



UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.

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In the Matter of: )  
)  
)

CERTAIN PRODUCTS AND )  
PHARMACEUTICAL COMPOSITIONS )  
CONTAINING RECOMBINANT )  
HUMAN ERYTHROPOIETIN )  
\_\_\_\_\_)

Investigation

No. 337-TA-\_\_\_\_\_

**COMPLAINT OF AMGEN INC. UNDER SECTION 337 OF THE  
TARIFF ACT OF 1930, AS AMENDED**

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- Exhibit 4:** U.S. Patent No. 5,621,080
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### Confidential Exhibits

- Exhibit A:** List for Foreign Patents and Applications
- Exhibit B:** Domestic Industry Claim Chart, U.S. Patent No. 5,441,868 claim 1 and exhibits
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- Exhibit D:** Domestic Industry Claim Chart, U.S. Patent No. 5,618,698 claim 7 and exhibits
- Exhibit E:** Domestic Industry Claim Chart, U.S. Patent No. 5,621,080 claim 4 and exhibits
- Exhibit F:** Domestic Industry Claim Chart, U.S. Patent No. 5,756,349 claim 7 and exhibits
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## I. INTRODUCTION

1.1 Complainant Amgen Inc. ("Amgen") respectfully requests the United States International Trade Commission to institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337"), and to remedy the unlawful importation into the United States, the unlawful sale for importation, and the unlawful sale within the United States after importation of articles that infringe the claims of valid and enforceable United States patents owned by Amgen.

1.2 Proposed Respondents Roche Holding Ltd., F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH (Penzberg and Mannheim), and Hoffmann La Roche, Inc. (hereafter collectively referred to as "Roche") are importing into the United States and are preparing to sell after importation a pharmaceutical composition that contains recombinant human erythropoietin ("EPO"), to which a polyethylene glycol ("PEG") polymer has been attached. Roche alternatively calls this composition "Ro50-3821," "R744" or "CERA" ("Continuous Erythropoiesis Receptor Activator") (hereinafter referred to as "PEG-EPO"). Roche's importation and use of PEG-EPO in the United States infringes one or more claims of the following six United States patents owned by Amgen: U.S. Patent No. 5,441,868, U.S. Patent No. 5,547,933, U.S. Patent No. 5,618,698, U.S. Patent No. 5,621,080, U.S. Patent No. 5,756,349, and U.S. Patent No. 5,955,422 (hereinafter the "Amgen Patents"). In addition, Amgen is informed and believes that PEG-EPO is made outside the United States by means of a process that is covered by one or more process claims of the Amgen Patents.

1.3 Amgen seeks a permanent exclusion order under 19 U.S.C. §§ 1337(d) and (f) prohibiting Proposed Respondents from importing certain products and

pharmaceutical compositions containing recombinant human EPO and from importing products made by means of a process covered by one or more claims of the Amgen Patents. Amgen also seeks an order directing Roche to cease any use, marketing, sale, offer to sell and/or distribution of products containing recombinant human EPO, and/or products made by means of a process covered by one or more claims of the Amgen Patents.

## **II. COMPLAINANT**

2.1 Complainant Amgen Inc. is a Delaware corporation with its principal place of business at One Amgen Center Drive in Thousand Oaks, California 91320-1799.

2.2 Founded in 1980, Amgen is a pioneer in the discovery, development and delivery of innovative therapeutic products based on advances in molecular biology, recombinant DNA technology and chemistry. For over a decade, Amgen's products have been improving the lives of millions of patients over a broad range of treatment indications. Amgen's success as a biotechnology company is attributable in part to the inventions of one of its original scientists, Dr. Fu-Kuen Lin, relating to recombinant human EPO, and the subsequent success of its EPO business.

## **III. PROPOSED RESPONDENTS**

3.1 Proposed Respondent Roche Holding Ltd. is the parent company for the group of wholly-owned or majority-owned Roche companies. Roche Holding Ltd., one of the largest pharmaceutical companies in the world, is headquartered in Basel, Switzerland at Grenzacherstrasse 124, CH-4070 Basel, Switzerland. Roche Holding Ltd. at times also goes by the name of the "Roche Group." The Roche Group has promoted PEG-EPO in presentations to investors.

3.2 Proposed Respondent F. Hoffmann-LaRoche Ltd. is a Swiss company headquartered in Basel, Switzerland at Grenzacherstrasse 124, CH-4070 Basel, Switzerland. F. Hoffmann-LaRoche Ltd. serves as the organizational unit for Roche's pharmaceutical division and is a named sponsor for the Proposed Respondents' United States clinical trials for PEG-EPO.

3.3 Proposed Respondent Roche Diagnostics GmbH is a German company that manufactures the recombinant human EPO (called "epoetin beta") that is the active ingredient of the PEG-EPO pharmaceutical composition that Roche is importing into the United States. The facilities of Roche Diagnostics GmbH responsible for the manufacture of epoetin beta are located at Nonnenwald 2, D-82377 Penzberg, Germany and Sandhofer Strasse 116, D-68305 Mannheim, Germany. The Roche Diagnostics GmbH facility located at Nonnenwald 2, D-82377 Penzberg, Germany is also responsible for distribution of PEG-EPO to the United States.

3.4 Proposed Respondent Hoffmann LaRoche, Inc. (hereinafter "Roche Nutley") is a wholly owned subsidiary of Roche Holding Ltd., and conducts pharmaceutical operations in the United States. Roche Nutley is organized under the laws of the State of New Jersey and has its principal place of business at 340 Kingsland Street, Nutley, New Jersey 07110. Roche Nutley is in the business of pharmaceutical discovery, development, manufacturing, marketing, and sales, and is currently hiring personnel to market and sell PEG-EPO in the United States. Roche Nutley is also responsible for distribution of PEG-EPO at least within the United States.

#### IV. NON-TECHNICAL DESCRIPTION OF AMGEN'S PATENTS

4.1 The six Amgen Patents at issue describe and claim several of Dr. Lin's pioneering inventions relating to EPO.

4.2 For many years before Dr. Lin's path-breaking inventions, there was a long-standing need for a therapeutically effective product to treat anemia and related blood disorders. Early attempts to recover a therapeutically effective EPO product from natural sources proved unsuccessful, yielding only very small quantities of highly unstable and/or impure proteins that were not therapeutically effective in treating anemic patients. Attempts to purify human EPO from cultured cells also proved futile, either because those cells were unavailable or because reports of their ability to produce EPO were overstated. Likewise, attempts to use conventional scientific techniques to identify the DNA and/or the amino acid sequence of human EPO also proved unsuccessful. Thus, before Dr. Lin's inventions, the world not only lacked the ability to obtain therapeutically effective human EPO, it also lacked the knowledge whether isolated human EPO could be therapeutically effective for the treatment of anemia or any other blood disorder.

4.3 Dr. Lin solved these problems through a succession of inventions that yielded the first—and to date only—therapeutically effective human EPO products. These pioneering inventions include Dr. Lin's isolation and characterization of DNA that encodes human EPO; identification of the amino acid sequence of human EPO; creation of vertebrate and other cells capable of producing human and other EPOs in abundance when grown in culture; development of methods for producing glycosylated EPO polypeptides; creation of non-naturally-occurring erythropoietin glycoproteins which themselves proved enormously valuable in unleashing research and diagnostics to better

understand EPO and anemia, and invention of the first therapeutically effective human EPO products, including pharmaceutical compositions effective for the therapeutic treatment of severely anemic patients. Indeed, no one to date, including Roche, has been able to create a safe and therapeutically effective EPO product, other than by using the inventions described and claimed by Dr. Lin, for the treatment of anemia or other erythropoietic disorders.

4.4 Dr. Lin's inventions demonstrated for the first time that recombinant human EPO could be an effective treatment for anemia and other blood disorders.

4.5 These pioneering inventions resulted in a succession of issued patents, both in the United States and around the world. In the United States, because Dr. Lin's patent application described a number of different inventions, the Patent Office required him to file and prosecute separate applications for each of his different inventions.

Ultimately, seven separate United States patents issued to Dr. Lin.

4.6 The first of these patents was U.S. Patent No. 4,703,008 (now expired and not asserted here), which issued on October 27, 1987. It described and claimed certain purified and isolated DNA sequences encoding EPO. Dr. Lin's next issued patent, U.S. Patent No. 5,441,868 (the "'868 patent"), is directed to processes for the production of glycosylated erythropoietin polypeptides having certain properties by growing certain mammalian host cells transformed or transfected with an isolated DNA sequence encoding human erythropoietin. Dr. Lin's third patent, U.S. Patent No. 5,547,933 (the "'933 patent"), is directed to non-naturally occurring human EPO glycoproteins having certain properties specified in various claims. Dr. Lin's next patent, U.S. Patent No. 5,618,698 (the "'698 patent"), is directed to processes for the production of EPO

polypeptides by growing cells having certain characteristics e.g., mammalian host cells transformed or transfected with non-EPO promoter DNA that is operatively linked to EPO DNA or cells having amplified EPO DNA. U.S. Patent No. 5,621,080 (the “‘080 patent”) is directed to non-naturally occurring EPO glycoproteins having certain properties, including a specified amino acid sequence, and pharmaceutical compositions containing such EPO glycoproteins. Dr. Lin’s U.S. Patent No. 5,756,349 (the “‘349 patent”) is directed to certain vertebrate cells capable of growth in culture that have been engineered to produce human erythropoietin as well as processes for producing erythropoietin comprising the step of culturing such cells under suitable nutrient conditions. And, U.S. Patent No. 5,995,422 (the “‘422 patent”) is directed to pharmaceutical compositions comprising a therapeutically effective amount of human erythropoietin purified from mammalian cells grown in culture.

4.7 Today, thanks to the inventions described and claimed in the Amgen Patents, millions of patients worldwide have been freed from the debilitating effects of chronic anemia and the health hazards of repeated blood transfusions. These inventions have also provided the tools to unleash research across many medical and scientific disciplines that have contributed significantly to our current understanding of erythropoiesis, anemia and the treatment of anemia. The pioneering nature of Dr. Lin’s inventions has been widely recognized by the scientific community, the United States Food and Drug Administration, the President of the United States, and a succession of courts both here and abroad.

## **V. DR. LIN’S PATENTS**

### **A. The Amgen Patents at Issue**

5.1 Six of Dr. Lin's U.S. patents, all assigned to and owned by Amgen, are at issue here:

a. The '868 Patent, issued on August 15, 1995, claims processes for the production of glycosylated EPO polypeptides having specified *in vivo* biological properties by growing certain mammalian host cells transformed or transfected with an isolated DNA sequence encoding human EPO. A certified copy of the '868 Patent is attached hereto as **Exhibit 1**.

b. The '933 patent, issued on August 20, 1996, claims non-naturally occurring human EPO glycoproteins having specified *in vivo* biological properties that are produced by the process of growing mammalian host cells transformed or transfected with an isolated DNA sequence encoding human EPO, pharmaceutical compositions containing said human EPO glycoproteins, and methods for using such pharmaceutical compositions. A certified copy of the '933 patent is attached hereto as **Exhibit 2**.

c. The '698 patent, issued on April 8, 1997, claims processes for the production of glycosylated EPO polypeptides having specified *in vivo* biological properties by growing certain mammalian host cells transformed or transfected with non-EPO promoter DNA that is operatively linked to EPO DNA or cells having amplified EPO DNA. A certified copy of the '698 Patent is attached hereto as **Exhibit 3**.

d. The '080 patent, issued on April 15, 1997, claims non-naturally occurring EPO glycoproteins having certain *in vivo* biological activity and a specified amino acid sequence, pharmaceutical compositions containing such EPO glycoproteins, and methods for using such pharmaceutical compositions.. A certified copy of the '080 Patent is attached hereto as **Exhibit 4**.

e. The '349 patent, issued on May 26, 1998, claims certain vertebrate cells capable of growth in culture that have been engineered to produce human EPO as well as processes for producing human EPO comprising the step of culturing said cells under suitable nutrient conditions. A certified copy of the '349 Patent is attached hereto as **Exhibit 5**.

f. The '422 patent, issued on September 21, 1999, claims pharmaceutical compositions comprising a therapeutically effective amount of human EPO purified from mammalian cells grown in culture. A certified copy of the '422 Patent is attached hereto as **Exhibit 6**.

5.3 The six Amgen Patents share a common specification and each claims priority from United States Patent Application Serial No. 561,024, which was filed on December 13, 1983, as well as from three continuation-in-part applications, Serial Nos. 582,185, 655,841, and 675,298, filed February 21, 1984, September 28, 1984, and November 30, 1984, respectively. Each of the Amgen Patents at issue is a continuation of a common ancestor — the application which issued as United States Patent No. 4,703,008 — which was at issue in the Federal Circuit's landmark decision in *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991) and has since expired.

5.4 Under Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by the following: (1) a certified copy and three additional copies of each of the prosecution histories of the '868, '933, '698, '080, '349 and '422 patents (each set bearing Bates Nos. AM-ITC000001 to AM-ITC000859, AM-ITC000860 to AM-ITC001621, AM-ITC001622 to AM-ITC001866, AM-ITC001867 to AM-ITC 002175, AM-ITC002176 to AM-ITC002502, and AM-

ITC002503 to AM-ITC003337, respectively); and (2) four copies of each reference document mentioned in the prosecution histories of each patent at issue (bearing Bates Nos. AM-ITC007865 to AM-ITC029666).

**B. Amgen's Ownership**

5.5 On December 13, 1983, Dr. Fu-Kuen Lin, the named inventor on each of the Amgen Patents, assigned to Amgen all of his right, title, and interest in U.S. Patent Application No. 561,024, which disclosed the inventions ultimately claimed in the issued '868, '933, '698, '080, '349, and '422 patents. A certified copy of that assignment is attached hereto as **Exhibit 7**. On February 20, 1984, November 29, 1984, and November 29, 1984, Dr. Lin assigned to Amgen all of his right, title, and interest to the series of continuation-in-part applications discussed above (application nos. 582,185, 655,841, and 675,298, respectively), each of which claimed priority to Dr. Lin's first filed application. A certified copy of each of these assignments is attached hereto as **Exhibits 8, 9, and 10**.

5.6 Amgen subsequently assigned each of these applications to Kirin-Amgen. Certified copies of these assignments are attached hereto as **Exhibit 11**. Kirin-Amgen has since re-assigned its U.S. rights to Amgen so that Amgen presently holds all right, title, and interest in and to the Amgen Patents. Certified copies of the assignments from Kirin-Amgen back to Amgen are attached hereto as **Exhibit 12**.

**VI. THE PRODUCT AT ISSUE**

6.1 On information and belief, the pharmaceutical composition Roche is currently importing into the United States contains recombinant glycosylated human EPO to which Roche has attached a polyethylene glycol polymer ("PEG").

6.2 On information and belief, the glycosylated human EPO in Roche's PEG-EPO has the amino acid sequence (protein sequence) and is glycosylated as described and claimed in the Amgen Patents.

6.3 On information and belief, the glycosylated human EPO in Roche's PEG-EPO stimulates the production of reticulocytes and red blood cells. It is the glycosylated human EPO in PEG-EPO, not the attached PEG polymer, that confers on PEG-EPO its reported ability to cause bone marrow cells to increase their production of reticulocytes and red blood cells. But for the recombinant glycosylated human EPO in PEG-EPO, Roche's imported product would not be a therapeutically effective pharmaceutical composition.

## **VII. PROPOSED RESPONDENTS' UNLAWFUL ACTIVITIES**

### **A. Roche's Infringing Processes, Products, and Pharmaceutical Compositions**

7.1 On information and belief, Roche is currently importing for use and imminent sale in the United States pharmaceutical compositions containing PEG-EPO.

7.2 On information and belief, Roche is offering for sale or imminently preparing to sell in the United States after importation pharmaceutical compositions containing PEG-EPO.

7.3 On information and belief, the recombinant glycosylated human EPO in Roche's PEG-EPO is made abroad by means of a process covered by one or more process claims of the Amgen Patents.

7.4 On information and belief, Roche manufactures the recombinant glycosylated human EPO in PEG-EPO by first growing genetically modified Chinese

Hamster Ovary (CHO) cells in culture. These cells, referred to as the DN2-3 $\alpha$ 3 cell line, were established by transfecting a CHO cell with an isolated cDNA sequence encoding human EPO. The EPO DNA in the DN2-3 $\alpha$ 3 cell line was amplified using a selectable marker gene (DHFR) and stepwise exposure to the selection agent methotrexate (MTX) and thus contains an increased number of copies of the EPO DNA.

7.5 On information and belief, Roche cultures the DN2-3 $\alpha$ 3 cell line in a culture medium under suitable nutrient conditions and isolates glycosylated human EPO from the cell culture media.

7.6 On information and belief, Roche licensed the DN2-3 $\alpha$ 3 cell line from Genetics Institute and uses that cell line to manufacture the recombinant glycosylated human EPO product it currently sells in Europe under the brand name NeoRecormon® (epoetin beta), as well as to manufacture the recombinant glycosylated human EPO in PEG-EPO.

7.7 On information and belief, Roche has formulated its imported PEG-EPO product into a pharmaceutical composition that includes a sodium phosphate buffer — a pharmaceutically acceptable diluent and/or carrier.

7.8 On information and belief, PEG-EPO is made by means of a process that includes growing mammalian cells transformed or transfected with an isolated DNA sequence encoding human EPO and isolating a glycosylated EPO polypeptide therefrom. PEG-EPO is made by means of a process that is covered by at least claims 1 and 2 of Amgen's '868 Patent. Its importation violates 19 U.S.C. § 1337(a)(1)(B)(ii) and infringes such claims under 35 U.S.C. § 271(g).

7.9 On information and belief, PEG-EPO contains a non-naturally occurring recombinant EPO glycoprotein product produced by mammalian cells transfected with a DNA sequence encoding human EPO and/or encoding the leader sequence of human erythropoietin and is being used in the United States to treat kidney dialysis patients. Roche thus infringes at least claims 3, 4, 5, and 11 of Amgen's '933 Patent by the importation, offer for sale, imminent sale and/or use in the United States of PEG-EPO and its importation violates 19 U.S.C. § 1337(a)(1)(B)(i).

7.10 On information and belief, PEG-EPO and pharmaceutical compositions containing PEG-EPO are made by means of a process that includes growing vertebrate cells comprising amplified DNA encoding human EPO and isolating the glycosylated EPO polypeptide expressed by said cells. PEG-EPO and pharmaceutical compositions containing PEG-EPO thus are made by means of a process that is covered by claims 4-9 of Amgen's '698 Patent. Their importation violates 19 U.S.C. § 1337(a)(1)(B)(ii) and also infringes such claims under 35 U.S.C. § 271(g).

7.11 On information and belief, pharmaceutical compositions containing PEG-EPO include a non-naturally-occurring recombinant EPO glycoprotein having the specified *in vivo* activity and an amino acid sequence equivalent to the mature amino acid sequence of Figure 6 in the '080 Patent. Roche thus infringes at least claims 4 and 6 of the '080 Patent by the importation, offer for sale, imminent sale and/or use in the United States of its PEG-EPO product and its importation violates 19 U.S.C. § 1337(a)(1)(B)(i).

7.12 On information and belief, PEG-EPO is made by means of a process that includes the step of culturing vertebrate cells which can be propagated *in vitro* and which are capable upon growth in culture of producing EPO in the medium of their growth in

excess of 100 U of EPO per  $10^6$  cells in 48 hours as determined by radioimmunoassay, said cells comprising non-human DNA sequences which control transcription of DNA encoding human EPO. PEG-EPO and pharmaceutical compositions containing PEG-EPO thus are made by means of a process that is covered by at least claim 7 of Amgen's '349 Patent. Their importation violates 19 U.S.C. § 1337(a)(1)(B)(ii) and also infringes claim 7 under 35 U.S.C. § 271(g).

7.13 On information and belief, pharmaceutical compositions containing PEG-EPO include human EPO purified from mammalian cells grown in culture. Roche thus infringes claim 1 of the '422 patent by the importation, offer for sale, imminent sale and/or use in the United States of pharmaceutical compositions containing PEG-EPO and its importation violates 19 U.S.C. § 1337(a)(1)(B)(i).

**B. Roche's Unlawful Importation**

7.14 On information and belief, Roche manufactures the glycosylated human EPO in PEG-EPO in Europe. It does not manufacture such EPO in the United States.

7.15 On information and belief, Roche has imported and is importing products containing glycosylated human EPO manufactured in Europe, as well as pharmaceutical compositions containing glycosylated human EPO, into the United States. In addition, Roche has used and is using the imported PEG-EPO and pharmaceutical compositions containing PEG-EPO in the United States to treat anemic patients under the auspices of clinical trials.

**C. Roche's Timeline to Market**

7.16 Roche has announced that it plans to sell a PEG-EPO pharmaceutical composition in direct competition with Amgen in the United States as soon as possible after it receives FDA approval to do so.

7.17 On information and belief, Roche is currently testing the safety and efficacy of pharmaceutical compositions containing PEG-EPO in both nephrology and oncology patients, and has publicly stated its intent to file imminently an application for FDA approval to sell PEG-EPO and/or pharmaceutical compositions containing PEG-EPO in the United States for the nephrology indication.

7.18 Roche has stated publicly that it intends to soon file in 2006 a Biologics License Application ("BLA") in the United States with the Food and Drug Administration ("FDA") seeking permission to market and sell its PEG-EPO product in the United States. To this end, it has closed enrollment in its pivotal Phase III clinical trial and its long-term safety study, it has announced completion of four Phase III clinical trials in nephrology, and is currently completing its collection of data from its Phase III trials to finalize its BLA submission for the nephrology indication.

7.19 According to the FDA's Performance Goals and Procedures Guideline for the Prescription Drug User Fee Act (PDUFA), FDA will act on Roche's BLA submission within 10 months after it is filed. Based on this schedule, Roche could have regulatory approval to market and sell its PEG-EPO product in the United States by as early as the first quarter of 2007.

7.20 In anticipation of this approval to market and sell PEG-EPO in the United States, Amgen is informed and believes that Roche has been and is making meaningful preparations to market and sell PEG-EPO in the United States, including:

- a. Hiring key management, support, and sales personnel, including actively recruiting Amgen marketing and medical personnel involved in the sale and use of recombinant human EPO, to market and sell PEG-EPO upon receipt of regulatory approval to market and sell PEG-EPO in the United States;
- b. Retaining outside consultants and vendors, including former Amgen employees, to assist in its marketing, promotion, and sale of PEG-EPO in the United States;
- c. Contacting potential customers, including large dialysis organizations ("LDOs") and nephrologists, to solicit interest in purchasing PEG-EPO from Roche upon regulatory approval in the United States; and
- d. Completing construction and commencing operations of a new facility in Penzberg Germany to manufacture the recombinant human EPO in PEG-EPO for export to the United States, at a reported cost of 182 million Euros.
- e. Engaging third-party payor organizations, including the Centers for Medicare and Medicaid Services, on matters relating to reimbursement and price for PEG-EPO's use in treating anemia in patients with end stage renal disease.

7.21 Most recently, in response to a district court lawsuit filed by Amgen against F. Hoffmann-LaRoche Ltd., Roche Diagnostics GmbH and Roche Nutley alleging infringement of the Amgen Patents (more fully described below at ¶ 11.1), Roche has stated that Amgen's patents do not stand in its way to market PEG-EPO and

that “there is no impediment to Roche moving ahead in the U.S.” with its PEG-EPO product.

7.22 These activities and announcements indicate that Roche anticipates selling its PEG-EPO product in the United States before the end of the first half of 2007.

**D. Claim Charts**

7.23 In accordance with Commission Rule 210.12 (a)(9)(vii), claim charts applying an exemplary claim from each of the Amgen Patents to the Roche’s PEG-EPO product and the processes by which it is made are attached to this Complaint.

7.24 Attached as **Exhibit 13** is the claim chart and accompanying exhibits applying claim 1 of the ‘868 patent to Roche’s process for making PEG-EPO.

7.25 Attached as **Exhibit 14** is the claim chart and accompanying exhibits applying claim 3 of the ‘933 patent to Roche’s PEG-EPO product.

7.26 Attached as **Exhibit 15** is the claim chart and accompanying exhibits applying claim 7 of the ‘698 patent, as well as claim 6 of the ‘698 patent from which claim 7 depends, to Roche’s process for making PEG-EPO.

7.27 Attached as **Exhibit 16** is the claim chart and accompanying exhibits applying claim 4 of the ‘080 patent, as well as claim 3 of the ‘080 patent from which claim 4 depends, to Roche’ PEG-EPO pharmaceutical composition.

7.28 Attached as **Exhibit 17** is the claim chart and accompanying exhibits applying claim 7 of the ‘349 patent, as well as claim 1 of the ‘349 patent from which claim 7 depends, to Roche’s process for using cells to make its PEG-EPO product.