James F. Hurst (*pro hac vice application to be filed*)
jhurst@winston.com
Maureen L. Rurka (*pro hac vice application to be filed*)
mrurka@winston.com
James M. Hilmert (*pro hac vice application to be filed*)
jhilmert@winston.com
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, IL 60601-9703
Telephone: (312) 558-5600
Facsimile: (312 558-5700

K. Joon Oh (SBN: 246142)
koh@winston.com
WINSTON & STRAWN LLP
101 California Street
San Francisco, CA 94111-5802
Telephone: (415) 591-1000
Facsimile: (415) 591-1400

Ian Nomura (SBN: 269048)
inomura@winston.com
WINSTON & STRAWN LLP
333 S. Grand Avenue
Los Angeles, CA 90071-1543
Telephone: (213) 615-1700
Facsimile: (213) 615-1750

Attorneys for Plaintiff
SANDOZ INC.

NC

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT

SANDOZ INC.,

Plaintiff,

v.

AMGEN INC. and HOFFMAN-LA ROCHE INC.,

Defendants.

Case No. CV 13 2904

COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT INVALIDITY AND NON-INFRINGEMENT

[REDACTED]

Plaintiff Sandoz Inc. brings this action for declaratory judgment of patent non-infringement and invalidity against Defendants Amgen Inc., and Hoffmann-La Roche Inc. Sandoz alleges as follows:

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

NATURE OF THE ACTION

1. This is a civil action arising under the patent laws of the United States, Title 35, United States Code, seeking a declaration of non-infringement, unenforceability, and invalidity of U.S. Patent Nos. 8,063,182 and 8,163,522.

2. The '182 and '522 patents issued in November 2011 and April 2012, respectively, without prior notice to the public, based on unpublished patent applications filed over fifteen years earlier on May 19, 1995. The '182 and '522 patents purport to claim proteins which bind tumor necrosis factor and methods for making such proteins. According to Amgen, the patents cover a protein called "etanercept," which Amgen markets under the brand name Enbrel. Enbrel is an FDA-approved biologic drug indicated to improve symptoms in patients with rheumatoid arthritis and other conditions.

3. In 2004, long before the '182 and '522 patents issued, Sandoz began developing a biologic drug containing etanercept to compete with Enbrel. Since that time, Sandoz has devoted substantial effort and tens of millions of dollars developing its etanercept product. Today, Sandoz has a complete and definite product that has been tested in humans and has proceeded to Phase III clinical trials. Following those trials, Sandoz intends to file an application with the U.S. Food and Drug Administration seeking approval to manufacture and sell its product. Sandoz expects to file its FDA application within the next [redacted] and expects approval approximately [redacted] thereafter. Upon approval, Sandoz intends to immediately market its product in the United States prior to the expiration of the '182 and '522 patents.

4. The '182 and '522 patents are invalid and unenforceable. Nevertheless, Amgen seeks to use the '182 patent and the '522 patent to block competition from Sandoz's product and to extend its patent monopoly on Enbrel until 2029—over a decade-and-a-half past the date that its previous patents covering Enbrel expired, and nearly three and a half decades after the patents were filed. Amgen has announced that the '182 and '522 patents provide it with market "exclusivity" against competitive products, and it has informed the public that it will maintain its exclusivity by enforcing its patent rights.

5. Amgen's patent position places a cloud of legal uncertainty over Sandoz's etanercept product and business operations. Because Amgen's applications were not published when Sandoz began developing etanercept, Sandoz was unaware of their existence until they issued. Sandoz took significant steps in preparation for commercializing etanercept in reliance on the expectation it would be able to begin marketing immediately upon FDA approval and without the cloud of potential infringement claims. Sandoz is now faced with the quandary that any further significant investment it makes in its etanercept product may be wasted, and its commercial marketing will be met with claims for substantial damages or injunctive relief, based on Amgen's allegations about its new patent position. To remove this cloud of uncertainty, Sandoz seeks a declaration that the '182 and '522 patents are invalid and that its etanercept product does not infringe any of their claims.

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

PARTIES

6. Plaintiff Sandoz Inc. is a company organized and existing under the laws of the state of New Jersey, having a principal place of business at 506 Carnegie Drive, Suite 400, Princeton, New Jersey 08540. Sandoz Inc. is in the business of manufacturing and bringing to market medicines and technologies for patients at affordable prices. Sandoz Inc. will be responsible for the marketing and distribution of a product containing etanercept in the United States.

7. On information and belief, Defendant Amgen Inc. is a company organized and existing under the laws of the State of California, having a principal place of business at One Amgen Center Drive, Thousand Oaks, California, 91320. Amgen develops, manufactures, and markets branded drug products and regularly conducts business throughout the United States, including the State of California. Amgen manufactures, markets, and distributes Enbrel throughout the United States, including in California, and is licensed to do business in the State of California.

8. On information and belief, Defendant Hoffmann-La Roche Inc. is a company organized and existing under the laws of New Jersey with a principal place of business at 340 North Kingsland Street, Nutley, New Jersey, 07110. The headquarters for commercial

operations for Roche are located at 1 DNA Way, South San Francisco, California, 94080. Roche develops, manufactures, and markets branded drug products, and continuously and systematically conducts business throughout the United States, including the State of California, and is licensed to do business in the State of California.

JURISDICTION AND VENUE

9. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States of America, Title 35 of the United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Amgen because, among other things, Amgen has continuous and systematic contacts with the State of California, including maintaining its headquarters and multiple facilities in California, and marketing, distributing, and selling its pharmaceutical products, including Enbrel, in California.

11. This Court has personal jurisdiction over Roche because, among other things, Roche has continuous and systematic contacts with the State of California, including maintaining a commercial headquarters and other facilities in the Northern District of California, and marketing, distributing, and selling its pharmaceutical products in California. In addition, on information and belief, Roche has an agreement with Amgen, which is located in California, to exclusively license Amgen under the '182 and '522 patents to make, use, and sell Enbrel.

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) because Amgen and Roche are subject to personal jurisdiction in this Judicial District.

INTRADISTRICT ASSIGNMENT

13. This action is not subject to divisional assignment because the case arises under intellectual property laws.

BACKGROUND

14. In the 1990s, Amgen's predecessor Immunex Corp. developed Enbrel, a treatment for TNF-dependent inflammatory disorders, comprising the protein etanercept.

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

Immunex submitted Biologic License Application ("BLA") No. 103795 with the FDA for permission to manufacture, market, and distribute Enbrel for the treatment of certain disorders. In 1998, the FDA approved Enbrel for the treatment of moderate to severe rheumatoid arthritis. Enbrel is now indicated for the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. Exhibit A at 1, 3–4 (Enbrel Prescribing Information).

15. Since Enbrel was first approved in 1998, Amgen and its precedessor Immunex have claimed it was protected by patents.

16. Immunex sought and obtained patent coverage related to Enbrel though a string of applications filed in the early 1990s. For example, the U.S. Patent and Trademark Office issued U.S. Patent No. 5,395,760 to Immunex in 1995, and issued U.S. Patent No 5,605,690 to Immunex in 1997.

17. In 2002, Amgen acquired Immunex, including the rights to BLA No. 103795 and its patent rights.

18. From the time of its acquisition of Immunex to the present, Amgen has marketed Enbrel in the United States, claiming that it was protected by the '760 and '690 patents.

19. The '760 patent expired in 2012. The '690 patent will expire in 2014.

THE '182 PATENT

20. On November 22, 2011—nearly two decades after Immunex first obtained patent coverage for etanercept and seven years after Sandoz began product development—the PTO unlawfully issued the '182 patent. The '182 patent states that it issued from an application filed in 1995. It is entitled "Human TNF Receptor Fusion Protein," identifies Roche as the assignee, and lists Manfred Brockhaus, Reiner Gentz, Dembic Zlatko, Werner Lesslauer, Hansruedi Lotscher, and Ernst-Jurgen Schlaeger as the inventors.

21. On information and belief, Roche currently claims to have right, title, and interest in the '182 patent.

22. Amgen has stated that it is the exclusive licensee under the '182 patent.

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

23. On information and belief, because Roche has exclusively licensed the '182 patent to Amgen, Roche lacks the authority to license the '182 patent to any third party, including Sandoz.

24. Upon information and belief, Amgen has the right to enforce the '182 patent, either in its own name, or by having the right to join Roche as a party to an infringement suit.

25. Amgen claims that the '182 patent covers etanercept.

26. The original application to which the '182 patent claims priority, U.S. Patent Application No. 07/580,013, was filed in 1990, more than twenty-one years before the '182 patent issued. Throughout the prosecution of the '182 patent, the claims were primarily, and for a time exclusively, focused on a protein and method of manufacturing the protein that is not etanercept. It was not until 2005, fifteen years later and around the time that Sandoz began its development program, that the prosecution focus shifted to a protein that Amgen claims is etanercept. No substantive prosecution began on the claims that purportedly cover etanercept until 2005.

27. This unexplained and unreasonable delay in prosecution resulted in a significant delay in patent issuance. This delay caused significant prejudice to Sandoz, which began development of its etanercept product without knowledge of the pending application, thereby acquiring intervening rights. According to Amgen's public statements, the term of the '182 patent is presently set to expire on November 22, 2028, seventeen years after its issuance and 38 years after the filing of the original application.

THE '522 PATENT

28. Five months after the PTO issued the '182 patent, on April 24, 2012, the PTO unlawfully issued the '522 patent. Like the '182 patent, the '522 patent issued from an application filed in 1995. It is entitled "Human TNF Receptor," names Roche as the assignee, and identifies Manfred Brockhaus, Reiner Gentz, Dembic Zlatko, Werner Lesslauer, Hansruedi Lotscher, and Ernst-Jurgen Schlaeger as the inventors.

29. On information and belief, Roche currently claims to have right, title, and interest in the '522 patent.

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

30. On information and belief, Amgen is the exclusive licensee under the '522 patent.

31. On information and belief, because Roche has exclusively licensed the '522 patent to Amgen, Roche lacks the authority to license the '522 patent to any third party, including Sandoz.

32. On information and belief, Amgen has the right to enforce the '522 patent, either in its own name, or by having the right to join Roche as a party to an infringement suit.

33. Amgen claims that the '522 patent protects Enbrel.

34. The '522 patent claims priority to the same original 1990 application, the '013 application as the '182 patent. Like the '182 patent, the prosecution of the '522 patent was unreasonably and inexplicably delayed due to Amgen's and Roche's belated change in the focus of the claims late in prosecution to those purportedly covering etanercept. Prior to issuance, Sandoz acquired intervening rights. According to Amgen, the term of the '522 patent is presently set to expire April 24, 2029, 39 years after the original application was filed.

SANDOZ'S PRODUCT DEVELOPMENT

35. Sandoz began developing its own etanercept product in 2004. At that time, Sandoz expected to be able to manufacture and sell its product immediately upon receiving FDA approval because, to its knowledge, all relevant patents purporting to cover etanercept would have expired before then. Sandoz timed its product development such that its commercial marketing would coincide with, or post-date, the expiration of these patents, including the Immunex patents. Sandoz was unaware of the applications from which the '182 and '522 patents issued, because those applications were unpublished and were not publicly available.

36. Since 2004, Sandoz has undertaken a comprehensive process development for its etanercept product. Sandoz first developed a cell line focusing on comparable quality attributes compared to Enbrel. Sandoz then developed an upstream process with a final selected cell-line clone, followed by extensive downstream process development and proof

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

of similarity to Enbrel, including physicochemical and bioanalytical characterization of its product. Sandoz transferred its processes to large scale production to perform Phase I clinical trials. Sandoz also conducted significant development for the drug product, a pre-filled syringe containing etanercept.

37. Sandoz engaged in drug substance process optimization for Phase III clinical studies, produced the drug substance for the Phase III clinical trials, and conducted a comparability exercise to the Phase I drug substance involving extensive method development and validation studies. Following the comparability exercise, Sandoz produced the drug product for Phase III clinical trials. Sandoz also developed an extensive drug substance characterization program to validate that its drug substance is etanercept, and is comparable to Enbrel.

38. This analysis and process development required investments of about [redacted] in direct costs, plus additional indirect costs.

39. Starting in 2009, Sandoz has also engaged in a preclinical development program designed to meet the FDA's regulatory requirements. This preclinical development program included two pharmacokinetic studies in rabbits, a four-week toxicity study in cynomolgus monkeys, and two efficacy studies in transgenic mice. Sandoz has invested more than [redacted] in direct and indirect investment into this program, plus indirect costs, and the program is ongoing.

40. Beginning in 2010, Sandoz initiated meetings with the FDA regarding an application for its etanercept product. Sandoz continues to meet regularly with FDA officials regarding regulatory requirements to support its application and to seek input on its clinical research program. These meetings have cost more than [redacted] plus indirect costs.

41. After the initiation of meetings with the FDA, Sandoz began its Phase I clinical study program. In 2011 and 2012, Sandoz conducted two Phase I clinical trials in humans. The Phase I clinical study program required investment of [redacted] plus indirect costs.

42. Finally, Sandoz recently initiated a Phase III clinical study testing the efficacy and safety of its etanercept product. The first patient was enrolled in June 2013. Sandoz

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

expects the Phase III study to require investment of at least [redacted] plus indirect costs. In total, Sandoz expects to invest more than [redacted] in development of the product, plus indirect costs.

43. Sandoz is preparing to file an application with the FDA for regulatory approval to market and sell etanercept in the United States. As part of this effort, Sandoz will be required to increase its production capabilities, mainly to meet the expected demand for its etanercept product. Sandoz will be required to expand its physical space as well as add equipment in order to increase its manufacturing capacity four-fold. This expansion project has already begun and will take years to complete. Sandoz has already invested [redacted] in this manufacturing expansion, just to get a rough estimate of costs and plans. In the end, it will likely cost [redacted] to obtain the extension, most of which is attributable to the need for increased manufacturing capacity for etanercept. All of these steps that Sandoz has taken and will need to continue to take, create opportunity costs for Sandoz. Money and resources that Sandoz has invested—and will need to continue to invest in etanercept to continue its development program—would have been and could be invested elsewhere. The issuance of these patents, arising unexpectedly at the eleventh hour of Sandoz's development program, is forcing Sandoz to make difficult decisions about its future investments surrounded by a cloud of uncertainty.

44. In sum, Sandoz has been engaged in the development of its etanercept product for over nine years, has engaged in systematic efforts to meet the FDA's regulatory requirements, and has taken substantial steps toward the commercialization of its product. Sandoz's etanercept product is not subject to change in way that is relevant to the current dispute. If Sandoz wishes to use the results of the extensive studies it has already run, which it has already invested in, and designed based on its interactions with the FDA (which it does), Sandoz cannot alter its product before submission of its application. As such, the dispute regarding whether Sandoz's etanercept product will infringe any valid and enforceable claim of the patents at issue is sufficiently real and fixed to allow adjudication of all relevant issues.

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

NATURE OF THE CONTROVERSY BETWEEN THE PARTIES

45. There is a real, immediate, and substantial controversy between Sandoz, on the one hand, and Amgen and Roche, on the other, regarding the validity and infringement of the '182 and '522 patents.

46. Sandoz, on the one hand, seeks to enter the United States market with an affordable etanercept product that will compete with Enbrel, and contends that the '182 and '522 patents do not cover that product and are invalid. Although the '182 and '522 patent are invalid and do not cover either Enbrel or Sandoz's etanercept product, Amgen claims that the '182 and '522 patents cover both Enbrel and etanercept generally, and seeks to exclude competition from Sandoz and other potential competitors based on its exclusive license from Roche to those patents.

47. Enbrel currently faces no competition from generic or other branded etanercept products in the United States. In the absence of any competition, Enbrel sales alone comprised 25% of Amgen's total 2012 revenues, making it Amgen's second largest product by revenue. In its 2012 Annual Report, Amgen reported that it had in excess of $4.2 billion in sales of Enbrel in the United States and Canada.

48. The '182 and '522 patents are critical to Amgen's long-term strategy for Enbrel. Based on the rights in the '182 and '522 patents it has acquired from Roche, Amgen claims to possess a patent monopoly until April 2029—another sixteen years of exclusive sales. By maintaining exclusivity over etanercept against biosimilar competition, Amgen has been able to increase the price of Enbrel for its own benefit and to the detriment of the general public, and, upon information and belief, intends to continue to do so. In 2012, for example, Amgen increased its United States revenues from Enbrel by 15%, principally by raising the cost of the drug for American patients and their insurers.

49. According to Amgen's 2012 Annual Report, Amgen's currently markets and co-promotes Enbrel in the United States pursuant to a collaboration agreement with Pfizer Inc. Under the agreement, Amgen currently pays Pfizer a percentage of annual gross profits on Enbrel sales in the United States and Canada attributable to all approved indications on a

scale that increases as gross profits increase. The co-promotion term of the agreement expires October 31, 2013. Thereafter, Amgen will be required to pay Pfizer significantly smaller royalties for three years. Effective November 1, 2016, Amgen will not pay Pfizer any further royalties on Enbrel sales. Consequently, Enbrel stands to become more profitable for Amgen in the future, under the extended patent term Amgen claims based on the '182 and '522 patents.

50. For these and other reasons, in its 2012 Annual Report, Amgen advised the public that both the '182 and the '522 patents were "material" to its Enbrel sales, and hence, material to its overall business.

51. Amgen intends to enforce its position in these patents to prevent any generic or biosimilar version of Enbrel from competing in the U.S. market. In both its 2011 and 2012 Annual Reports, Amgen explained: "Our success depends in part on our ability to obtain and defend patent rights and other intellectual property rights that are important to the commercialization of our products and product candidates."

52. Amgen has repeatedly broadcast its claims that the '182 and '522 patents cover etanercept and its intent to use those patents to ensure product "exclusivity" for Enbrel against biosimilar etanercept products.

53. In a press release immediately following the issuance of the '182 patent, Amgen stated its view that "[t]he patent describes and claims the fusion protein that is etanercept, and by statute, the '182 patent has a term of 17 years from today."

54. In December 2011, the Pacific Coast Business Times quoted an Amgen representative as stating: "This newly issued patent to the fusion protein that is etanercept adds to [existing] patent protection," and "We are confident in our ability to protect our products and, as we previously stated, we do not envision Enbrel biosimilar competition in the United States for the foreseeable future."

55. At an Oppenheimer & Co. Healthcare Conference in December 2011, Amgen's representative announced: "Recently you may have also seen some news pertaining to a new patent that has been issued that is a patent just known as the 182 patent. It is a composition-

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

of-matter patent that goes out to 2028, and with a broad patent estate that we have now established for Enbrel, we feel that the market exclusivity for Enbrel is going to be prolonged and we don't anticipate any biosimilar competition in the foreseeable future."

56. In a conference call discussing Amgen's first quarter 2012 earnings, Amgen's CEO stated, with reference to the '182 and '522 patents: "Of course, we look forward to ongoing intellectual property protection for Enbrel. Enbrel is a franchise that we've enjoyed successfully for the past 14 years, and we're looking forward to a number of more years of Enbrel as the market leader in this category."

57. In a November 2012 Piper Jaffray Healthcare Conference, Amgen's representative again broadcast its alleged patent "exclusivity" for etanercept: "Our second-largest category, which is Enbrel. You might recall last year there was a lot of uncertainty in terms of the exclusivity of Enbrel, but we have a new patent that has been issued that goes out to 2029. So there is kind of a renewed lease on Enbrel's life so we do have extended exclusivity on this product."

58. At a JP Morgan Healthcare Conference in 2013, Amgen's representative likewise stated, based on the '182 and '522 patents: "Enbrel, as I hope you are all aware, is a product for which we will enjoy patent exclusivity now for an extended period of time."

59. At a May 2012 Deutsche Bank Health Care Conference, Amgen's representative repeated: "On Enbrel, recently we secured a new patent that goes out to 2028, and this kind of emboldens our view that we are going to have added exclusivity on this product. And this has also given us confidence to look at ways to further invest in this particular brand. . . . Given this added exclusivity that we now have on Enbrel, we are not expecting any biosimilar competition for Enbrel in the foreseeable future."

60. At a JP Morgan Healthcare Conference in January 2012, Amgen's representative announced: "Now we've talked at length this year about our confidence in the long-term outlook for Enbrel but I went to reiterate this morning that our confidence only grew in the long-term outlook for Enbrel in November when a patent was issued in favor of Enbrel that gives us patent protection extending now well into the future. So we believe we

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

have a strong broad intellectual property estate covering Enbrel and we intend to invest and try to maintain another decade of leadership for this important molecule for Amgen."

61. Amgen has, moreover, consistently asserted its patents to attempt to prevent competing products from entering the market. Gordon Binder, the CEO of Amgen from 1988 to 2000, explained Amgen's belief that "[i]f you don't defend your patents, it's the same as having no patents . . . . Nobody else is going to defend your patents. . . . A company that doesn't defend its patents is on the way to going out of business." *See* Los Angeles Times, November 27, 1990, "Patent Ruling Will Be Critical For Drug Maker".

62. Kevin Sharer, the CEO of Amgen until May 2012, more recently vowed that Amgen will assert its patents covering its anemia drugs Aranesp® and Epogen® in court or at the International Trade Commission against the launch by a competitor in the U.S., stating that "[w]ill defend our franchise – we will not cede anything." *Wall Street Journal Online*, January 26, 2007.

63. In a public conference call discussing the results of Amgen's second quarter 2012 earnings, Amgen's current CEO, Robert Bradway stated: "As you know, we are – we have consistently demonstrated that we have the will and the skill to defend our intellectual property, and you should expect that we'll do that with respect to our G-CSF franchise as well as our other franchises." Further, he warned the public: "you should expect that we will assert our IP rights, and to the extent that they infringe, you should expect that we'll deal with that through the appropriate channel."

64. Just a few months ago, Amgen reiterated its intent to "defend its own drugs against biosimilar competition." *Wall Street Journal Online*, February 7, 2013.

65. Consistent with its stated policy, Amgen has exhibited a pattern of asserting its patents and seeking declaratory judgments in situations where others have sought regulatory approval to launch products in competition with Amgen. *See, e.g., Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 579 F. Supp. 2d 199 (D. Mass. 2008); *Amgen, Inc. v. Hoffmann-La Roche Ltd.*, 456 F. Supp. 2d 267 (D. Mass. 2006).

66. On information and belief, several companies who were engaged in developing

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

generic versions of etanercept abandoned their development activities following Amgen's public statements about its patents.

67. On information and belief, Amgen and Roche have not licensed and have no intention on licensing the '182 or '522 patents to Sandoz to permit Sandoz to commercialize its etanercept product in the United States.

68. On June 14, 2013, Sandoz wrote a letter to Amgen and Roche informing them of its etanercept product and requested a covenant not to sue on the '182 and '522 patents for Sandoz's importation, offers for sale, and sales of etanercept in the United States.

69. Neither Amgen nor Roche responded to Sandoz's request.

70. Based on the foregoing, Sandoz has adverse legal interests with the defendants, and moreover, reasonably apprehends a patent infringement lawsuit from Amgen and Roche on the '182 and '522 patents for Sandoz's intended sale of its etanercept product.

71. The issuance of the '182 and '522 patents disrupted nine years of Sandoz's settled expectations regarding its rights to develop and ultimately commercialize its etanercept product. The emergence of these submarine patents has placed Sandoz in a position of either proceeding with its commercialization plans and facing a patent lawsuit, or abandoning its extensive product development activities and millions of dollars in investments. Further, the emergence of these patents has placed upon Sandoz the present choice of allocating further investment and resources to a product that may be charged with infringement and/or potentially enjoined for a period of 15 years, depending on the nature and resolution of Amgen's patent claims.

72. The dispute is thus real and immediate. Sandoz intends to import its etanercept product into this country, use the product, offer its product for sale, and sell its product within the United States after approval. Sandoz needs patent clarity now because it has already invested significant time and expense to develop its product and must continue to do so to complete its application and receive FDA approval. Sandoz thus faces the prospect of incurring significant additional expenses and efforts, while facing the certain prospect of litigating the validity and infringement of '182 and '522 patents at a future date. To clarify

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

its rights, Sandoz seeks a declaratory judgment that its etanercept product would not infringe any valid claim of the '182 and '522 patents.

COUNT 1

Declaratory Judgment of Non-Infringement of the '182 Patent

73. Sandoz re-alleges and incorporates by reference the allegations in paragraphs 1 to 72 above.

74. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

75. There is a real, immediate, substantial, and justiciable controversy between Sandoz, on the one hand, and Amgen and Roche on the other hand, concerning whether the use, offering for sale or importation of Sandoz's etanercept products will infringe any valid and enforceable claim of the '182 patent.

76. This controversy is amenable to specific relief through a decree of a conclusive character.

77. The use, sale, offer for sale, or importation into the United States of Sandoz's etanercept product will not infringe any valid and enforceable claim of the '182 patent.

78. Sandoz is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of its etanercept product will not infringe, directly or indirectly, any valid claim of the '182 patent.

COUNT 2

Declaratory Judgment of Invalidity of the '182 Patent

79. Sandoz re-alleges and incorporates by reference the allegations in paragraphs 1 to 78 above.

80. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

81. There is a real, immediate, substantial, and justiciable controversy between Sandoz, on the one hand, and Amgen and Roche, on the other hand, concerning whether the claims of the '182 patent are invalid for failure to comply with the statutory prerequisites of

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112 and/or statutory or obviousness-type double patenting.

82. This controversy is amenable to specific relief through a decree of a conclusive character.

83. The claims of the '182 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112 and/or statutory or obviousness-type double patenting.

84. Sandoz is entitled to a judicial declaration that the claims of the '182 patent are invalid.

COUNT 3

Declaratory Judgment of Unenforceability of the '182 Patent

85. Sandoz re-alleges and incorporates by reference the allegations in paragraphs 1 to 84 above.

86. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

87. There is a real, immediate, substantial, and justiciable controversy between Sandoz, on the one hand, and Amgen and Roche, on the other hand, concerning whether the claims of the '182 patent are unenforceable due to prosecution laches.

88. This controversy is amenable to specific relief through a decree of a conclusive character.

89. The claims of the '182 patent are unenforceable due to prosecution laches.

90. Sandoz is entitled to a judicial declaration that the claims of the '182 patent are unenforceable.

COUNT 4

Declaratory Judgment Of Non-Infringement Of The '522 Patent

91. Sandoz re-alleges and incorporates by reference the allegations in paragraphs 1 to 90 above.

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

92. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

93. There is a real, immediate, substantial, and justiciable controversy between Sandoz, on the one hand, and Amgen and Roche, on the other hand, concerning whether the use, sale, offer for sale, or importation into the United States of Sandoz's etanercept product will infringe any valid and enforceable claim of the '522 patent.

94. This controversy is amenable to specific relief through a decree of a conclusive character.

95. The use, sale, offer for sale, or importation into the United States of Sandoz's etanercept product will not infringe any valid and enforceable claim of the '522 patent.

96. Sandoz is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of its etanercept product will not infringe, directly or indirectly, any valid claim of the '522 patent.

COUNT 5

Declaratory Judgment Of Invalidity Of The '522 Patent

97. Sandoz re-alleges and incorporates by reference the allegations in paragraphs 1 to 96 above.

98. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

99. There is a real, immediate, substantial, and justiciable controversy between Sandoz, on the one hand, and Amgen and Roche, on the other hand, concerning whether the claims of the '522 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112 and/or statutory or obviousness-type double patenting.

100. This controversy is amenable to specific relief through a decree of a conclusive character.

101. The claims of the '522 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation,

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

one or more of §§ 101, 102, 103, and/or 112 and/or statutory or obviousness-type double patenting.

102. Sandoz is entitled to a judicial declaration that the claims of the '522 patent are invalid.

COUNT 6

Declaratory Judgment Of Unenforceability Of The '522 Patent

103. Sandoz re-alleges and incorporates by reference the allegations in paragraphs 1 to 102 above.

104. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

105. There is a real, immediate, substantial, and justiciable controversy between Sandoz, on the one hand, and Amgen and Roche, on the other hand, concerning whether the claims of the '522 patent are unenforceable due to prosecution laches.

106. This controversy is amenable to specific relief through a decree of a conclusive character.

107. The claims of the '522 patent are unenforceable due to prosecution laches.

108. Sandoz is entitled to a judicial declaration that the claims of the '522 patent are unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Sandoz prays that the Court enter judgment in its favor and against Defendants as follows:

A. Declaring that all claims of the '182 patent are invalid.

B. Declaring that Sandoz's etanercept product has not, does not, and will not infringe any valid and enforceable claim of the '182 patent.

C. Declaring that the use, offer to sell, sale, and/or importation into the United States of Sandoz's etanercept product does not, and will not, infringe any valid and enforceable claim of the '182 patent.

D. Declaring that the '182 patent is unenforceable due to prosecution laches.

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802

E. Declaring that all claims of the '522 patent are invalid.

F. Declaring that Sandoz's etanercept product has not, does not, and will not infringe any valid and enforceable claim of the '522 patent.

G. Declaring that the use, offer to sell, sale, and/or importation into the United States of Sandoz's etanercept product does not, and will not, infringe any valid and enforceable claim of the '522 patent.

H. Declaring that the '522 patent is unenforceable due to prosecution laches.

I. Declaring this an exceptional case in favor of Sandoz and awarding attorneys' fees pursuant to 35 U.S.C. § 285.

J. Awarding costs and expenses.

K. Awarding any and all such other relief as the Court determines to be just and proper.

Dated: June 24, 2013

WINSTON & STRAWN LLP

By: _____

James F. Hurst
Maureen L. Rurka
James M. Hilmert
K. Joon Oh
Ian Nomura

Attorneys for Plaintiff
SANDOZ INC.

SF:356886.2

Winston & Strawn LLP
101 California Street
San Francisco, CA 94111-5802