roche of CERA customers through long-term exclusive dealing arrangements, payments, anticompetitive contracting practices, and outright threats unreasonably restrains trade and harms competition, and threatens to continue to do so, in the ESRD ESA and CKD ESA markets. Amgen's tactics threaten either to block Roche's entry with CERA or to make that entry less robust than it otherwise would be.

61. Roche has no effective means to counteract Amgen's anticompetitive conduct aimed at denying Roche important customers. One of two LDOs that together control

70% of the purchases in the ESRD ESA market is foreclosed from Roche through a newly minted long-term exclusive dealing arrangement. In addition, while Roche is confident that it will prevail against Amgen's baseless infringement claims, it is unlikely to convince vulnerable dialysis center customers, whose patients must have access to ESAs to treat their anemia and who depend on product discounting in order to remain in business caring for such patients, to adopt CERA and take the risk that Amgen will punish them and their patients by making discounts or ESA products unavailable to them in the unlikely event that Amgen's patent case blocks CERA. The smaller potential customer base greatly reduces the chance that Roche can obtain the economies it needs to make CERA a serious alternative to Amgen's dominance.

62. Amgen's anticompetitive, strong-arm tactics with customers, its sham litigation before the ITC, and its knowing attempt to enforce in this Court patents obtained through fraud on the PTO threaten to maintain Amgen's monopoly over the ESRD ESA market, and to help Amgen achieve monopoly power in the CKD ESA market. At the very least, Amgen's conduct will hinder the introduction of additional competition into the highly concentrated CKD and ESRD ESA markets. Amgen's course of conduct also amounts to a misuse of its patents.

63. Amgen's conduct has harmed, and will continue to harm, not only Roche and competition, but also ESRD and CKD patients and those who pay for their treatment. Amgen's anticompetitive raising of Roche's costs of entering with CERA threatens insurers, patients, and immediate purchasers of drugs with higher prices. Amgen's anticompetitive course of conduct, moreover, threatens to delay, hinder, or outright block the successful entry of an alternative ESA drug, CERA, that offers patients and doctors the first real choice of an alternative, and potentially better, ESA. Consumers also will suffer higher prices than otherwise

may well be available if Roche can enter the ESA market unsaddled by anticompetitively increased costs and hindered access to customers. Amgen's anticompetitive conduct also threatens to burden American taxpayers with higher government Medicare and Medicaid expenses as the lack of competition enables Amgen to keep ESA prices artificially high.

COUNT I

(Monopolization And Attempted Monopolization (15 U.S.C. § 2))
(Walker Process Antitrust Claim — ESRD ESA and CKD ESA Markets)

64. The allegations of paragraphs 1 through 63 are incorporated in this count as if fully set forth herein.

65. As detailed with particularity in paragraphs 38-45 of Roche's Answer above, among other paragraphs of Roche's Answer and Counterclaims, the patents-in-suit are unenforceable because individuals associated with the filing and prosecution of these patents acting as agents and/or with knowledge of plaintiff Amgen intentionally and willfully misled the PTO by misrepresenting and omitting material information, which, if known by the PTO, would have resulted in the PTO not allowing these patents.

66. Knowing that the patents-in-suit were obtained by fraud and the commission of inequitable conduct before the PTO, Amgen nonetheless commenced the present action for infringement of the patents-in-suit against Roche.

67. Amgen has (i) publicized the litigation to potential CERA purchasers; and (ii) engaged in a campaign to threaten and intimidate potential customers of Roche by (a) informing them of this litigation and asserting to them that Roche's activities and ESA product infringe the patents-in-suit, or (b) threatening such customers with suit for contributory patent infringement, all while knowing that these patents were obtained by fraud and are, invalid, unenforceable and not infringed.

68. Such conduct constitutes a knowing, willful and intentional attempt to enforce patents procured by fraud and to improperly maintain and/or obtain monopoly power (which the conduct dangerously threatens) in the ESRD ESA and CKD ESA markets in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

69. Amgen has acted with specific intent to unlawfully monopolize the relevant markets, as evidenced by the anticompetitive conduct alleged herein, and without legitimate business justification.

70. As a direct and proximate result of the foregoing, competition in the relevant markets has been, and will continue to be, injured to the detriment of consumers who will be subject to reduced choice, retarded quality in terms of product attributes, and likely higher prices.

71. As a direct and proximate result of the foregoing, Roche has been injured in its business and property, and is threatened with additional losses from Amgen's conduct.

COUNT II

(Monopolization And Attempted Monopolization (15 U.S.C. § 2))
(Sham Litigation – ESRD ESA and CKD ESA Markets)

72. The allegations of paragraphs 1 through 71 are incorporated in this count as if fully set forth herein.

73. Amgen has engaged in an anticompetitive attempt to impede or block an actual and/or potential competitor through instituting a sham lawsuit, coupled with the publicizing of that lawsuit to potential customers of Roche.

74. Inter, alia, Amgen commenced a proceeding against Roche before the International Trade Commission asserting alleged infringement of the patents-in-suit. The Commission summarily dismissed Amgen's complaint, after extensive and costly litigation,

based on the finding that there was no unfair act of importation under the statute, because there was no act of infringement.

75. Amgen's ITC case was brought without any reasonable basis or prospect of success. Amgen acted with specific intent to maintain and/or achieve monopoly power in the ESRD ESA and CKD ESA markets (which its baseless conduct dangerously threatened) and without legitimate business justification. Accordingly, Amgen's conduct violated Section 2 of the Sherman Act, 15 U.S.C. § 2.

76. As a direct and proximate result of the foregoing, among other sham litigation before this court, competition in the relevant markets has been, and will continue to be, injured to the detriment of consumers who will be subject to reduced choice, retarded quality in terms of product attributes, and likely higher prices.

77. As a direct and proximate result of the foregoing, Roche has been injured in its business and property, and is threatened with additional losses from Amgen's conduct.

Count III

(Monopolization of ESRD ESA Market (15 U.S.C. § 2))

78. The allegations of paragraphs 1 through 77 are incorporated in this count as if fully set forth herein.

79. Amgen has monopoly power in the market for ESAs sold for ESRD in the United States. Amgen long has possessed 100% of the market, which is protected by high entry barriers.

80. Amgen's conduct alleged herein amounts to willful acquisition and/or maintenance of monopoly power in the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Amgen's conduct is anticompetitive and lacks any legitimate business justification.

81. As a direct and proximate result of the foregoing, competition in the relevant market has been and will continue to be injured, to the detriment of consumers who will be subject to reduced choice, retarded quality in terms of product attributes, and likely higher prices.

82. As a direct and proximate result of the foregoing, Roche has been injured in its business and property, and is threatened with additional losses from Amgen's conduct designed to foreclose and exclude Roche from the relevant market.

COUNT IV

(Attempted Monopolization of CKD ESA Market (15 U.S.C. § 2))

83. The allegations of paragraphs 1 through 82 are incorporated in this count as if fully set forth herein.

84. Amgen has the specific intent to monopolize the market for the sale of ESA Drugs sold for CKD in the United States. Amgen's anticompetitive conduct, as alleged herein, has been undertaken to achieve, maintain, and extend monopoly power and lacks any legitimate business justification. Amgen has a dangerous probability of achieving monopoly power in the market, which is protected by high entry barriers, to the extent it does not already possess monopoly power in the relevant market.

85. Amgen's conduct alleged herein constitutes the unlawful attempt to monopolize the relevant market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

86. As a direct and proximate result of the foregoing, competition in the relevant market has been and will continue to be injured, to the detriment of consumers who will be subject to reduced choice, retarded quality in terms of product attributes, and likely higher prices.

87. As a direct and proximate result of the foregoing, Roche has been injured in its business and property, and is threatened with additional losses from Amgen's conduct designed to foreclose and exclude Roche from the relevant market.

COUNT V

(Unreasonable Restraints of Trade in the ESRD ESA and CKD ESA Markets (15 U.S.C. § 1))

88. The allegations of paragraphs 1 through 87 are incorporated in this count as if fully set forth herein.

89. Amgen, as alleged herein, has entered into one or more contracts, combinations, or conspiracies with third parties that are in and/or affect interstate commerce among the several States.

90. The effect of Amgen's agreement(s) are, and will be, to restrain trade, cause anticompetitive effects, and expand and reinforce Amgen's market power in the relevant markets alleged herein. Amgen's agreement(s) lack any legitimate business justification. Accordingly, Amgen's agreement(s) comprise unreasonable restraints of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

91. As a direct and proximate result of the foregoing, competition in the relevant market has been and will continue to be injured, to the detriment of consumers who will be subject to reduced choice, retarded quality in terms of product attributes, and likely higher prices.

92. As a direct and proximate result of the foregoing, Roche has been injured in its business and property, and is threatened with additional losses from Amgen's conduct designed to foreclose and exclude Roche from the relevant market.

COUNT VI

(Tortious Interference With Prospective Business Relationships)

93. The allegations of paragraphs 1 through 92 are incorporated in this count as if fully set forth herein.

94. Roche had prospective advantageous business relationships with third parties, including but not limited to distributors, customers, and LDOs.

95. Amgen had knowledge of Roche's prospective business relations as set forth above.

96. Amgen knowingly interfered with Roche's business relations as set forth above.

97. Amgen's interference with Roche's prospective business relations was improper in motive and means. Upon information and belief, Amgen has purposefully engaged in such conduct to improperly and unjustifiably interfere with Roche's relationships as set forth above and damage its business relationships and goodwill.

98. The acts and conduct of Amgen complained of herein constitute the tort of intentional interference with prospective business relations.

99. As a result of Amgen's intentional interference with Roche's potential business relations, Roche has suffered monetary damages in an amount yet to be determined.

COUNT VII

(Discouraging Competition In Violation Of California's Cartwright Act)

100. The allegations of paragraphs 1 through 99 are incorporated in this count as if fully set forth herein.

101. Amgen's anticompetitive activities described above constitute violations of California's Cartwright Act, Cal. Bus. & Prof. Code §§ 1670, *et seq.*

102. As a direct and proximate result of the foregoing, Roche has been injured in its business and property.

COUNT VIII

(Discouraging Competition In Violation Of The New Jersey Antitrust Act)

103. The allegations of paragraphs 1 through 102 are incorporated in this count as if fully set forth herein.

104. Amgen's attempted monopolization and anticompetitive activities constitute violations of N.J.S.A. §§ 56:9-3 and 56:9-4 of the New Jersey Antitrust Act.

105. As a direct and proximate result of the foregoing, Roche has been injured in its business and property, and is threatened with additional losses from Amgen's conduct designed to foreclose and exclude Roche from the relevant market.

COUNT IX

(Unfair and Deceptive Business Practices in Violation of Mass. Gen. Laws ch. 93A)

106. The allegations of paragraphs 1 through 105 are incorporated in this count as if fully set forth herein.

107. Amgen is engaged in trade or commerce within the meaning of Mass. Gen. L. Ch. 93A.

108. Roche is engaged in trade or commerce within the meaning of Mass. Gen. L. Ch. 93A.

109. The conduct of Amgen, as set forth above, constitutes unfair or deceptive acts or practices.

110. The conduct of Amgen, as described above, was knowing and willful.

111. Roche has been damaged in an amount to be determined at trial by Amgen's unfair and deceptive business practices.

COUNT X

(Declaratory Judgment of Patent Invalidity)

112. The allegations of paragraphs 1 through 111 are incorporated in this count as if fully set forth herein.

113. On August 15, 1995, August 20, 1996, April 8, 1997, April 15, 1997, May 26, 1998, and September 21, 1999, the PTO issued to Amgen the ’868, ’933, ’698, ’080, ’349, and ’422 patents respectively, upon one or more applications filed in the name of Fu-Kuen Lin.

114. There is an actual and justiciable controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 between Roche and Counterclaim-Defendant Amgen with respect to the validity of the ’868, ’933, ’698, ’080, ’349, and ’422 patents.

115. The ’868, ’933, ’698, ’080, ’349, and ’422 patents are invalid because they fail to satisfy the conditions for patentability specified in 35 U.S.C. §§ 101, 102, 103, 112, 116 and 282, and because of obviousness-type double patenting.

COUNT XI

(Declaratory Judgment of Non-Infringement)

116. The allegations of paragraphs 1 through 115 are incorporated in this count as if fully set forth herein.

117. There is an actual and justiciable controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 between Roche and Counterclaim-Defendant Amgen with respect to the infringement of the ’868, ’933, ’698, ’080, ’349, and ’422 patents.

118. Roche has not infringed and is not infringing any claim of the '868, '933, '698, '080, '349, and '422 patents. Moreover, the activities alleged in the Complaint do not constitute infringement under 35 U.S.C. § 271(e)(1).

COUNT XII

(Declaratory Judgment of Unenforceability)

119. The allegations of paragraphs 1 through 118 are incorporated in this count as if fully set forth herein.

120. There is an actual and justiciable controversy within the meaning of 28 U.S.C. §§ 2201 and 2202 between Roche and Counterclaim-Defendant Amgen with respect to the unenforceability of the '868, '933, '698, '080, '349, and '422 patents.

121. The patents-in-suit are unenforceable because of all the foregoing allegations including that individuals associated with the filing and prosecution of these patents acting as agents and/or with knowledge of plaintiff Amgen misrepresented material facts with the intent to deceive the PTO for purposes of overcoming a double patenting rejection based on Amgen's earlier filed and issued '008 patent.

122. Among Amgen's inequitable acts, are that the '933 and '080 patents are unenforceable because individuals associated with the filing and prosecution of these patents acting as agents and/or with knowledge of the plaintiff Amgen misrepresented and failed to disclose material inconsistencies regarding alleged differences between r-EPO, which Amgen received patent claims on, and u-EPO, which was in the prior art.

123. Wholly apart from Amgen's fraud on the PTO, the patents-in-suit are unenforceable because Amgen misused those patents in initiating sham litigation before the ITC and because Amgen misused those patents by engaging in an anticompetitive scheme to coerce or otherwise induce ESA customers to forgo CERA.

PRAYER FOR RELIEF

WHEREFORE, Roche prays for judgment in its favor and against Plaintiff Amgen as follows:

A. Dismissal of Amgen's Complaint with prejudice, and denial of each and every prayer for relief contained therein;

B. A judgment declaring that Amgen's conduct as alleged herein is unlawful;

C. A judgment awarding to Counterclaim-Plaintiff Roche the damages it has sustained as a result of the illegal conduct of Amgen, in an amount to be proven at trial, to be trebled by law, plus interest (including pre-judgment interest), attorneys' fees and costs of suit;

D. A judgment declaring that the '868, '933, '698, '080, '349, and '422 patents are invalid;

E. A judgment declaring that Roche has not infringed and is not infringing the '868, '933, '698, '080, '349, and '422 patents in violation of 35 U.S.C. § 271;

F. A judgment declaring that the '868, '933, '698, '080, '349, and '422 patents were obtained by knowing and willful fraud on the PTO and are unenforceable;

G. A judgment declaring that this is an exceptional case, pursuant to 35 U.S.C. § 285, and awarding Roche its reasonable attorneys' fees;

H. Awarding Roche all costs, interest (including prejudgment and postjudgment interest), etc. as to which it is legally entitled; and

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

DEMAND FOR JURY TRIAL

Roche demands a trial by jury on all issues so triable.

Dated: November 6, 2006

Respectfully Submitted

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ROCHE DIAGNOSTICS GmbH,
and HOFFMANN-LA ROCHE INC.

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Nicole A. Rizzo
Nicole A. Rizzo

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