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 Civ. 12237 WGY **DEFENDANTS' FIRST AMENDED 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, hereby amend their answer and counterclaims to the Complaint For Declaratory Judgment Of Infringement ("Complaint") of Amgen, Inc. ("Amgen") as follows:

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 (2005); *see also id.* § 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 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) (2006).

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") and U.S. Patent No. 4,667,016; and the claims of the '349, '933,

'080, and '422 patents are invalid for double patenting over the claims of the '868 and '698 patents.

SEVENTH DEFENSE – INEQUITABLE CONDUCT BEFORE THE PATENT OFFICE

INTRODUCTION

38. Applicants for patents have a general duty of candor and good faith in their dealings with the Patent and Trademark Office ("PTO") and an affirmative obligation to disclose to the PTO all information that they know to be material to the examination of a pending application pursuant to 37 C.F.R. § 1.56 (2006). This duty extends to the applicants and their representatives, such as their attorneys, and all others associated with the prosecution, including "every person who is substantively involved in the preparation or prosecution of the application." *Id.*

39. In 1987 Amgen obtained the '008 patent which essentially claimed the isolated DNA sequence encoding EPO, and mammalian host cells transformed with this DNA sequence "in a manner allowing" these cells to express EPO and to glycosylate the biologically active EPO (referred to herein as "the DNA and host cell claims"). *See, e.g.*,'008 patent col. 40 ll. 1-3, 7-10, 60-62 (claims 2, 4, and 24). Amgen has enjoyed the full term of protection of this patent, which expired in 2004.

40. From 1995 to 1999 Amgen obtained new patents, which essentially claimed methods for making EPO protein by utilizing mammalian cells transformed with the DNA sequence encoding EPO (the '868, '698 and '349 patents), and the EPO protein expressed by the transformed mammalian cells (the '933, '080, and '422 patents). Amgen has asserted these method and product claims against Roche as part of this lawsuit.

41. These six patents 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.

42. 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, knowingly and willfully concealed and misrepresented material evidence with the intent to deceive the PTO over the 16 years that Amgen prosecuted the ’868, ’933, ’698, ’080, ’349 and ’422 patents, and the now expired ’008 patent.

Inequitable Conduct Relating To Double Patenting

43. The patents-in-suit are unenforceable because individuals including, but not limited to, Michael Borun, Steven Odre and Stuart Watt, associated with the filing and prosecution of these patents and acting as agents and/or with the 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.

44. During Amgen’s prosecution of application Ser. No. 113,179 (the “’179 application”), which issued as the ’868 patent, Amgen faced a double patenting rejection of all its pending claims (70 and 72-75) on grounds that these process claims were not patentably distinct from claims 1-6 of the ’008 patent because it would have been obvious to one of skill to use the claimed erythropoietin encoding DNA of the ’008 patent in prior art methods for host cell expression. Amgen overcame that rejection only by (1) misleading the examiner into believing that a dispositive judicial determination had already confirmed that none of the ’008 patent claims encompassed subject matter of its pending ’179 application process claims, (2) misleading the examiner into believing that the Patent Office in interference proceedings had

already determined the subject matter of its pending '179 application process claims to be patentably distinct from any of the '008 claims, and (3) by failing to disclose arguments it made before the Patent Office Board of Patent Appeals and Interferences (the "Board"), as well as in opposition proceedings in Europe involving Genetics Institute's EP 411 678 (the '678 patent) and EP 209 539 (the '539 patent), inconsistent with and refuting its arguments for patentability of its pending '179 application process claims.

45. In particular, during the '179 prosecution, Amgen misrepresented the court's decision in *Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532 (Fed. Cir. 1990), as holding that the "rights in the subject matter of '008 patent claims do not extend to the subject matter of the process claims herein . . . ." ('179 FH, Applicant's Amendment and Remarks Under 37 C.F.R. §§ 1.111 and 1.115 dated 10/7/94, at 7). The Federal Circuit considered only whether the composition claims fell within the ambit of 19 USC § 1337(g), which provides patentees the right to bring actions against foreign companies that allegedly infringe a patented process abroad. Significantly, the Court did not address whether the product claims were patentably distinct from the process Amgen was attempting to claim in the '179 application. The Court held only that the claims of the '008 patent could not be used in Section 1337(g) actions because they were not directed to a process.

46. Additionally, during the '179 prosecution, Amgen misrepresented to the examiner that in connection with Interference No. 102,096 (the "Fritsch I interference") (with its sole count identical to claim 2 of the '008 patent) and Interference No. 102,097 (the "Fritsch II interference") (with its sole count identical to then pending '179 application claim 65) "it has thus been the position of the Patent and Trademark Office that the production process subject matter claimed herein was patentably distinct from the DNA-related subject matter claimed in

U.S. 4,703,008." ('179 FH, Applicant's Amendment and Remarks Under 37 C.F.R. §§ 1.111 and 1.115 dated 10/7/94, at 7).

47. Not only did this misrepresent the position of the Board, which made no such conclusion, Amgen failed to inform the examiner that in the Fritsch II interference it took the entirely contradictory position that its process claims were inherently part and parcel of the same invention as claimed in its '008 patent.

> While the count is directed to a process for preparing *in vivo* biologically active EPO using a mammalian host cell transfected or transformed with an isolated DNA sequence encoding human EPO [i.e., the process patent claims], and the litigation was directed to the purified and isolated DNA sequence and host cells transfected or transformed thereby [i.e., the '008 DNA claims], **it is evident that these are only different manifestations of the same invention** as acknowledged by Fritsch et al in their Motion Q here (and in Motion G in Interference No. 102,096). Clearly, the whole purpose and intent of the purified and isolated DNA sequence encoding human EPO (and host cells transfected therewith) at issue in the litigation was to express *in vivo* biologically active human EPO. Stated otherwise, the process language of the Lin patent claims at issue in the litigation ("encoding human EPO") [see '008 patent claims] is, for all intents and purposes, a description of the present count. (*Fritsch v. Lin*, Interference No. 102,097, Brief. for the Senior Party Lin at 25-26. (emphasis added)).

Significantly, not only did Michael Borun submit Applicant's October 7, 1994 Amendment and Remarks in the '179 prosecution, Mr. Borun appears "of counsel" on the Lin Brief, evidencing his obvious familiarity with these contradictory positions that Amgen relied on during the interference and his knowing and intentional misrepresentation of those positions in prosecuting the '179 application.

48. Tellingly, Amgen also failed to inform the examiner that in the Fritsch II interference, it had argued that resolving priority issues in regard to the count for the DNA

sequence in the Fritsch I interference would necessarily determine those issues in regard to its process claims:

> The same is true with regard to the count of Interference 102,097 [process for making EPO], **if Lin was the first to invent a host cell containing a DNA sequence in a manner allowing the host cell to express rEPO as determined by the Court [DNA count], he is of necessity the first to invent the process of making rEPO using such the host cell** (see the count of Interference 102,097) [process for making EPO]." (Interference No. 102,097, Lin Reply Brief at 3 (emphasis in original)).
>
> "Fritsch [Genetics Institute] errs in saying that the District Court case did not involve the count (process for making EPO) of Interference No. 102,097. **The Court assessed the priority evidence regarding the DNA sequence used to make EPO and the reduction to practice of the sequence necessarily and inherently includes the use of that sequence to make EPO according to the count of Interference No. 102,097."** (Interference No. 102,097, Lin Reply Brief at 9 (emphasis in original)).

49. Moreover, Amgen failed to disclose arguments it made during opposition proceedings in Europe involving Genetics Institute's EP 411 678 ('678 patent) and EP 209 539 ('539 patent) that were similarly inconsistent with and refuted its arguments for the patentability of its '179 application process claims.[1] In this regard, Amgen acknowledged that its process and resulting *in vivo* biologically active erythropoietin was merely an obvious and inherent result of

[1] In addition, Amgen also failed to disclose inconsistent arguments made during the following proceedings in Europe: (1) Ortho Pharmaceutical Corp. v. Boehringer Mannheim GmbH (Landgericht Dusseldorf (4 O 150/91)) (Patent infringement action for E 0 148 605), (2) Boehringer Mannheim GmbH v. Janssen-Cilag GmbH (4 O 229/91, Landgericht Dusseldorf) (Cilag I), EP 0 205 564 (3) Boehringer Mannheim GmbH v. Janssen-Cilag GmbH (4 O 58/92, Landgericht Dusseldorf) (Cilag II), EP 0 411 678; (4) Boehringer Mannheim GmbH v Kirin-Amgen, (3 Ni 32/93, Bundespatentgericht (BPG)) and appeals therefrom and (5) Kirin-Amgen and Ortho Pharmaceuticals v. Boehringer Mannheim GmbH and Boehringer Mannheim UK Ltd., The High Court Of Justice Chancery Division, Patents Court (CH 1993-K-No. 937).

expressing the DNA sequence encoding human erythropoietin in a host cell: "the particular type of glycosylation linkages was simply a result of the type of host cell used to produce the recombinant erythropoietin." (EP 411 678 Opposition Proceedings, Statement of Grounds submitted by Amgen 10/8/92). Amgen's consistent pattern of failing to apprise the United States examiners of material information from European proceedings is similarly shown through its failure to disclose arguments that were raised during the opposition proceedings to its Kirin-Amgen European Patent Application No. 0 148 605 regarding the high materiality of errors in the data corresponding to Example 10 of its US patent application.

50. Lastly, Amgen also asserted that it was inappropriate for the Examiner to consider prior art (the Yokota 4,695,542 patent) in conjunction with the claims of the '008 patent to show that the pending claims were obvious ('179 FH Applicant's Amendment and Remarks Under 37 C.F.R. §§ 1.111 and 1.115 dated 10/7/94, at 10). Amgen presented no authority in support of this proposition, and consequently misstated the law, which provides that consideration of prior art may be necessary to determine whether one of skill in the art would deem the later claim to be merely an obvious variation on the earlier one.

51. Throughout its response to the PTO's office action rejection on double patenting, Amgen therefore intentionally misrepresented its own understanding of the claims, misrepresented the facts of prior proceedings and misstated legal standards. This fraud on the PTO was motivated by Amgen's need to improperly extend the life of its EPO invention by maintaining and prosecuting applications that issued into patents, which were obvious over an earlier issued and now expired patent. In response, examiner Martinell allowed all of Amgen's pending claims, plainly demonstrating the examiner's reliance on Amgen's misrepresentations. But for these misrepresentations, the examiner would not have allowed the '179 claims to issue,

as they did in the ’868 patent, in any patent entitled to a term exceeding that of the earlier commonly owned ’008 patent. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001).

52. Amgen’s misrepresentations during prosecution of the ’179 application (which issued as the ’868 patent) relating to the patentability of its pending product claims over the ’008 patent are just as material to the product claims of the other later issued patents in the ’179 family, the ’698, ’422 and ’349 patents. But for such misrepresentations, examiner Martinell would not have allowed the claims of these patents to issue, as they did, in patents having a term exceeding that of Amgen’s earlier commonly owned ’008 patent.

53. Moreover, Amgen’s understanding, (and admissions to the Patent Office) that the claimed product described by the pending ’178 claims was merely the inherent product of the process Amgen was attempting to claim in the ’179 prosecution renders these misrepresentations just as material to Amgen’s prosecution of process claims in the ’178 line of applications, which ultimately issued as the ’080 and ’933 patents, as they were to the claims of the ’868 patent. (*see infra*, §§ 54-64). But for such misrepresentations, examiner Martinell would not have allowed the claims of these patents to issue, as they did, in patents having a term exceeding that of Amgen’s earlier commonly owned ’008 patent.

INEQUITABLE CONDUCT RELATING TO FAILURE TO DISCLOSE THE BASIS FOR AN EXAMINER’S REJECTIONS OF SUBSTANTIALLY SIMILAR CLAIMS IN CO-PENDING APPLICATIONS

54. Amgen’s patents-in-suit all issued from one of two co-pending lines of applications, originating from applications Ser. Nos. 07/113,178 (the ’178 application) and 07/113,179 (the ’179 application), which Amgen filed on October 23, 1987 as continuations of Ser. No. 675,298, which issued October 27, 1987 as the ’008 patent. The ’178 line ultimately led

to the ’080 and ’933 patents, while the ’179 line ultimately led to the ’868, ’698, ’422 and ’349 patents.

55. As exemplified below, on numerous occasions during the prosecution of these co-pending lines of applications, the examiner in one line of co-pending applications issued rejections to claims that were substantially similar to claims that Amgen was prosecuting in the other co-pending line. The existence and grounds for such rejections in one co-pending line constituted highly material information that Amgen had a duty to disclose in the other co-pending line either under the pre-1992 “reasonable examiner” standard, or the new Patent Office standard set forth in 37 C.F.R. §1.56 (1992). *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367-8 (Fed. Cir. 2003). A prior rejection of a substantially similar claim refutes, or is inconsistent with the position that those claims are patentable. An adverse decision by another examiner, therefore, meets the materiality standard under the amended Rule 56. *Id.*

56. Here, the patents-in-suit are unenforceable because individuals associated with the filing and prosecution of these patents, in arguing for the patentability of pending claims in one line of applications knowingly took positions inconsistent with highly material arguments that examiners raised against the patentability of substantially similar claims in the other co-pending line of applications, but nonetheless knowingly and intentionally failed to disclose those rejections.

57. Amgen’s intent to deceive the patent office is further evidenced by the fact that at least Amgen attorneys Steven Odre and Michael Borun were both involved throughout the prosecution of the ’178 and ’179 lines of applications, and therefore, had intimate knowledge regarding the proceedings of both lines of applications. (*See* ’178 FH, Preliminary Amendment dated 10/23/87; ’178 FH, Exam’r Interview Summary Record dated 7/20/88; ’178 FH, Exam’r

Interview Summary Record dated 11/18/93; '774 FH, Exam'r Interview Summary Record dated 3/14/96; '179 FH, Preliminary Amendment dated 10/23/87; '179 FH, Exam'r Interview Summary Record dated 9/14/88; '179 FH, Exam'r Interview Summary Record dated 9/7/94.) In addition, Mr. Borun was intimately involved in and therefore, aware of material details of the prosecution of the applications which led to the '008 patent. (*See* '179 FH, Decl. Accompanying Petition to Make Special Because of Actual Infringement dated 2/9/88).

58. In prosecution of the '179 application, Amgen submitted a Second Preliminary Amendment canceling all pending claims and entering five new claims 65-69. Among these the only independent claim (65) recited "a process for the preparation of an *in vivo* biologically active glycosylated polypeptide comprising the steps of:

> (a) growing a mammalian host cell which is capable of effecting post-translational glycosylation of polypeptides expressed therein and which is transformed or transfected with an isolated DNA sequence encoding a polypeptide having a primary structural conformation sufficiently duplicative of that of naturally occurring human erythropoietin to allow possession of the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, or the progeny thereof, under nutrient conditions suitable to allow, in sequence,
>
> > (i) transcription within said host cell of said DNA to mRNA in the sequence of transcription reactions directed by the nucleotide sequence of said DNA;
> >
> > (ii) translation within said host cell of said mRNA to a polypeptide in the sequence of translation reactions directed by the nucleotide sequence of said transcribed mRNA;
> >
> > (iii) glycosylation within said host cell of said polypeptide in a pattern directed by the amino acid sequence of said translated polypeptide and sufficiently duplicative of the pattern of glycosylation of naturally occurring human erythropoietin to allow possession by the translated glycosylated polypeptide product of the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells; and
>
> (b) isolating the glycosylated polypeptide so produced.

The dependent claims further characterized the claimed process in terms of host cell expression of cDNA (68) or genomic DNA (69) sequences, particularly in a CHO cell (66) or COS cell (67). ('179 FH, Second Preliminary Amendment dated 5/24/88 at 3-4).

59. In the first Office Action dated August 3, 1988, Examiner Tanenholtz rejected the pending claims to a host cell expression process for making a glycosylated recombinant EPO (rEPO) as obvious and unpatentable over Yokota et al. (US Pat. No. 4,695,542) which taught production of a glycosylated protein by expressing of a DNA sequence encoding the protein in a mammalian host cell, and also in view of Gething et al. 1984 (Modern Approaches to Vaccines pages 263-268), which indicated that eukaryotic cells innately possessed the property of glycosylating proteins. ('179 FH, Office Action dated 8/3/88, at 3). Among other things, the Examiner noted that "it would be expected that where one expresses the cDNA gene encoding erythropoietin using the Yokota et al. procedures the resulting erythropoietin would necessarily be glycosylated."

60. In this same time period, in its co-pending '178 application, Amgen sought to prosecute substantially similar claims directed to the product of the process described by its pending '179 application claims. Significantly, Examiner Tanenholtz was not involved in the '179 prosecution, which was before a different examiner, Jeff Kushan. In particular, in its December 1, 1988 Amendment and Reply, Amgen added new claims 61-66 directed to a human erythropoietin glycoprotein product "having a primary structural conformation sufficiently duplicative of that of a naturally occurring human erythropoietin to allow possession of the *in vivo* biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells" and further characterized as a product derived "from eukaryotic host cell expression (61) of exogenous cDNA (62) or genomic DNA (63) sequences, particularly in

mammalian host cells (64) such as COS (65) and CHO(66) cells." ('178 FH, Amendment and Reply Under 37 C.F.R. §1.111 and 1.115 dated 10/23/87, at 5-6).

61. The substantial similarity of these pending '178 claims to the pending process claims of the '179 application (and Amgen's awareness of that fact) is evident through Amgen's response to Examiner Tanenholtz' August 3, 1988 Office Action in the '179 prosecution. There, Amgen argued that pending claims 65-69 were directed to "a novel series of process steps wherein a mammalian host cell (including such non-human, non-kidney cells as COS and CHO cells as specified in claims 66 and 67) capable of glycosylating the expressed polypeptides is first transformed or transfected with a DNA sequence (including, e.g., cDNA and genomic DNA as specified in claims 68 and 69) encoding a specifically delineated polypeptide, i.e., one having a sufficient amino acid sequence homology to natural human erythropoietin to allow it to qualify, amino acid sequence-wise, for potential in vivo biological activity. (The DNA reagent employed in the transformation/transfection process is itself the novel and unobvious subject matter of claim 7 of U.S. Patent 4,703,008 and the resulting host cells are as recited in claim 24 of the Patent)." ('179 FH, Applicant's Reply dated 9/27/88, at 2).

62. Amgen's characterization of its pending '179 claims strikingly demonstrates that Amgen's '178 application claims were directed to nothing more than the inherent product of '179 claims 65-69. Aware of the high materiality of Examiner Tanenholtz's rejection in the '179 prosecution to the substantially similar claims then pending in the '178 prosecution, Amgen knowingly and intentionally failed to disclose that rejection, or the basis for that rejection to Examiner Kushan in the '178 prosecution.

63. Amgen's failure to disclose Tanenholtz' August 3, 1988 rejection in the '178 prosecution took on even greater significance in view of Amgen's subsequent actions in the

'178 prosecution. On February 10, 1989, examiner Kushan issued a Final Office Action rejecting all the pending claims on several grounds. Among the rejections, Kushan objected to the claimed description of the glycoprotein product as having "glycosylation sufficiently duplicative of that of a naturally occurring human erythropoietin" as indefinite in "not particularly pointing out what the actual glycosylation comprises." ('178 FH, Office Action dated 2/10/89, at 2). Notably, examiner Kushan never raised the argument that Tanenholtz had raised as to the obviousness of the process used to make the claimed rEPO product, nor did he raise the Yokota or Gething references that Tanenholtz had cited.

64. In response, Amgen replaced all pending claims with new claims 67-75, which defined the claimed product solely through the process through which it was made. In particular, Amgen noted that "[a]ll product claims in the subject application are now product-by-process claims. Independent claim 67, and thus all of the pending claims, specifically define the erythropoietin of the subject invention as a 'glycoprotein product of the expression of an exogenous DNA sequence in a eucaryotic host cell....' These product-by-process claims are presented in an effort to positively recite the physical properties of recombinant erythropoietin, and to further define the product of the subject invention since the recombinant erythropoietin claimed cannot be precisely defined except by the process by which it is produced." ('178 FH, Amendment under Rule 116 dated 6/2/89, at 3-4). Amgen once again failed to disclose the rejection by Tanenholtz as to the obviousness of this process.

65. In fact, throughout the remainder of the '178 prosecution, Amgen continued to argue the novelty of claims to a glycosylated erythropoietin product knowing that its arguments were wholly inconsistent with the basis of Examiner Tanenholtz' 1988 rejection of

claims directed to that process as obvious, but never bringing that rejection to the attention of the '178 examiners.

66. In an Amendment dated July 11, 1989, Amgen left all its product-by-process claims pending, amending only claim 67 to specify that the claimed product of host cell expression was one produced through a process using a non-human host cell, in order to distinguish the claimed erythropoietin product from the erythropoietin product produced by using a human cell line in the process taught by Sugimoto. ('178 FH, Amendment dated 7/11/89, at 5). Once again, Amgen failed to disclose the rejection by Tanenholtz as to the obviousness of the process described in the pending claims.

67. In the subsequent Amendment dated January 10, 1990, Amgen cancelled claims 67-75, replacing them with new claims 76-83, which Amgen indicated "are similar to cancelled claims 67-75, but which specify that the DNA sequences encode human erythropoietin. These new claims parallel claim 2 of U.S. Patent No. 4,703,008 (Lin '008 patent), the parent of the instant application." ('178 FH, Amendment under Rule 116, dated 1/10/90, at 5).

68. In addition, Amgen argued against suspending prosecution during the co-pending *Fritsch v. Lin* interferences No. 102,096 (Fritsch I) involving the Lin '008 patent and No. 102,097 (Fritsch II) involving the Lin '179 process application, in view of the December 11, 1989 decision in *Amgen, Inc., v. Chugai Pharm. Co., Ltd. and Genetics Instit., Inc.* Civil Action No. 87-2617-Y. In particular, Amgen indicated that against an anticipation attack based on Dr. Fritsch's work at Genetics Institute, not only had the Court upheld claims of the Lin '008 patent directed to the purified and isolated DNA sequence for human erythropoietin, it had also upheld claims to a host cell transformed with such a sequence. ('178 FH, Amendment under Rule 116 dated 1/10/90, at 5-6). Amgen asserted the Court's decision was therefore "fully dispositive" not

only of any priority issue in both interferences, including the Fritsch II interference involving the '179 application, but also of any priority issue in the subject '178 application, stating: "if Lin was the first to invent the DNA encoding erythropoietin and the use of that DNA in a host cell to produce recombinant erythropoietin, then clearly he was the first to invent a recombinant erythropoietin product produced using such a host cell." *Id*. at 6. Knowing this, Amgen again knowingly and intentionally failed to disclose the rejection by Tanenholtz as to the obviousness of the process, while at the same time arguing that its amendment rendered the claims "in condition for immediate allowance and issuance of a patent." *Id.* at 5.

69. Amgen continued prosecution of the '178 claims in the '874 application, which Amgen filed on February 28, 1994. On April 8, 1994, Amgen submitted a voluminous Information Disclosure Statement ("IDS"), listing almost 400 references, including references of record in the '178 prosecution, the '179 prosecution, the European Opposition Proceeding involving Amgen's EP 148,605, defendant's section 282 notice from *Amgen v. Chugai*, as well as admitted exhibits from *Amgen v. Chugai*. ('874 FH, IDS dated 4/8/94). Significantly, a biotechnology examiner would only have spent approximately 20 hours examining any individual application, such as the '874 application. (*See*, *e.g.*, U.S. Gen. Accounting Office, GAO-RCED-89-120BR, Biotechnology, Backlog of Patent Applications, at 20 (1989)). Although the 4/8/94 IDS included the Yokota and Gething references cited in the '179 prosecution by examiner Tanenholtz, had the examiner devoted all his time merely to reviewing the cited references, he would have had only about three minutes for each reference. Amgen's continued failure to bring the rejection by Tanenholtz to the attention of the examiners in the '178 line of applications, or to point out the relevance of the Yokota and Gething references to

that rejection, assured that the material nature of these references would remain buried under a mountain of other art.

70. Amgen's failure to disclose relevant rejections from its co-pending '179 line continued in its prosecution of the '874 application. In a Preliminary Amendment, Amgen cancelled all pending claims, which it replaced with new claims 84-89 (which going forward were renumbered as claims 87-97). ('874 FH, Preliminary Amendment dated 6/13/94). Among the new pending independent claims, Amgen again included product-by-process claims defining the claimed human erythropoietin glycoprotein solely through the process by which it was produced. For example, claim 86 (renumbered as 89) recited:

> The *in vivo* biologically active human erythropoietin glycoprotein product of the process comprising the steps of:
>
> (a) growing, under suitable nutrient conditions, mammalian host cells transformed or transfected with an isolated DNA sequence encoding the human erythropoietin amino acid sequence set out in FIG 6 or a fragment thereof; and
>
> (b) isolating a glycosylated erythropoietin polypeptide therefrom.

Amgen again failed to raise the 8/3/88 rejection by Tanenholtz that the process of host cell expression incorporated into this claim would have been obvious over Yokota et al 4,695,542 and Gething et al (Modern Approaches to Vaccines pages 263-268).

71. Amgen filed both application Ser. No. 468,556, which ultimately issued as the '080 patent, as well as application Ser. No. 487,774, which ultimately issued as the '933 patent, as continuation applications from the '874 application. Amgen's failure to disclose the highly relevant and material rejections it received during the '179 prosecution, as described herein, during prosecution of the '178 and '874 applications, therefore critically tainted the prosecution of both the '080 and '933 patents. Accordingly, on these grounds, both the '080 and '933 patents should be held unenforceable for inequitable conduct before the Patent Office.

72. Amgen's pattern of intentionally withholding material information from the examiners is further evidenced by its failure conversely to disclose rejections it received in the course of prosecuting claims in the '178 line of applications during its prosecution of the '179 application as well as in further continuations of the '179 application, specifically, application Ser. No. 609,741, Ser. No. 957,073, and Ser. No. 100,197. The '178 application contained pharmaceutical composition claims that were substantially similar to those of the '741, '073 and '197 applications, which eventually issued as the '422 patent. In addition, as also noted, ***supra***, in paragraphs 58-64, the '178 application contained product-by-process claims that were substantially similar to the process claims of the '179 application, which eventually issued as the '868 patent.

73. In particular, during the prosecution of substantially similar claims in the '179, '741, '073 and '197 applications, Amgen failed to disclose the following rejections made during the prosecution of the '178 application:

(1) The June 2, 1988 rejection by Examiner Kushan rejecting, among others, claim 55 under 35 U.S.C. 103 as being unpatentable over Miyake et al, Takezawa et al, Chiba et al or Sugimoto et al in view of Papayannopoulo et al. Amgen argued for the patentability of claims substantially similar to rejected claim 55 in the '741, '073 and '197 applications and failed to disclose the prior rejection by Examiner Kushan. (*See* '741 FH, Preliminary Amendment dated 11/6/90; '073 FH; and '197 FH Amendment Under Rule 1.116 dated 12/20/93);

(2) The February 10, 1989 rejection by Examiner Kushan rejecting, among others, claims 61-66 under 35 U.S.C. §103 as being unpatentable over Miyake et al, Chiba et al, Takezawa et al or Sugimoto et al and claims 55 and 61-66 under 35 U.S.C. 103 as being unpatentable over Miyake et al, Chiba et al, Takezawa et al or Sugimoto et al, in view of Papayannaopoulo et al. Amgen argued for the patentability of claims substantially similar to the rejected claims in the '179, '741, '073 and '197 applications and again failed to disclose the prior rejections by Examiner Kushan. (*See* '741 FH, Preliminary Amendment dated 11/6/90; '073 FH; '197 FH Amendment Under Rule 1.116 dated 12/20/93; and '179 FH Applicant's Second Preliminary Amendment dated 5/24/88, Applicant's Amendment and Response Under 37 C.F.R. §§1.115 and 1.111 dated 1/3/94);

(3) The June 20, 1989 rejection by Examiner Kushan rejecting, among others, claims 67-73 under 1) the doctrine of obviousness-type double patenting as being unpatentable over the prior invention as set forth in claim 1 to 11 of U.S. Patent No. 4,667,016, 2) 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Sugimoto et al. and 3) 35 U.S.C. 103 as unpatentable over Sugimoto et al. in view of Papayannopoulo et al. Amgen argued for the patentability of claims substantially similar to the rejected claims in the '179, '741, '073 and '197 applications and again failed to disclose the prior rejection by Examiner Kushan. (*See* '741 FH, Preliminary Amendment dated 11/6/90; '073 FH; '197 FH Amendment Under Rule 1.116 dated 12/20/93; and '179 FH Applicant's Second Preliminary Amendment dated 5/24/88, Applicant's Amendment and Response Under 37 C.F.R. §§1.115 and 1.111 dated 1/3/94);

(4) The September 18, 1989 rejection by Examiner Kushan rejecting, among others, claims 67-73 under the doctrine of obviousness-type double patenting as being unpatentable over the prior invention as set forth in claim 1 to 11 of U.S. Patent No. 4,667,016. Amgen argued for the patentability of claims substantially similar to the rejected claims in the '179, '741, '073 and '197 applications and again failed to disclose the prior rejection by Examiner Kushan. (*See* '741 FH, Preliminary Amendment dated 11/6/90; '073 FH; '197 FH Amendment Under Rule 1.116 dated 12/20/93; and '179 FH Applicant's Second Preliminary Amendment dated 5/24/88, Applicant's Amendment and Response Under 37 C.F.R. §§1.115 and 1.111 dated 1/3/94).

INEQUITABLE CONDUCT RELATING TO MISREPRESENTATIONS REGARDING ALLEGED DIFFERENCES BETWEEN R-EPO AND U-EPO

Contradictory Statements of Amgen's Scientist

74. Amgen, and those acting on its behalf who were substantively involved in the prosecution of the patents-in-suit, knowingly 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.

75. In order to obtain allowance for its protein claims, Amgen distinguished its recombinant EPO ("r-EPO") from natural urinary EPO ("u-EPO") by representing that the average carbohydrate composition, glycosylation, and molecular weight of its r-EPO were

different from that of naturally occurring human EPO proteins. Amgen incorporated these alleged differences into claims of the '933 and '080 patents as elements of patentability and proceeded to argue to the PTO, even in the face of its own contradictory data, that these elements made these claims patentable over u-EPO.

76. 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 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.

77. Two declarations, which have *never been previously considered by this or any U.S. Court*, contain sworn statements by an Amgen scientist which utterly contradict positions that Amgen took in arguing patentability of its then pending EPO claims to the PTO.

78. Dr. Thomas W. Strickland became involved in Amgen's EPO project in August 1984 and worked on the purification of r-EPO. Dr. Strickland was also involved in the prosecution of Amgen's protein patents related to EPO. In December 1988, during the prosecution of the '178 application, Amgen submitted a declaration by Amgen's scientist, Dr. Strickland, stating that Amgen's recombinant EPO product was chemically distinct, and therefore novel and patentable over natural human EPO that was isolated and purified from urine ("the 1988 Strickland declaration"). Specifically, Strickland stated:

> recombinant erythropoietin as described by Serial No. 113,178 has a different carbohydrate composition than naturally occurring urinary erythropoietin.

('178 FH, Strickland Decl. dated 11/30/88, at 15).

79. The prosecution history for the '178 application shows that the assertions made in the 1988 Strickland declaration were crucial for the patentability of Amgen's product

claim to EPO. The Examiner Interview Summary Record dated 1/26/89 makes it clear that the Examiner interpreted the declaration to relate to differences in carbohydrate content. As stated by the Examiner:

> [D]iscussed effect of declaration on 102 aspects of the original rejection. Discussed effect on 103-based arguments of the difference in glycosylation **(carbohydrate content)**.

('179 FH, Exam'r Interview Summary Record dated 1/26/89 (emphasis added)).

80. Amgen made this argument (both in 1988 in order to obtain the '933 patent, and then later in the Fritsch v. Lin interference proceeding) knowing it was false, and then continued to hide that fact from the patent office. The clear evidence for this is that the 1988 declaration by Strickland was directly contradicted by Dr. Strickland himself in two later declarations filed in connection with two opposition proceedings in Europe to Genetics Institute's erythropoietin patents EP 411 678 ("the '678 patent) and EP 209 539 ("the '539 patent").

81. In February 1992, Amgen submitted the first declaration by Dr. Strickland in support of Amgen's European opposition proceedings against the Genetics Institute '678 patent ("the 1992 Strickland declaration"). (Strickland European Decl. dated 2/13/92). The '678 patent contained claims drawn to a method for producing glycosylated recombinant EPO, which Amgen opposed by arguing, in part, that r-EPO and u-EPO were the same. Strikingly, the '678 patent reported its r-EPO as being analytically identical to human EPO purified from urine (u-EPO). The 1992 Strickland declaration argued that the '678 patent claims produced a protein that is indistinguishable in terms of carbohydrate composition from a protein that was produced by Amgen in 1985 using the procedures set forth in Example 10 of Amgen's European patent EP 148 605 ("the '605 patent"), which is the European counterpart to the '933 patent. Based on experiments discussed in the 1992 Strickland declaration, Strickland concluded that the

carbohydrate composition of the 1985 EPO prepared in accordance with Example 10 of Amgen's '605 patent was the same, within the range of experimental and analytical error, as the EPO of the Genetics Institute '678 patent which in turn, according to that '678 patent was chemically identical to u-EPO. The 1992 Strickland declaration was not disclosed to the PTO.

82. In May 1994, Amgen submitted another declaration by Dr. Strickland in support of Amgen's European opposition proceedings against Genetic Institute's '539 patent ("the 1994 Strickland declaration"). The Genetics Institute patent had claims directed to a recombinant EPO product, which Amgen again opposed by arguing, in part, that r-EPO and u-EPO were the same. In this declaration, Dr. Strickland stated:

> In order to demonstrate the viability of the specific disclosure of Example 10 of EP 148605 [counterpart U.S. patent], reverse phase HPLC was used to purify rEPO directly from cell culture media in which the rEPO had been expressed from CHO cells as described in Example 10. The results show that by following the disclosure of example 10 homogeneous erythropoietin is obtained that meets all the requirements of claim 2 of EP **209539**, *i.e.*, ...(b) a molecular weight of about 34,000 daltons on SDS-PAGE ...

(Strickland European Decl. dated 5/14/94, at 2 (emphasis added)). According to this declaration, r-EPO prepared in accordance with Example 10 had a molecular weight of 34,000 daltons, the same as that of u-EPO as reported at Col. 5, line 48 of the '933 patent, and not higher, as reported in Example 10.

83. Significantly, Amgen submitted an IDS for the U.S. Application Ser. No. 202874 which listed dozens of references that were part of the European proceedings involving EPO. However, the 1992 and 1994 Strickland declarations were not disclosed to the PTO. Amgen's knowing and intentional failure to disclose material information from Amgen's European opposition proceedings is evidenced at least by the direct involvement of Amgen attorneys Steven Odre and Stuart Watt in those proceedings, which included personally attending

oral proceedings in Europe. (EP 411 678, EPO Opposition Proceedings , Record of Public Oral Proceedings Before the Opposition Division, dated 12/16/94). Additionally, the claims of the later issued ’698, ’080, ’349 and ’422 patents from the same family as the ’933 patent, are sufficiently interrelated with the ’933 claims and have a substantial relationship with the inequitable acts such that these patents should also be deemed unenforceable under the doctrine of "infectious unenforceability."

Additional Contradictory Statements

84. In addition to the contradictory statements made by Amgen in the 1992 and 1994 Strickland declarations, Amgen and its employees, including even the named inventor of the Amgen EPO Patents, have made numerous statements, in publications and to the FDA, that directly contradict positions Amgen has taken before the PTO during the prosecution of the patents in suit. These additional contradictory statements further evidence Amgen’s intent to deceive the PTO. *See Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1319 (Fed. Cir. 2006) (“Intent . . . may be inferred from the totality of the evidence.”). Tellingly, Amgen’s conduct throughout prosecution reveals a consistent pattern of purposely failing to disclose material information to the examiners. During the prosecution of the ’349 and ’422 patents, Amgen made no effort to inform the PTO of the then pending litigation against TKT (Civil Act. No. 97-10814-WGY).

85. Lin, the inventor of the patents in suit, reported in a publication that “[r-EPO] has an apparent [molecular weight] of 34,000 when analyzed in an electrophoretic transfer blot.” Lin et al, *Cloning and Expression of the Human Erythropoietin Gene*, 82 Proc. Nat’l Acad. Sci., 7580, 7582 (1985). The specification for the ’933 patent states that the molecular weight of natural EPO was also "approximately 34,000 dalton." (’933 patent, Col. 5, lines 48-

50). Lin, therefore, knew as of 1985 that the molecular weights of r-EPO and u-EPO were the same, yet, as shown in Example 10 of the '933 patent which issued from an application that was filed in 1995, continued to state that the molecular weight of r-EPO was higher than that of u-EPO.

86. In addition, two Amgen scientists, Dr. Joan Egrie, and Dr. Thomas Strickland, reported in a publication that "Both the purified natural and recombinant EPO preparations were characterized . . . by Western analysis. . . . By Western analysis, the recombinant and human urinary EPO migrate identically." Egrie et al *Characterization and Biological Effects of Recombinant Human Erythropoietin*, 172 Immunobiology 213 (1986). If r-EPO and u-EPO "migrate identically" that means that the two products have the same apparent molecular weight. Therefore, the finding that r-EPO and u-EPO "migrate identically" contradicts Dr. Egrie's data reported in Example 10 in the '933 patent. This publication, however, was withheld from the Examiner of the '933 patent.

87. Additional internal documents from Dr. Egrie provide evidence regarding glycosylation inconsistent with the positions that Amgen took during prosecution of its patents. (*See* AM-ITC 00828987-88). This information was never disclosed to the examiner.

88. Another Amgen scientist, Jeff Browne, corroborated the published findings of Egrie and Strickland, stating in a publication that human u-EPO and CHO-cell derived r-EPO migrate identically in SDS-polyacrylamide gels. Browne et al, *Erythropoietin: Gene Cloning, Protein Structure, and Biological Properties*, 51 Cold Spring Harbor Symposia on Quantitative Biology 693-702, 698 (1986). This publication also was not disclosed to the Examiner. Additionally, in order to receive approval for its r-EPO drug, Amgen made statements to the FDA that directly contradict the positions Amgen took in arguing patentability

of its EPO claims to the PTO. Significantly, these statements were not submitted to the Examiner of the '933 patent. (*See* Amgen PLA, Vol. 4, pg 762 and Figure 9.C-1 (June 1989)).

EIGHTH DEFENSE - UNCLEAN HANDS

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

NINTH DEFENSE - PUBLIC HEALTH AND WELFARE

90. 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

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

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

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

94. 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.

95. 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.

96. 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

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

TWELFTH DEFENSE - OMITTED

98. OMITTED

THIRTEENTH DEFENSE - PROSECUTION LACHES ESTOPPEL

99. 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 Erythropoiesis Stimulating Agent ("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 unlawful and anticompetitive 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 with respect to 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's anticompetitive scheme includes bringing a baseless action in the International Trade Commission ("ITC") against Roche solely for the purpose of hindering, delaying, and raising the costs of CERA's introduction. Amgen has repeated its cost-imposing litigation tactics in this Court, maintaining patent infringement assertions with respect to three claims of U.S. Patent No. 5,621,080 (the "'080 patent") *even though* the Federal Circuit has already rejected the basis for those claims and *even though* Amgen admits that it has no basis to believe Roche infringes that patent. Amgen's objectively baseless litigations, brought for the sole purpose of harming Roche through the litigation *process* rather than its *outcome*, has raised entry barriers and facilitated Amgen's anticompetitive maintenance of its monopoly and near-monopoly power in the relevant markets by raising rivals' costs, distracting and harassing key individuals involved in Roche's effort to obtain FDA approval for CERA, and burdening Roche's potential customers.

1. *Amgen's Sham Litigation Before The ITC*

46. Amgen initiated a sham litigation against Roche in April 2006, when Amgen requested that the ITC open an investigation of Roche activity that, Amgen asserted, infringed certain Amgen patents. Amgen's ITC litigation was objectively baseless, for two reasons.

47. *First*, ***unlike this Court***, the ITC can only award relief based upon a finding of either (i) actual importation of an infringing product; or (ii) a commercial sale for importation of an infringing product. Amgen had no basis for asserting that Roche engaged in *any* infringing activities or made any commercial CERA sales. Indeed, Amgen had no basis to assert that *any* Roche importation of CERA fell outside 35 U.S.C. § 271(e)(1)'s safe harbor for

conduct relating to Roche's obtaining FDA approval for CERA. Tellingly, even before Amgen filed its Complaint with the ITC, the ITC Commission requested Amgen to provide briefing on the issue of how an ITC investigation can be maintained in view of the fact that all of the alleged infringing activities are protected under the safeguard provision of 35 U.S.C. § 271(e)(1). In that briefing, Amgen did not deny that there was no current infringement, but instead pointed to four factors supposedly demonstrating "imminent" or "incipient" infringement as a basis for relief:

- Hiring regional sales directors and regional medical liaisons;
- Allocating a marketing budget for product launch;
- Preparing potential physician customers by renting space at a trade show, providing grants to relevant associations, and sponsoring meetings for doctors;
- Completing construction and commencing operations of an overseas manufacturing plant.

Amgen Briefing Memorandum, dated April 27, 2006, at 15. Conspicuously, none of these activities constitute an actual alleged infringing use of the patented technology.

48. That Amgen's initiation of an ITC action based on an *actual* infringement theory was objectively baseless is confirmed by its outcome: After far-reaching discovery that, as explained below, significantly harmed Roche, the Administrative Law Judge ("ALJ") summarily rejected Amgen's Complaint. The ITC itself then rejected summarily Amgen's subsequent appeal and terminated the investigation.

49. *Second*, Amgen lacked any objective basis for seeking relief based on an argument for extending or changing the law. Knowing that it could not demonstrate actual importation of infringing product, Amgen argued that the ITC could award relief based on "imminent" or "incipient" non-exempt infringement. Amgen had no objective basis for seeking

ITC relief based on such a theory. The ITC by statute cannot find a violation unless there is an actual infringing "importation" or commercial "sale for importation." So-called "imminence" relief cannot be granted when neither circumstance is present. Indeed, as the ALJ explained in rejecting Amgen's "imminence" argument, *no* case had *ever* awarded relief on an "imminence" theory *absent* such a commercial "sale for importation." Tellingly, Congress added "sale for importation" to the statute in 1988 in reflection of courts' granting of "incipiency" or "imminence" relief *in that circumstance* -- that is, when there is a commercial "sale for importation" of infringing product. The limitations on available relief in ITC cases is in sharp contrast to the powers of this Court, which may issue injunctive or declaratory relief in patent matters without reference to those limitations. As explained before Congress's 1988 amendment of the statute: "the Commission lacks authority to issue a declaratory judgment before the products at issue have been imported." *In re Certain Fluidized Bed Combustion Sys.*, No. 337-TA-213, ITC LEXIS 8013 (U.S.I.T.C. Mar. 21, 1985).

50. As Amgen, of course, had no basis for asserting that Roche had made any *commercial* CERA sales, Amgen could not legitimately seek imminence relief. Nor did Amgen have an objectively reasonable ground for seeking a change in the law based on *Certain Variable Speed Wind Turbines and Components Thereof*, No. 337-TA-376, Initial Determination, 1996 ITC LEXIS 251 (May 30, 1996), which suggested in *dicta* the possibility of extending "imminence" relief where no decision had previously extended it -- where there is no commercial sale but the defendant had executed a contract for sales in addition maintaining a large stockpile overseas that it threatened imminently to import. *See id.* at *31. Amgen knew full-well when it brought its ITC action that Roche was in no such position. Moreover, while Congress in adding "sale for importation" to the statute in 1988 did not intend to *limit* the scope

of the ITC's power, the language Congress used surely evidenced no intent to *expand* "imminence" relief beyond where it actually had been granted in the past (*e.g.*, commercial sales for importation).

51. The baselessness of Amgen's imminence argument is evidenced by the back-of-the-hand manner in which the ITC rejected it. The ITC Commission, in its Notice of Investigation, dated May 9, 2006, specifically refused to even consider Amgen's "imminence" argument. Rather, the ITC in its May 9, 2006, notice of investigation directed the ALJ to focus solely on Amgen's equally baseless argument of present infringing activity:

> In instituting this investigation, the Commission is mindful of the provision of 35 U.S.C. § 271(e), which states that 'it shall not be an act of infringement to make, use, offer to sell, or sell within the United States...a patented invention...solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drug...' Accordingly, the Commission directs the presiding administrative law judge to consider at an early date any motions for summary determination based upon 35 U.S.C. § 271(e).

52. The baselessness of Amgen's suit, and Amgen's subjective intent to harm Roche through the ITC *process* rather than any favorable *outcome* from that process, are further evidenced by the course the matter took. Roche, on May 19, 2006, filed for summary determination of no infringement based on Section 271(e)(1). In response, Amgen successfully petitioned the ALJ for broad-reaching discovery into Roche's current acts of importing CERA into the U.S. in order to oppose Roche's motion. As a result, Roche provided to Amgen within a period of a few weeks, close to half a million pages of documents, and offered 16 deponents in three countries for more than 100 hours of testimony.

53. Yet when confronted with specific interrogatory requests seeking information about non-exempt acts of alleged infringement, Amgen made only conclusory

statements that there were uses within the U.S. unrelated to FDA approval, and again reiterated its baseless position that hiring a sales force and soliciting potential customers warranted relief on an "incipient" infringement theory. *See* Amgen's Objections and Responses To Respondents' First Set of Interrogatories, dated May 30, 2006, at 24. When it came time to actually respond on the merits to Roche's motion for summary determination, Amgen could only point to two alleged instances of non-exempt use: (1) a University of Iowa Pharmacokinetic Study; and (2) future Phase IIIb studies which were to be submitted to the FDA. These allegations were particularly suspect in view of the fact that the discovery record showed that both these studies were intended for submission to the FDA and therefore exempt under Section 271(e)(1).

54. The ITC Commission Staff accordingly supported Roche's Motion for Summary Determination of No Infringement and opposed Amgen's position of current and incipient infringement. The ITC Commission Staff found that (1) Roche "satisfied their summary determination burden and h[ad] made out a *prima facie* case that the imported CERA was solely for uses reasonably related to the FDA approval process and thus within the Section 271(e)(1) safe harbor;" and (2) the Staff was "not aware of any contrary information and Amgen must do more than rely on only attorney argument and speculation that there may be other undisclosed importations or uses of CERA." Commission Investigative Staff's Response to Respondents' Motion for Summary Determination of No Violation of Section 337, dated June 26, 2006, at 7-8. The ITC Commission Staff also outright rejected Amgen's theory of incipient infringement based on the ***Wind Turbines*** case. The Staff stated in relevant part:

> As it did in its motion to compel, Amgen is also expected to argue that infringement is "imminent"...The Staff does not expect, however, that Amgen will be able to identify any accused product currently in the United States targeted for these imminent infringing uses. Amgen relies on the Commission's opinion in [***Wind Turbines***] for the proposition that the Commission may

> consider incipient infringement. However, as set forth in the Staff's response to the parties' motions regarding the scope of discovery, *Wind Turbines* does not mandate a consideration of incipient infringement (potential future importation outside the Section 271(e) exemption) with respect to the pending motion. Respondents' early motion for summary determination on the Section 271(e) issue was clearly contemplated by the Commission, as evidenced by the specific direction to the Judge in the Notice of Investigation...As set forth above, Respondents have shown that do date there have been no non-exempt imports and hence no violation of Section 337. Amgen is not expected to successfully counter this showing. The pending motion should not be denied based on speculation concerning future uses of the accused product that may fall outside the Section 271(e) safe harbor. This course of conduct would needlessly waste the resources of the parties and the Commission.

Id. at 9 (emphasis added).

55. As expected, the ALJ agreed with Roche and the ITC Commission Staff and granted Roche's Motion for Summary Determination. Specifically, the ALJ "reject[ed] [Amgen's] contention that the issue before [him] is whether 'importation for a non-exempt use is imminent." Order No. 6, Initial Determination, dated July 7, 2006. Instead, the ALJ reviewed the comprehensive record and determined that all of Roche's uses of CERA fell within the safe harbor provision of Section 271(e)(1). With respect to the two alleged non-exempt uses identified by Amgen, the University of Iowa Study and the Phase IIIb studies, the ALJ categorically ruled that these activities were reasonably related to FDA approval, and therefore protected by the safe harbor. *Id.* at 16-17. Finally, the ALJ rejected Amgen's incipiency argument as a matter of law:

> Hence, in Wind Turbines there was a contract for commercial sale of the accused product to a customer in the United States which associated to a "sale for importation" within the meaning of section 337. The administrative law judge finds no evidence put forth by [Amgen] which establishes that there exists a contract entered into by [Roche] for commercial sale of CERA to a customer in the United States. Thus, the administrative law judge rejects

> [Amgen's] contention that these are the "exact circumstances here" as was in Wind Turbines.

Id. at 20.

56. On August 31, 2006, the ITC Commission adopted the ALJ's Initial Determination and terminated the investigation.

57. Amgen's sole purpose of bringing the baseless ITC action was to increase Roche's costs and delay CERA's entry, regardless of the suit's outcome. Amgen succeeded in its anticompetitive objective. Amgen's sham ITC action caused substantial anticompetitive effects by raising already high barriers to entry in the relevant markets, hindering and imposing costs on a new entrant, and interfering with that entrant's FDA approval process and customers.

58. Amgen's sham ITC litigation raised already high entry barriers by imposing substantial litigation costs on Roche, the only firm today poised to challenge Amgen's ESA dominance of the relevant markets. Amgen's imposing of substantial defense costs also caused anticompetitive effects by imposing unnecessary costs on a new entrant into the relevant monopolized and near-monopolized ESA markets, thereby hindering that entry and harming competition and consumers.

59. Amgen also harmed Roche and competition by using 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. Amgen served subpoenas on at least the following dialysis center customers or potential customers of Roche: Dialysis Purchasing Alliance; Fresenius Medical Care; Gambro Inc., and Davita Inc.

60. Amgen's scorched-earth tactics in its baseless ITC action also harmed Roche and competition by distracting key Roche employees from company business, including

business related to the FDA approval and launch of CERA. These included the depositions of Dr. Buch, Dr. Char, Ms. Conte, Dr. Dinella, Mr. Englesbe, Dr. Farid. Dr. Franzino, Dr. Joseph, Dr. Kingma-Johnson, Mr. Knickmeier, Mr. Kokino, Dr. Marcopulos, Dr. Much, Dr. Schorle, Dr. Shah. and Dr. Van Der Auwera -- Roche employees with duties relating to CERA's FDA approval efforts, CERA clinical trials, or otherwise involved in planning CERA's launch.

2. *Amgen's Sham Litigation Before This Court*

61. Amgen's sham litigation practices extend to the current case before this Court. Amgen's assertion of baseless patent claims in this action is both itself independently unlawful and highlights Amgen's subjective intent to harm Roche regardless of outcome in the ITC case.

62. Amgen has asserted at least the following claims of U.S. Patent No. 5,621,080 ("the '080 patent ") against Roche's CERA, even though Amgen knows that its allegations are objectively baseless.

> 3. A non-naturally occurring erythropoietin glycoprotein having the in vivo biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells, wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6.
>
> 4. A pharmaceutical composition comprising a therapeutically effective amount an erythropoietin glycoprotein product according to claim 1, 2 or 3.
>
> 6. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 4 in an amount effective to increase the hematocrit level of said patient.

63. Each of these claims require that the erythropoietin glycoprotein comprises the 166 amino acid sequence of Figure 6 of the patent specification. However, the Federal Circuit in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1308 (Fed. Cir.

2006), held that a glycoprotein comprising the mature 165 amino acid sequence could not infringe these claims either literally or by the doctrine of equivalents. With respect to the doctrine of equivalents, the Federal Circuit determined that Amgen surrendered any claims to the mature 165 mature amino acid sequence during the prosecution of the '080 patent, and, as a result, was barred from claiming this equivalence based upon the prosecution history estoppel doctrine enunciated by *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1372 (Fed. Cir. 2003). The Court reasoned:

> In sum, we uphold the district court's finding that the 165-amino acid EPO equivalent was foreseeable at the time of the third preliminary amendment. The district court erred, however, in finding that Amgen successfully rebutted the *Festo* presumption of surrender of equivalents under both the tangentially related rebuttal argument and the "some other reason" rebuttal argument. This means that HMR/TKT cannot be found to have infringed the claims 2-4 of the '080 patent under the doctrine of equivalents. Accordingly, the judgment of infringement of claims 2-4 is reversed.

Hoechst, 457 F.3d. at 1316.

64. Amgen's claims that Roche infringes the '080 patent in this case, however, presuppose that Roche's CERA "contains" the mature 165 amino acid sequence of EPO. Specifically, Amgen has maintained these claims despite the fact that Roche's BLA for CERA, which Amgen has had access to since June 2006, discloses that the EPO starting material consists of 165 amino acids. ITC-R-BLA-00004029. This, of course, is the very theory that the Federal Circuit told Amgen that it could not maintain, and demonstrates that Amgen's claim of infringement of the '080 patent is objectively baseless. The Federal Circuit has already determined that the '080 patent cannot be infringed by a 165 amino acid protein, either literally or by the doctrine of equivalents.

65. Amgen has also asserted claim 9 of the '933 patent against Roche in the current suit, even though this Court, and the Federal Circuit on at least two occasions, stated that this claim was invalid for lack of definiteness. This Court in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 165 (D. Mass. 2001) held that:

> For the reasons set forth above, the Court declares:
> Claims 1, 2, and 9 of the '933 patent are not infringed, and, if this finding is error, those claims are invalid for lack of an adequate written description, indefiniteness, and lack of enablement.

Id. The Federal Circuit on appeal affirmed this Court's decision of lack of definiteness of claims 1,2, 9 of the '933 patent. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003) ("Applying these legal maxims to the facts of this case, we agree with the district court that the claims requiring "glycosylation which differs" are invalid for indefiniteness."). Moreover, as recently as August 2006, the Federal Circuit once again reiterated its position that claims 1,2, 9 of the '933 patent were invalid for lack of definiteness. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, n.5 (Fed. Cir. 2006) ("As noted above, in *Amgen II*, we affirmed the ruling of the district court in *Amgen I* that claims 1, 2, and 9 of the '933 patent are invalid. *Amgen II*, 314 F.3d at 1342."). Nevertheless, Amgen continues to assert claim 9, *which was invalidated by the Federal Circuit as early as 2003*, against Roche in this case.

66. Accordingly, Roche expected at the very least that, following the Federal Circuit's August 2006 decision in the *Hoechst Marion Roussel* case, that Amgen would withdraw its claims of infringement of the '080 patent and claim 9 of the '933 patent . But demonstrating Amgen's subjective intent to harm Roche through the litigation process rather than any expected favorable outcome, Amgen has *maintained* its '080 infringement claims and claim 9 of the '933 patent, and, astoundingly, continues to *press* them. In so doing, Amgen has

demonstrated both that it had and continues to have no basis for bringing those claims and revealed that it's sole objective in maintaining those claims is to harass Roche and raise its costs. Without explaining *how* Roche could infringe the '080 patent given Amgen's contention that CERA contains a mature 165 amino acid sequence, Amgen has asserted that the Federal Circuit decision is not final and that it wants discovery to determine the matter (Plaintiff's Response to First Set of Interrogatories, dated January 9, 2007, at 4). Amgen also could not explain how claim 9 of the '933 patent, which was invalidated by the Federal Circuit, could still be asserted in this case.

67. The only reason Amgen is pressing the '080 claims and claim 9 of the '933 patent, therefore, is to raise Roche's already high costs of entering with CERA by running up Roche's litigation bill and potentially delaying CERA's launch through baseless proceedings. The effect of Amgen's sham infringement claims based on the '080 and '933 patents is to harm Roche, competition, and consumers by raising already high entry barriers in the relevant ESA markets and shackling a new entrant, Roche, that might reduce Amgen's monopoly and near-monopoly power, with higher litigation costs from defending three baseless claims, discovery-related burdens, and other anticompetitive obstacles to its eventual entry.

B. Attempted Enforcement of Fraudulently Obtained Patents

68. 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 38-53 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

69. 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.

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

71. 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.

72. 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.

73. 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.

74. 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.

75. 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

76. 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

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

78. 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.

79. 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.

80. 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.

81. Amgen's anticompetitive, strong-arm tactics with customers, its sham litigation before the ITC and this Court, 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.

82. 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)

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

84. As detailed with particularity in paragraphs 38-53 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. In particular, Amgen knowingly misled the PTO to overcome a double-patenting objection that would have led the PTO to deny each of the six patents-in -suit in this action.

85. As alleged in paragraphs 38-53 of Roche's answer above, in issuing each of the six patents-in-suit, the PTO justifiably relied on the misrepresentations that Amgen made before it, and on the assumption that Amgen had acted in accordance with its duty of candor in bringing to the attention of the PTO any information material to the prosecution of the six patents-in-suit.

86. 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.

87. 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.

88. 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.

89. 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.

90. 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.

91. 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

OMITTED

92. OMITTED

93. OMITTED

94. OMITTED

95. OMITTED

96. OMITTED

97. OMITTED

98. OMITTED

Count III

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

99. The allegations of paragraphs 1 through 98 are incorporated in this count as if fully set forth herein.

100. 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.

101. 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.

102. 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.

103. 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))

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

105. 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.

106. 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.

107. 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.

108. 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))

109. The allegations of paragraphs 1 through 108 are incorporated in this count as if fully set forth herein.

110. 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.

111. 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.

112. 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.

113. 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)

114. The allegations of paragraphs 1 through 113 are incorporated in this count as if fully set forth herein.

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

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

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

118. 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.

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

120. 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)

121. The allegations of paragraphs 1 through 120 are incorporated in this count as if fully set forth herein.

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

123. 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)

124. The allegations of paragraphs 1 through 123 are incorporated in this count as if fully set forth herein.

125. 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.

126. 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 the Massachusetts Consumer and Business Protection Act, Mass. Gen. Laws ch. 93A)

127. The allegations of paragraphs 1 through 126 are incorporated in this count as if fully set forth herein.

128. Amgen is engaged in trade or commerce within the meaning of Mass. Gen. Laws ch. 93A.

129. Roche is engaged in trade or commerce within the meaning of Mass. Gen. Laws ch. 93A.

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

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

132. 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)

133. The allegations of paragraphs 1 through 132 are incorporated in this count as if fully set forth herein.

134. 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.

135. 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.

136. 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)

137. The allegations of paragraphs 1 through 136 are incorporated in this count as if fully set forth herein.

138. 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.

139. 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)

140. The allegations of paragraphs 1 through 139 are incorporated in this count as if fully set forth herein.

141. 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.

142. 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.

143. 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.

144. 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: March 30, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

By their Attorneys,

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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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