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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IMMUNEX CORPORATION; AMGEN MANUFACTURING, LIMITED; and HOFFMANN-LA ROCHE INC. Plaintiffs, v. SAMSUNG BIOEPIS CO., LTD., Defendant.	Civil Action No. _____ **COMPLAINT & DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiffs, Immunex Corporation; Amgen Manufacturing, Limited; and Hoffmann-La Roche Inc. (collectively "Plaintiffs"), by and through their undersigned attorneys, for their Complaint against Defendant Samsung Bioepis Co., Ltd. ("Bioepis") allege as follows:

I. THE PARTIES

A. Plaintiffs

1. Immunex Corporation ("Immunex") is a corporation organized and existing under the laws of the State of Washington with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen Inc. acquired Immunex in July 2002, and Immunex became a wholly-owned subsidiary of Amgen Inc.

2. Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of the Territory of Bermuda, with its principal place of business at Road 31 km 24.6, Juncos, Puerto Rico 00777. AML is a wholly-owned subsidiary of Amgen Inc.

3. Hoffmann-La Roche Inc. ("Roche") is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424.

B. Bioepis

4. On information and belief, Bioepis is a corporation organized and existing under the laws of South Korea, with its principal place of business at 107, Cheomdan-daero Yeonsu-gu Incheon, 406-840 South Korea. On information and belief, Bioepis develops, manufactures, and seeks regulatory approval for biosimilar products, and imports, markets, distributes, offers to sell, and sells those biosimilar products in the State of New Jersey and throughout the United States.

II. NATURE OF THE ACTION

5. This is an action for patent infringement arising under 35 U.S.C. § 271, including § 271(e)(2)(C)(ii), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("the BPCIA"), and for relief under the BPCIA. This action involves patents that cover etanercept (the active ingredient of the biologic drug product, ENBREL®), its method of manufacture, certain materials used in its manufacture, and certain approved therapeutic uses of etanercept. Immunex and AML (collectively, "Immunex/AML") and Roche bring this suit to enjoin Bioepis from infringing their patents and to secure any recoverable damages resulting from Bioepis's infringement.

6. The asserted patents (collectively, "the Patents-in-Suit) are as follows:

- United States Patent Nos. 8,063,182 ("the '182 Patent") and 8,163,522 ("the '522 Patent") (collectively, the "Roche Patents"); and
- U.S. Patents Nos. 7,915,225 ("the '225 Patent"), 8,119,605 ("the '605 Patent"), and 8,722,631 ("the '631 Patent") (collectively, "the Immunex Patents").

7. Roche owns the '182 and '522 Patents. Immunex is the exclusive licensee of all commercial rights in the Roche Patents, including all rights to sell ENBREL® in the United States and its territories.

8. Immunex owns the '225, '605, and '631 Patents.

9. Immunex has granted AML an exclusive license (or, with respect to the '182 and '522 Patents, an exclusive sublicense) to the Patents-In-Suit.

10. According to files available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761066, on April 25, 2019, the U.S. Food and Drug Administration ("FDA"), approved Bioepis's

abbreviated Biologics License Application 761066 ("aBLA"). On information and belief, Bioepis submitted that aBLA pursuant to the BPCIA, specifically 42 U.S.C. § 262(k) (also known as § 351(k) of the Public Health Service Act ("PHSA")), seeking authorization from the FDA to engage in the commercial manufacture, use, or sale of a biosimilar version of Immunex's ENBREL®, which Bioepis calls Eticovo (etanercept-ykro).

11. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. Subject to certain conditions, the abbreviated pathway (also known as "the (k) pathway") permits a biosimilar applicant (here, Bioepis) to rely on the prior clinical tests, data, and results, and the prior licensure and approval status, of the innovative biological product (here, ENBREL®). Immunex is the sponsor of the reference product, ENBREL®, which the FDA has approved for a number of different indications (*i.e.*, therapeutic uses).

12. As alleged herein, Bioepis infringed the Patents-In-Suit under 35 U.S.C. § 271(e)(2)(C)(ii) when it submitted its aBLA seeking FDA approval to engage in the commercial manufacture, use or sale of Bioepis's etanercept biosimilar product before the expiration of the Patents-In-Suit.

13. As alleged herein, Bioepis would also infringe one or more claims of each of the Patents-In-Suit, under 35 U.S.C. § 271(a), (b), and/or (g), should it make, use, offer for sale, or sell within the United States, or import into the United States Bioepis's etanercept biosimilar product before the expiration of the Patents-In-Suit.

III. JURISDICTION AND VENUE

A. Subject-Matter Jurisdiction

14. This Court has subject-matter jurisdiction over Immunex/AML and Roche's claims under 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

B. Personal Jurisdiction

15. This Court has personal jurisdiction over Bioepis by virtue of the fact that, on information and belief, Bioepis filed an aBLA seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis's biosimilar product in the State of New Jersey and throughout the United States, which directly gives rise to Plaintiffs' claims of patent infringement. On information and belief, the FDA approved that application on April 25, 2019.

16. On information and belief, Bioepis, by itself or through others, intends to use, induce others to use, offer for sale, sell within the United States, and import into the United States, including the District of New Jersey, its etanercept biosimilar product.

17. This Court also has personal jurisdiction over Bioepis by virtue of Bioepis's contacts with New Jersey and the exercise of such personal jurisdiction is fair and reasonable. Litigating this suit in New Jersey does not burden Bioepis. For example, Bioepis did not object to personal jurisdiction when sued by another patent holder in this district. *Janssen Biotech, Inc. v. Samsung Bioepis, Co. Ltd*., Case No. 2:17-cv-03524 (MCA).

C. Venue

18. Venue is proper in this District pursuant to 28 U.S.C. § 1391(c)(3). Bioepis is a foreign corporation and is therefore subject to suit in any judicial district. *Brunette Machine Works, Ltd. v. Kockum Industries, Inc*., 406 U.S. 706, 713-14 (1972); *In re HTC Corp*., 889 F.3d 1349, 1357-58 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 1271 (2019).

IV. BACKGROUND

A. TNF and TNF Receptors

19. Tumor necrosis factor ("TNF") is a cell-signaling protein involved in various biological effects that include the regulation of immune response, inflammation, and other processes. Scientists first identified it as a biological factor that was toxic to tumor cells; hence

the name "tumor necrosis factor." The body's overproduction of TNF is also implicated in various autoimmune diseases and other inflammatory disorders.

20. TNF's biological effects can be mediated via specific TNF receptors on the membranes of certain cells. Such TNF receptors can specifically bind to TNF. This binding can trigger reactions inside the cell, which can give rise to a number of different responses, including inflammation, cell growth, and cell death.

21. The TNF receptors include: an extracellular region that binds to its ligand, TNF; a transmembrane region that anchors the receptor onto the cell membrane; and an intracellular region that provides signaling inside the cell. In the body, using natural biological processes, and in the lab, using biochemical techniques, the TNF-binding extracellular region can be cleaved from the cell membrane, leaving a TNF-binding soluble fragment of the TNF receptor.

22. Scientists knew, at the time of the filing of the Patents-In-Suit, that there were two cell-membrane-bound receptors specific to human TNF. One of these receptors was sometimes referred to as the human "p75 TNF receptor," and the other as the human "p55 TNF receptor." The p75 TNF receptor protein has an apparent molecular weight of about 75 kilodaltons on a non-reducing SDS-polyacrylamide gel; the p55 TNF receptor has an apparent molecular weight of about 55 kilodaltons.

B. Immunex's Investment in ENBREL® (etanercept)

23. Etanercept, the active ingredient in ENBREL®, is a dimeric fusion protein consisting of the extracellular ligand-binding portion of the human 75 kilodalton (p75) tumor necrosis factor receptor linked to the Fc portion of human IgG1. The Fc component of etanercept contains the CH2, the CH3, and hinge, but not the CH1 domain of IgG1. Etanercept is produced by recombinant DNA technology in a Chinese hamster ovary (CHO) mammalian cell expression system.

24. By binding to and inhibiting TNF from interacting with TNF receptors, etanercept can reduce certain inflammatory responses implicated in certain conditions such as rheumatoid arthritis, psoriasis, psoriatic arthritis, and others.

25. The FDA has approved ENBREL® for the following indications: rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. At the time of its first approval, and since, scientists and physicians have heralded ENBREL® as a major advance in treating these disorders.

26. Immunex conducted Phase I testing to determine whether ENBREL® was safe to administer to patients with rheumatoid arthritis; results published in 1993 indicated that it was. Immunex then conducted Phase II testing to begin determining whether ENBREL® improved symptoms of rheumatoid arthritis; results indicating that it did improve symptoms were published in 1996. Immunex conducted Phase III testing and invested a substantial amount of time and resources testing ENBREL® to demonstrate that it was safe and effective for certain disorders. Immunex invested considerable time and resources, and took considerable risk, in conducting these tests and obtaining their results.

27. Based on the results of clinical testing in rheumatoid arthritis, Immunex filed Biologic License Application ("BLA") No. 103795. As a result, in November 1998, the FDA first approved ENBREL®, pursuant to BLA No. 103795, for treating moderate to severe rheumatoid arthritis. Immunex holds the rights to BLA No. 103795.

28. Immunex's further clinical testing revealed that ENBREL® was safe and effective to treat certain additional conditions. Based on Immunex's further clinical testing, Immunex filed supplements to BLA No. 103795, requesting that the FDA approve ENBREL® for certain additional indications. As a result, the FDA approved ENBREL® for treating polyarticular

juvenile idiopathic arthritis in 1999, psoriatic arthritis in 2002, ankylosing spondylitis in 2003, and plaque psoriasis in 2004. These approvals are the direct result of Immunex's very significant investments in the development and clinical trials of ENBREL®.

C. Bioepis's Knowledge of the Patents-In-Suit, Its Etanercept Biosimilar, and Its Abbreviated BLA

29. As alleged herein, Immunex's '225 Patent had issued by the time that Samsung Bioepis was formed in 2012. Immunex's '605 Patent issued in February 2012, and the '631 Patent in May 2014. Roche's '182 Patent had issued the year before Bioepis's formation, in 2011, and Roche's '522 Patent issued in April 2012. In the context of the relevant circumstances here, Bioepis was either aware of each of these patents or was willfully blind to their existence.

30. According to its website, Bioepis is part of the Samsung Group. Bioepis's website states that its first six targets for biosimilar drugs were "worth up to 52.9 billion USD in the global market, with an average growth rate of 21% per year. The size is estimated to mark 22.9 billion USD by 2020." Given the size of that market, it is reasonable to infer that before and while undertaking to develop a biosimilar, Bioepis would determine whether and what patents protected the innovative drug Bioepis sought to target. Consistent with that inference, Bioepis's website advises that Bioepis was aware that the manufacture, use, offer for sale, sale, or importation of its biosimilars might be prohibited by patents: "Biosimilars can be manufactured when the original product's patent expires."
http://www.samsungbioepis.com/en/newsroom/detail/Samsung-Bio-Business-Possible-Recreation-of-the-Semiconductor-Legend.html.

31. Based on the circumstances, it is reasonable to infer that Bioepis was aware, or at least willfully blind to the existence, of each of the five Patents-In-Suit during the development and FDA approval process for Bioepis's etanercept biosimilar product.

32. Bioepis is piggybacking on the fruits of Immunex/AML and Roche's trailblazing efforts. Bioepis has developed an etanercept biosimilar that, on information and belief, has the identical primary amino acid sequence as Immunex's ENBREL®.

33. On information and belief, Bioepis previously submitted aBLA 761066 referencing Immunex's ENBREL® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use or sale of Bioepis's etanercept biosimilar product before the expiration of the Patents-In-Suit.

34. According to the FDA-approved label, Bioepis's etanercept biosimilar product, etanercept-ykro, like Immunex's ENBREL®, "is a dimeric fusion protein consisting of the extracellular ligand-binding portion of the human 75 kilodalton (p75) tumor necrosis factor receptor (TNFR) linked to the Fc portion of human IgG1. The Fc component of etanercept-ykro contains the CH2 domain, the CH3 domain and hinge region, but not the CH1 domain of IgG1. Etanercept-ykro is produced by recombinant DNA technology in a Chinese hamster ovary (CHO) mammalian cell expression system." On information and belief, Bioepis's etanercept biosimilar specifically binds human TNF.

35. On information and belief, in seeking FDA approval for its etanercept biosimilar product, Bioepis extensively and explicitly relied on the clinical trials data that Immunex had invested in and developed when applying for and securing FDA approval for ENBREL®.

36. On information and belief, Bioepis copied the FDA-approved label for Immunex's ENBREL® in seeking and receiving approval for its etanercept biosimilar product. Bioepis's etanercept biosimilar product, like Immunex's ENBREL®, has been approved for five indications: treating rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. In addition, the route of administration of

Bioepis's etanercept biosimilar is the same as that of Immunex's ENBREL®, and the approved dosage form and strength of Bioepis's etanercept biosimilar represents a subset of the approved forms and strengths of Immunex's ENBREL®.

37. On information and belief, Bioepis knows and intends that the FDA-approved label for its biosimilar etanercept product will encourage, recommend, or promote uses of its product for the indications for which it was approved and according to the treatment directions that the label sets forth—regimens that infringe the Immunex Patents, as alleged herein.

D. Bioepis's Failure to Comply with the BPCIA

38. The BPCIA provides that "[w]hen a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the 'confidential information')." 42 U.S.C. § 262(*l*)(1)(B).

39. The referenced paragraph (2) provides that "[n]ot later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

> (A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and
>
> (B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor." 42 U.S.C. § 262(*l*)(2).

40. Bioepis has failed to provide to Immunex any of the information specified by 42

U.S.C. § 262(*l*)(2), including the application and information required under § 262(*l*)(2)(A). Such failure removed any limits on Plaintiffs' ability to bring an action for a declaration of infringement, validity, or enforceability of any patent that claims Bioepis's biosimilar etanercept or the use thereof. 42 U.S.C. § 262(*l*)(9)(C); 28 U.S.C. § 2201(b).

41. The BPCIA requires that "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A).

42. Bioepis has not yet provided Immunex the notice of commercial marketing that 42 U.S.C. § 262(*l*)(8)(A) requires. Based on Bioepis's failure to provide Immunex with the application and information required under § 262(*l*)(2)(A), it is reasonable to infer that Bioepis might not provide notice to Immunex in accordance with § 262(*l*)(8)(A). Bioepis should be prohibited from beginning commercial marketing of its biosimilar product for at least 180 days from the date Bioepis provides such notice to Immunex.

V. THE PATENTS-IN-SUIT

A. The '182 and '522 Patents

43. In the late 1980s, Roche and Immunex scientists were early pioneers in isolating, characterizing, cloning, and sequencing p55 and p75 versions of the human TNF receptors, respectively.

44. Roche scientists were the first to publish the human p55 TNF receptor gene's amino acid sequence. *See* Loetscher *et al.*, "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," *Cell*, 61:351-359 (April 20, 1990).

45. In May 1990, Immunex scientists were the first to publish the p75 TNF receptor gene's amino acid sequence. *See* Smith *et al.*, "A Receptor for Tumor Necrosis Factor Defines an Unusual Family of Cellular and Viral Proteins," *Science* 248:1019-1023 (1989). Shortly

thereafter, Roche scientists also published the p75 receptor's amino acid sequence, confirming the results published in Smith. Dembic *et al.*, "Two human TNF receptors have similar extracellular, but distinct intracellular, domain sequences," *Cytokine* 2(4):231-237 (1989).

46. On August 31, 1990, Roche scientists filed European Patent Application No. 90116707.2, which disclosed and taught the novel concept of fusing the extracellular fragment of the TNF receptors with a portion of the human immunoglobulin heavy chain (*i.e.*, all of the domains of the constant region of a human immunoglobulin IgG heavy chain other than the first domain of said constant region). These Roche scientists also filed a United States patent application on September 10, 1990, which claimed priority to said European patent application.

47. The Roche Patents both issued from applications that claim priority to the European patent application filed on August 31, 1990.

48. The '182 Patent is directed to a fusion protein incorporating a TNF-binding portion of the p75 TNF receptor and covers etanercept. The '522 Patent is directed to nucleic acids, host cells, and methods of using such nucleic acids and host cells to make the p75 TNF receptor fusion protein. Both Roche Patents could have been identified in Immunex's list pursuant to 42 U.S.C. § 262(*l*)(3)(A) had Bioepis complied with § 262(*l*)(2)(A).

B. The '225, '605, and '631 Patents

49. In developing etanercept as a therapeutic, Immunex also developed regimens for, and obtained patents directed towards, using etanercept to treat psoriasis and/or psoriatic arthritis. The '225 Patent, the '605 Patent, and the '631 Patent ("the Immunex Patents"), owned by Immunex, disclose and claim methods of using etanercept to treat psoriasis and/or psoriatic arthritis.

50. The Immunex Patents claim priority to a provisional application filed on August 11, 1999. The Immunex Patents also claim priority to non-provisional applications filed

August 13, 1999, and June 23, 2000.

51. As a general matter, the Immunex Patents contain claims to using etanercept to treat psoriasis and/or psoriatic arthritis, and further specify certain dosage regimens to follow.

52. The manner in which etanercept is used—according to the labels for both ENBREL® and Bioepis's etanercept biosimilar product—to treat psoriasis (or psoriasis and/or psoriatic arthritis) today falls within the scope of the claims of the Immunex Patents. Each of the Immunex Patents could have been identified in Immunex's list pursuant to 42 U.S.C. § 262(*l*)(3)(A) had Bioepis complied with § 262(*l*)(2)(A).

COUNT 1: FAILURE TO SUPPLY NOTICE OF COMMERCIAL MARKETING UNDER 42 U.S.C. § 262(*l*)(8)(A)

53. Paragraphs 1-42 are incorporated by reference as if fully set forth herein.

54. The BPCIA provides that "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A).

55. Bioepis has not provided notice to Immunex pursuant to 42 U.S.C. § 262(*l*)(8)(A); by its terms, that subsection operates to bar Bioepis from commercial marketing pending, at a minimum, such notice, followed by 180 days.

56. On information and belief, Bioepis is prepared imminently to begin to use, offer, for sale, and sell in the United States, and import into the United States, its etanercept biosimilar product.

57. Immunex/AML and Roche are entitled to injunctive relief preventing Bioepis from commercial marketing consistent with the notice period provided by that statute.

COUNT 2: INFRINGEMENT OF THE '182 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)(ii)

58. Paragraphs 1-48 are incorporated by reference as if fully set forth herein.

59. The United States Patent and Trademark Office ("USPTO") duly and legally issued the '182 Patent, titled "Human TNF Receptor Fusion Protein," on November 22, 2011. A true and correct copy of the '182 Patent is attached to this Complaint as Exhibit 1.

60. Claims of the '182 Patent cover etanercept and pharmaceutical compositions that are made from etanercept. Thus, the '182 Patent could have been identified in Immunex's list pursuant to 42 U.S.C. § 262(*l*)(3)(A) had Bioepis complied with § 262(*l*)(2)(A).

61. On information and belief, Bioepis infringed claims of the '182 Patent by submitting an aBLA referencing Immunex's ENBREL® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis's etanercept biosimilar product before the expiration of the '182 Patent.

62. On information and belief, Bioepis has known of the '182 Patent since Bioepis was founded or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis's etanercept biosimilar product before the expiration of the '182 Patent and in violation of Immunex/AML and Roche's patent rights.

63. Immunex/AML and Roche are entitled to a judgment that Bioepis has infringed one or more claims of the '182 Patent by submitting an aBLA referencing Immunex's ENBREL® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis's etanercept biosimilar product before the expiration of the '182 Patent.

64. Immunex/AML and/or Roche would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis's FDA approved etanercept biosimilar product.

Immunex/AML and Roche do not have an adequate remedy at law and are entitled to injunctive relief preventing Bioepis from such infringement of one or more claims of the `182 Patent.

COUNT 3: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '182 PATENT UNDER 35 U.S.C. § 271(a)

65. Paragraphs 1-48 are incorporated by reference as if fully set forth herein.

66. On information and belief, Bioepis has sought and obtained FDA approval of Bioepis's biosimilar etanercept product under 42 U.S.C. § 262(k) by reference to Immunex's ENBREL®, and now holds the biological license granted by FDA for Bioepis's biosimilar etanercept product.

67. On information and belief, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Bioepis's etanercept biosimilar product, which would constitute infringement of one or more claims of the '182 Patent under 35 U.S.C. § 271(a).

68. An actual controversy has arisen and now exists between the parties concerning whether Bioepis's using, offering to sell, or selling within the United States, or importing into the United States, its etanercept biosimilar product has infringed and/or will infringe one or more claims of the '182 Patent.

69. Immunex/AML and Roche are entitled to a declaratory judgment that Bioepis has infringed and/or would infringe one or more claims of the '182 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis's etanercept biosimilar product before the expiration of the '182 Patent.

70. Immunex/AML and/or Roche would be irreparably harmed if Bioepis is not enjoined from infringing one or more claims of the '182 Patent. Immunex/AML and Roche do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Bioepis from

making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis's etanercept biosimilar product before the expiration of the '182 Patent.

COUNT 4: INFRINGEMENT OF THE '522 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)(ii)

71. Paragraphs 1-48 are incorporated by reference as if fully set forth herein.

72. The USPTO duly and legally issued the '522 Patent, titled "Human TNF Receptor," on April 24, 2012. A true and correct copy of the '522 Patent is attached to this Complaint as Exhibit 2.

73. Claims of the '522 Patent cover, among other things, methods of making etanercept and certain materials used in such methods. Thus, the '522 Patent could have been identified in Immunex's list pursuant to 42 U.S.C. § 262(*l*)(3)(A) had Bioepis complied with § 262(*l*)(2)(A).

74. On information and belief, Bioepis infringed claims of the '522 Patent by submitting an aBLA referencing Immunex's ENBREL®, seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis's etanercept biosimilar product before the expiration of the '522 Patent.

75. On information and belief, Bioepis has known of the '522 Patent since its issuance or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis's etanercept biosimilar product, before the expiration of the '522 Patent and in violation of Immunex/AML and Roche's patent rights.

76. Immunex/AML and Roche are entitled to a judgment that Bioepis has infringed one or more claims of the '522 Patent by submitting an aBLA referencing Immunex's ENBREL® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture,

use, or sale of Bioepis's etanercept biosimilar product before the expiration of the '522 Patent.

77. Immunex/AML and/or Roche would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis's FDA approved etanercept biosimilar product. Immunex/AML and Roche do not have an adequate remedy at law and are entitled to injunctive relief preventing Bioepis from such infringement of one or more claims of the '522 Patent.

COUNT 5: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '522 PATENT UNDER 35 U.S.C. § 271(g)

78. Paragraphs 1-48 are incorporated by reference as if fully set forth herein.

79. On information and belief, Bioepis intends to and will immediately begin to import into the United States, and offer to sell, sell, and use within the United States, Bioepis's etanercept biosimilar product, which would constitute infringement of one or more claims of the '522 Patent under 35 U.S.C. § 271(g) because Bioepis's etanercept biosimilar product is made by the claimed process.

80. The etanercept made by Bioepis's process that infringes the '522 Patent is the essential active ingredient of Bioepis's etanercept biosimilar product. On information and belief, there is no subsequent process that materially changes that active ingredient, including during any fill and finish of the biosimilar product.

81. An actual controversy has arisen and now exists between the parties concerning whether Bioepis's importing into the United States, or offering to sell, selling, or using within the United States (irrespective of where manufacturing occurred), its etanercept biosimilar product, before the expiration of the '522 Patent, has infringed and/or will infringe one or more claims of the '522 Patent.

82. Immunex/AML and Roche are entitled to a declaratory judgment that Bioepis has

infringed and/or will infringe one or more claims of the ’522 Patent by making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis’s etanercept biosimilar product before the expiration of the ’522 Patent.

83. Immunex/AML and/or Roche will be irreparably harmed if Bioepis is not enjoined from infringing one or more claims of the ’522 Patent. Immunex/AML and Roche do not have an adequate remedy at law and are entitled to injunctive relief preventing Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis’s etanercept biosimilar product before the expiration of the ’522 Patent.

COUNT 6: INFRINGEMENT OF THE ’225 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)(ii)

84. Paragraphs 1-52 are incorporated by reference as if fully set forth herein.

85. The USPTO duly and legally issued the ’225 Patent, titled “Soluble Tumor Necrosis Factor Receptor Treatment of Medical Disorders,” on March 29, 2011. A true and correct copy of the ’225 Patent is attached to this Complaint as Exhibit 3.

86. The ’225 Patent is generally directed to methods of treating psoriasis and/or psoriatic arthritis by administering etanercept. Thus, the ’225 Patent could have been identified in Immunex’s list pursuant to 42 U.S.C. § 262*(l)*(3)(A) had Bioepis complied with § 262(*l*)(2)(A).

87. On information and belief, Bioepis has infringed the ’225 Patent by submitting an aBLA referencing Immunex’s ENBREL®, seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’s etanercept biosimilar product before the expiration of the ’225 Patent.

88. On information and belief, Bioepis has known of the ’225 Patent since Bioepis was founded or was at least willfully blind to its existence and contents. Despite such knowledge or willful blindness, Bioepis nonetheless filed its aBLA with the FDA, seeking approval under

42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis's etanercept biosimilar product before the expiration of the '225 Patent and in violation of Immunex/AML's patent rights. On information and belief, Bioepis copied ENBREL®'s labeling, which instructs physicians and patients to administer etanercept subcutaneously for treating psoriasis and/or psoriatic arthritis in specific dosages, which is covered by the '225 Patent.

89. Immunex/AML are entitled to a judgment that Bioepis has infringed one or more claims of the '225 Patent by submitting an aBLA referencing Immunex's ENBREL® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis's etanercept biosimilar product before the expiration of the '225 Patent.

90. Immunex/AML would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis's FDA approved etanercept biosimilar product. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief preventing Bioepis from such infringement of one or more claims of the '225 Patent.

COUNT 7: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '225 PATENT UNDER 35 U.S.C. § 271(b)

91. Paragraphs 1-52 are incorporated by reference as if fully set forth herein.

92. On information and belief, Bioepis sought and has received FDA approval for Bioepis's etanercept biosimilar product under 42 U.S.C. § 262(k) for treating psoriasis and/or psoriatic arthritis.

93. If a doctor were to administer to a patient, or a patient were to self-administer, Bioepis's etanercept biosimilar product for treating psoriasis and/or psoriatic arthritis pursuant to regimens, *i.e.*, methods, specified on the FDA-approved label for that product, performing such methods would directly infringe one or more claims of the '225 Patent.

94. As alleged herein, Bioepis took actions that it intended to cause doctors to administer to patients, or patients to self-administer, Bioepis's etanercept biosimilar product pursuant to those methods. Those actions included seeking FDA approval for a label that specified treatment methods that, if followed as expected, would infringe the '225 patent. On information and belief, Bioepis intends to advertise and otherwise inform doctors and patients that its etanercept biosimilar product is available to treat psoriasis and/or psoriatic arthritis using those claimed treatment methods.

95. As alleged herein, Bioepis was aware of the '225 Patent and knew that, if its etanercept biosimilar product were administered as specified in the FDA label for treating psoriasis and/or psoriatic arthritis, such administration would constitute infringement of the '225 patent.

96. Immunex/AML are entitled to a declaratory judgment that, by offering to sell, or selling within the United States, before the expiration of the '225 Patent, Bioepis's etanercept biosimilar product, the label for which instructs doctors and patients to follow regimens claimed in the '225 Patent for treating psoriasis and/or psoriatic arthritis, Bioepis would induce infringement of the '225 Patent.

97. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Bioepis from using, inducing others to use, offering to sell, or selling within the United States Bioepis's etanercept biosimilar product for treating psoriasis and/or psoriatic arthritis before the expiration of the '225 Patent.

COUNT 8: INFRINGEMENT OF THE '605 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)(ii)

98. Paragraphs 1-52 are incorporated by reference as if fully set forth herein.

99. The USPTO duly and legally issued the '605 Patent, titled "Soluble Tumor Necrosis Factor Receptor Treatment of Medical Disorders," on February 21, 2012. A true and

correct copy of the ’605 Patent is attached to this Complaint as Exhibit 4.

100. The ’605 Patent is generally directed to methods of treating psoriasis by administering etanercept. Thus, the ’605 Patent could have been identified in Immunex’s list pursuant to 42 U.S.C. § 262(*l*)(3)(A) had Bioepis complied with § 262(*l*)(2)(A).

101. On information and belief, Bioepis has infringed the ’605 Patent by submitting an aBLA referencing Immunex’s ENBREL® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’s etanercept biosimilar product before the expiration of the ’605 Patent.

102. On information and belief, Bioepis has known of the ’605 Patent since the patent’s issuance or was at least willfully blind to its existence and contents. Despite such knowledge or willful blindness, Bioepis nonetheless filed its aBLA with the FDA, seeking approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’s etanercept biosimilar product before the expiration of the ’605 Patent and in violation of Immunex/AML’s patent rights. On information and belief, Bioepis copied ENBREL®’s labeling that instructs physicians and patients to administer etanercept for treating psoriasis in specific dosages, which is covered by the ’605 Patent.

103. Immunex/AML are entitled to a judgment that Bioepis has infringed one or more claims of the ’605 Patent by submitting an aBLA referencing Immunex’s ENBREL® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’s etanercept biosimilar product before the expiration of the ’605 Patent.

104. Immunex/AML would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis’s FDA approved etanercept biosimilar product. Immunex/AML do

not have an adequate remedy at law and are entitled to injunctive relief preventing Bioepis from such infringement of one or more claims of the ’605 Patent.

COUNT 9: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’605 PATENT UNDER 35 U.S.C. § 271(b)

105. Paragraphs 1-52 are incorporated by reference as if fully set forth herein.

106. On information and belief, Bioepis sought and has received FDA approval for Bioepis’s etanercept biosimilar product under 42 U.S.C. § 262(k) for treating psoriasis.

107. If a doctor were to administer to a patient, or a patient were to self-administer, Bioepis’s etanercept biosimilar product for treating psoriasis pursuant to regimens, *i.e.*, methods, specified on the FDA-approved label for that product, performing such methods would directly infringe one or more claims of the ’605 Patent.

108. As alleged herein, Bioepis took actions that it intended to cause doctors to administer to patients, or patients to self-administer, Bioepis’s etanercept biosimilar product pursuant to those methods. Those actions included seeking FDA approval for a label that specified treatment methods that, if followed as expected, would infringe the ‘605 patent. On information and belief, Bioepis intends to advertise and otherwise inform doctors and patients that its etanercept biosimilar product is available to treat psoriasis using those claimed treatment methods.

109. As alleged herein, Bioepis was aware of the ’605 Patent and knew that, if its etanercept biosimilar product were administered as specified in the FDA label for treating psoriasis, such administration would constitute infringement of the ’605 patent.

110. Immunex/AML are entitled to a declaratory judgment that, by offering to sell, or selling within the United States, before the expiration of the ’605 Patent, Bioepis’s etanercept

biosimilar product, the label for which instructs doctors and patients to follow regimens claimed in the ’605 Patent for treating psoriasis, Bioepis would induce infringement of the ’605 Patent.

111. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Bioepis from using, inducing others to use, offering to sell, or selling within the United States Bioepis’s etanercept biosimilar product for treating psoriasis before the expiration of the ’605 Patent.

COUNT 10: INFRINGEMENT OF THE ’631 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)(ii)

112. Paragraphs 1-52 are incorporated by reference as if fully set forth herein.

113. The USPTO duly and legally issued the ’631 Patent, titled “Soluble Tumor Necrosis Factor Receptor Treatment of Medical Disorders,” on May 13, 2014. A true and correct copy of the ’631 Patent is attached to this Complaint as Exhibit 5.

114. The ’631 Patent is generally directed to methods of treating psoriasis and/or psoriatic arthritis by administering etanercept subcutaneously in specific dosages. Thus, the ’631 Patent could have been identified in Immunex’s list pursuant to 42 U.S.C. § 262(*l*)(3)(A) had Bioepis complied with § 262(*l*)(2)(A).

115. On information and belief, Bioepis has infringed the ’631 Patent by submitting an aBLA referencing Immunex’s ENBREL® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’s etanercept biosimilar product before the expiration of the ’631 Patent.

116. On information and belief, Bioepis has known of the ’631 Patent since the patent’s issuance or was at least willfully blind to its existence and contents. Despite such knowledge or willful blindness, Bioepis nonetheless filed its aBLA with the FDA, seeking approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of

Bioepis's etanercept biosimilar product, before the expiration of the '631 Patent and in violation of Immunex/AML's patent rights. On information and belief, Bioepis copied ENBREL®'s labeling, which instructs physicians and patients to administer etanercept subcutaneously for treatment of psoriasis and/or psoriatic arthritis in specific dosages, which is covered by the '631 Patent.

117. Immunex/AML are entitled to a judgment that Bioepis has infringed one or more claims of the '631 Patent by submitting an aBLA referencing Immunex's ENBREL® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis's etanercept biosimilar product before the expiration of the '631 Patent.

118. Immunex/AML would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis's FDA approved etanercept biosimilar product. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief preventing Bioepis from such infringement of one or more claims of the '631 Patent.

COUNT 11: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '631 PATENT UNDER 35 U.S.C. § 271(b)

119. Paragraphs 1-52 are incorporated by reference as if fully set forth herein.

120. On information and belief, Bioepis sought and has received FDA approval for Bioepis's etanercept biosimilar product under 42 U.S.C. § 262(k) for treating psoriasis and/or psoriatic arthritis by administering etanercept subcutaneously in specific dosages.

121. If a doctor were to administer to a patient, or a patient were to self-administer, Bioepis's etanercept biosimilar product for treating psoriasis and/or psoriatic arthritis pursuant to regimens, *i.e.*, methods, specified on the FDA-approved label for that product, performing such methods would directly infringe one or more claims of the '631 Patent.

122. As alleged herein, Bioepis took actions that it intended to cause doctors to administer to patients, or patients to self-administer, Bioepis's etanercept biosimilar product pursuant to those methods. Those actions included seeking FDA approval for a label that specified treatment methods that, if followed as expected, would infringe the '631 patent. On information and belief, Bioepis intends to advertise and otherwise inform doctors and patients that its etanercept biosimilar product is available to treat psoriasis and/or psoriatic arthritis using those claimed treatment methods.

123. As alleged herein, Bioepis was aware of the '631 Patent and knew that, if its etanercept biosimilar product were administered as specified in the FDA label for treating psoriasis and/or psoriatic arthritis, such administration would constitute infringement of the '631 patent.

124. Immunex/AML are entitled to a declaratory judgment that, by offering to sell, or selling within the United States, before the expiration of the '631 Patent, Bioepis's etanercept biosimilar product, the label for which instructs doctors and patients to follow regimens claimed in the '631 Patent for treating psoriasis and/or psoriatic arthritis, Bioepis would induce infringement of the '631 Patent.

125. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Bioepis from using, inducing others to use, offering to sell, or selling within the United States Bioepis's etanercept biosimilar product for treating psoriasis and/or psoriatic arthritis before the expiration of the '631 Patent.

PRAYER FOR RELIEF

WHEREFORE, Roche (with respect to the '182 and '522 Patents) and Immunex/AML (with respect to all Patents-In-Suit) respectfully request that this Court enter judgment in their favor against Bioepis and grant the following relief:

Temporary and preliminary injunctive relief

A. A temporary restraining order enjoining the commercial making, using, offering for sale, and selling in the United States, or importing into the United States, of Bioepis's etanercept biosimilar product pending briefing and this Court's decision on a motion for preliminary injunction;

B. A preliminary injunction enjoining the commercial making, using, offering for sale, and selling in the United States, or importing into the United States, of Bioepis's etanercept biosimilar product until no less than 180 days after Bioepis provides the notice of commercial marketing that the BPCIA requires; and

C. A preliminary injunction enjoining the commercial making, using, offering for sale, and selling in the United States, or importing into the United States, of Bioepis's etanercept biosimilar product pending a final determination in this matter as to infringement, validity, and enforceability of the asserted claims of the '182 and '522 Patents.

Judgments and permanent injunctive relief for infringement under 35 U.S.C. § 271(e)(2)(C)(ii)

A. A judgment under 35 U.S.C. § 271(e)(2)(C)(ii) that by submitting to the FDA Bioepis's aBLA to obtain approval of Bioepis's etanercept biosimilar product, Bioepis has infringed one or more claims of each of the Patents-In-Suit;

B. Based on that judgment, a permanent injunction against the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Bioepis's etanercept biosimilar product before the expiration of the last to expire of the Patents-In-Suit; and

C. A declaration that this is an exceptional case and awarding attorneys' fees and costs pursuant to 35 U.S.C. § 285.

Judgments, and relief, for infringement under 35 U.S.C. § 271(a)

A. A judgment that Bioepis has infringed or will infringe one or more claims of the '182 Patent by making, using, offering for sale, or selling within the United States, or importing into the United States, Bioepis's etanercept biosimilar product during the term of the '182 Patent;

B. Based on that judgment, a permanent injunction against future infringement by Bioepis, as well as by its officers, employees, agents, representatives, affiliates, assignees, successors, and affiliates, and all persons acting on behalf of, at the direction of, or in active concert with it, until the '182 Patent expires; and

C. A declaration that this is an exceptional case and awarding attorneys' fees and costs pursuant to 35 U.S.C. § 285.

Judgments, and relief, for infringement under 35 U.S.C. § 271(g)

A. A judgment that Bioepis has infringed or will infringe one or more claims of the '522 Patent by importing into the United States, or offering to sell, selling, or using its etanercept biosimilar product within the United States during the term of the '522 Patent;

B. Based on that judgment, a permanent injunction against future infringement by Bioepis, as well as by its officers, employees, agents, representatives, affiliates, assignees, successors, and affiliates, and all persons acting on behalf of, at the direction of, or in active concert with it, until the '522 Patent expires; and

C. A declaration that this is an exceptional case and awarding attorneys' fees and costs pursuant to 35 U.S.C. § 285.

Judgments, and relief, for infringement under 35 U.S.C. § 271(b)

A. A judgment that Bioepis will induce infringement of one or more claims of the '225, '605, and '631 Patents by having, among other acts, intentionally sought and obtained a

label that encourages others to administer Bioepis's etanercept biosimilar product in manners covered under claims of those Patents;

B. Based on that judgment, a permanent injunction against future inducing infringement by Bioepis, as well as by its officers, employees, agents, representatives, affiliates, assignees, successors, and affiliates, and all persons acting on behalf of, at the direction of, or in active concert with it, until August 13, 2019 expiry of the Immunex Patents; and

C. A declaration that this is an exceptional case and awarding attorneys' fees and costs pursuant to 35 U.S.C. § 285.

On all counts: Other relief

A. On all counts, such other relief as this Court may deem just, necessary, or proper pursuant to 28 U.S.C. § 2202.

DEMAND FOR A JURY TRIAL

Immunex/AML and Roche hereby demand a jury trial on all issues so triable.

Dated: April 29, 2019

s/ Liza M. Walsh
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RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: April 29, 2019

s/ Liza M. Walsh

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RULE 11.2 CERTIFICATION

United States Patent Nos. 8,063,182 ("the '182 Patent"), 8,163,522 ("the '522 Patent"), 7,915,225 ("the '225 Patent"), 8,119,605 ("the '605 Patent"), and 8,722,631 ("the '631 Patent") are the subject of the pending action in this judicial district *Immunex Corp. v. Sandoz Inc.*, Civil Action No. 2:16-cv-01118-CCC-MF.

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: April 29, 2019

s/ Liza M. Walsh

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