IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs, v. SAMSUNG BIOEPIS CO., LTD., Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs Genentech, Inc. ("Genentech") and City of Hope (collectively, "Plaintiffs") bring this Complaint for declaratory and injunctive relief against Defendant Samsung Bioepis Co., Ltd. ("Bioepis") to address Bioepis's infringement of 21 patents relating to Genentech's groundbreaking breast cancer drug Herceptin®.

NATURE OF THE CASE

1. Breast cancer is a serious disease affecting over 2.8 million women in the United States. Approximately 20-25% of those women suffer from "HER2-positive" breast cancer. This is a particularly aggressive form of the disease characterized by overexpression of human epidermal growth factor receptor 2 (i.e., "HER2") proteins due to excessive HER2 gene amplification.

2. In the early 1990s, a diagnosis of HER2-positive breast cancer was effectively a death sentence: patients had an average life expectancy of only 18 months. The quality of life for those patients was markedly poor—the disease rapidly metastasized (*i.e.*, spread to other parts of the body). The only available treatments were invasive and disfiguring surgery and chemotherapeutic drugs with harsh side effects, and those treatments added little to the patient's

life span.

3. The treatment of HER2-positive breast cancer, and the lives of millions of women suffering from the disease, changed dramatically with Genentech's development of Herceptin®. Herceptin® was the first drug of its kind—an antibody called trastuzumab that specifically targeted the biological mechanism that makes HER2-positive breast cancer such an aggressive form of the disease.

4. Although the scientific community was initially skeptical that such an antibody-based therapy could work, Genentech's specific methods of using Herceptin® proved remarkably effective. Indeed, after Genentech revealed the results of its clinical studies, the scientific community hailed Herceptin® as "the beginning of a whole new wave of biological drugs that modulate the causes of cancer"[1] and a sign that "the whole field of cancer research has turned a corner."[2]

5. Since FDA approval of Herceptin® in 1998, Genentech has worked diligently to develop new methods of using Herceptin®—including improved dosing schedules and broader indications—to expand access to therapy and improve the quality of life for millions of patients worldwide. This research has greatly expanded the number of patients who are able to benefit from Herceptin®. To further expand access to this lifesaving drug, Genentech also provides Herceptin® free of charge to patients who are uninsured or cannot afford treatment and assists with out-of-pocket prescription-related expenses. All told, Genentech has spent over two decades, and billions of dollars, developing Herceptin® into the life-saving drug it is today.

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[1] Gina Kolata and Lawrence M. Fisher, *Drugs to Fight Breast Cancer Near Approval*, NEW YORK TIMES (FRONT PAGE) (Sept. 3, 1998).

[2] Robert Langreth, *Breast-Cancer Drug Is Backed by FDA Panel*, Wall Street J. (Sept. 3, 1998).

6. Genentech's groundbreaking work developing Herceptin® was the result of years of research from a group of talented scientists. The United States Patent and Trademark Office recognized that innovative work by granting Genentech numerous patents claiming Herceptin®, its manufacture, and its use. And as one of the pioneers in the biotechnology field, Genentech collaborated with scientists at research institutions such as the City of Hope to make foundational inventions, such as efficient techniques for making antibodies that can be used as drugs.

7. Seeking to profit from the success of Plaintiffs' innovations, Bioepis is seeking FDA approval of a biosimilar version of Herceptin® called SB3. SB3 is a copycat product for which Bioepis is seeking the same label indications and usage as Herceptin®. In fact, Bioepis is relying upon Genentech's own studies demonstrating the safety and efficacy of Herceptin® to obtain approval of its biosimilar product.

8. In 2010, Congress provided a pathway for resolving patent disputes relating to biosimilar products through the Biologics Price Competition and Innovation Act ("BPCIA"). *See* 42 U.S.C. § 262(*l*). Bioepis has declined to follow the process outlined in the BPCIA, which requires biosimilar applicants and innovator companies to exchange certain information concerning the biosimilar product and the patents that may be infringed by the manufacture and sale of the biosimilar product. Bioepis and Genentech have, however, exchanged limited information to narrow the scope of the patent disputes involving SB3.

9. Plaintiffs thus bring this action for infringement pursuant to 35 U.S.C. § 271(e)(2) based upon Bioepis's submission of its aBLA for SB3. Plaintiffs also seek a declaratory judgment pursuant to 42 U.S.C. § 262(*l*)(9) and 28 U.S.C. § 2201 that the manufacture, use, offer to sell, sale, or importation into the United States of Bioepis's biosimilar product would infringe the 21 patents described below. Pursuant to 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b),

and/or 35 U.S.C. § 283, Plaintiffs also seek a preliminary and/or permanent injunction barring Bioepis's manufacture, use, offer to sell, sale, or importation of its biosimilar product prior to the expiration of those patents. In the event that Bioepis imports, manufactures, or launches its biosimilar product, and/or otherwise practices the patented inventions in the United States prior to the expiration of those patents, Plaintiffs also seek monetary damages, including lost profits, and any further relief as this Court may deem just and proper.

PARTIES

10. Plaintiff Genentech is a corporation organized and existing under the laws of the State of Delaware with its corporate headquarters at 1 DNA Way, South San Francisco, California 94080.

11. Genentech was founded in 1976 and for four decades has been at the forefront of innovation in the field of therapeutic biotechnology. Today, Genentech employs a large number of researchers, scientists, and post-doctoral staff members who routinely publish in top peer-reviewed journals and are among the leaders in total citations to their work by researchers. Genentech currently markets numerous approved pharmaceutical and biologic drugs for a range of serious or life-threatening medical conditions, including various forms of cancer, heart attacks, strokes, rheumatoid arthritis, and respiratory diseases.

12. Plaintiff City of Hope is a California not-for-profit organization, with its principal place of business at 1500 East Duarte Road, Duarte, California 91010.

13. Founded in 1913, the City of Hope is a leading research hospital that incorporates cutting-edge research into patient care for cancer, diabetes, and other serious diseases.

14. Upon information and belief, Defendant Bioepis is a company organized and existing under the laws of the Republic of Korea with its principal place of business located at 107, Cheomdan-daero, Yeonsu-gu, Incheon, Republic of Korea.

15. Bioepis is a biopharmaceutical company that is, among other things, engaged in the development of biologic drugs, including a proposed biosimilar version of Genentech's Herceptin® product, SB3 ("Bioepis's aBLA product"). Upon information and belief, Bioepis intends to market and distribute such biopharmaceutical products in the United States, including through its distributor and commercialization partner Merck & Co., Inc. Upon information and belief, Bioepis's aBLA product will be distributed and sold in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

16. This action arises under the BPCIA, 42 U.S.C. § 262(*l*) and the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1332, and 1338.

17. Venue is proper with respect to Bioepis, a Korean company, in this Court pursuant to 28 U.S.C. § 1391(c)(3).

18. This Court has personal jurisdiction over Bioepis because it has filed an Abbreviated Biologics License Application ("aBLA") for SB3 with the FDA seeking approval to market its aBLA product, which reliably indicates that it will market its proposed biosimilar product in Delaware if approved. Alternatively, this Court has personal jurisdiction over Bioepis pursuant to Federal Rule of Civil Procedure 4(k)(2).

THE PARTIES' PRE-SUIT EXCHANGES

19. On December 20, 2017, Bioepis announced that it had submitted, and FDA had accepted for review, an aBLA for SB3 to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Bioepis aBLA product, a biosimilar version of trastuzumab, which is subject to BLA No. 103792 to Genentech.[3]

20. Under 42 U.S.C. § 262(*l*)(2), Bioepis was required to provide Genentech with a copy of its aBLA and such other information that describes the process or processes used to manufacture its aBLA product within 20 days of FDA's acceptance of its aBLA for review (i.e., no later than January 9, 2018).

21. On December 27, 2017, Genentech wrote to Bioepis to request a copy of its aBLA and to identify exemplary categories of additional information about the process or processes used to manufacture its aBLA product necessary to evaluate whether its aBLA product would infringe Genentech's patents.

22. On January 8, 2018, Bioepis provided Genentech with redacted versions of four subsections of its aBLA, which represented a tiny fraction of its entire aBLA. Bioepis therefore failed to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) to provide Genentech with, among other things, its aBLA within twenty days of the FDA's acceptance of its aBLA.

23. On January 12, 2018, Genentech wrote to Bioepis about its failure to comply with § 262(*l*)(2)(A) and to reiterate its request for at least an unredacted copy of Bioepis's complete aBLA.

[3] http://www.samsungbioepis.com/en/newsroom/detail/Samsung-Bioepis-SB3-Trastuzumab-Biosimilar-Candidate.html.

24. During January and February 2018, Genentech and Bioepis engaged in further correspondence regarding Bioepis's failure to provide Genentech with its aBLA as required by 42 U.S.C. § 262(*l*)(2)(A).

25. On February 15, 2018, and February 20, 2018, Bioepis provided Genentech with additional subsections of its aBLA. These subsections still represented only a small fraction of Bioepis's entire aBLA.

26. On March 1, 2018, Genentech agreed to provide Bioepis with a list of patents for which it believed a claim of patent infringement could reasonably be asserted based on Genentech's review of the limited set of aBLA documents that Bioepis produced. Genentech reiterated its objections about Bioepis's failure to comply with the requirements of § 262(*l*)(2)(A) and noted that its provision of this patent list would not waive those objections.

27. After its review of Bioepis's limited production of aBLA subsections, Genentech wrote to Bioepis on March 30, 2018, to identify deficiencies in Bioepis's production of manufacturing information and request specific information concerning the manufacture of Bioepis's biosimilar product. Bioepis responded on April 16, 2018 and refused to produce any additional aBLA subsections or information about its aBLA product.

28. Despite Bioepis's non-compliance (and without waiving Genentech's objection to such non-compliance), Genentech provided a list of patents for which it believed a claim of patent infringement could reasonably be asserted on April 23, 2018 ("Genentech's Apr. 23, 2018 List"), and informed Bioepis that it was not prepared to license any of the listed patents to Bioepis. Genentech expressly reserved its rights to supplement or revise this list in light of any additional information provided by Bioepis, and it noted that Bioepis's failure to comply with its

disclosure obligations under § 262(*l*)(2) caused Bioepis to forfeit any rights under the BPCIA that were contingent upon its compliance with those obligations.

29. Bioepis did not disclose all of the information relevant to establishing whether the manufacture of Bioepis's aBLA product will infringe each of the patents identified on Genentech's Apr. 23, 2018 list, despite Genentech's request that Bioepis provide sufficient "other information that describes the process or processes used to manufacture" as required by 42 U.S.C. § 262(*l*)(A). Bioepis's failure to provide sufficient information under those circumstances supports Genentech's contention that manufacturing Bioepis's aBLA product will infringe such patents.

30. On June 22, 2018, Bioepis responded to Genentech's Apr. 23, 2018 List by providing a statement purporting to describe the factual and legal bases for its opinion that the patents on Genentech's Apr. 23, 2018 List are not infringed, invalid, and/or unenforceable ("Bioepis's June 22, 2018 Statement"). Bioepis's June 22, 2018 Statement contains numerous deficiencies. For example, it—like Bioepis's document productions—failed to fully describe Bioepis's manufacturing process, such that Genentech was unable to evaluate many of Bioepis's non-infringement arguments.

31. On August 17, 2018, and subject to its objections, Genentech provided its response to Bioepis's June 22, 2018 Statement ("Genentech's Aug. 17, 2018 Response"). Genentech included responses to Bioepis's non-infringement and invalidity statements for each of the patents addressed in Bioepis's June 22, 2018 Statement and maintained that SB3 will infringe at least 21 Genentech patents. With its Aug. 17, 2018 Response, Genentech proposed that Bioepis agree that all 21 of these patents be included in an infringement action concerning

SB3. Bioepis responded to Genentech's proposal on August 23, 2018, and the parties engaged in further discussions regarding the patents to be asserted in this litigation.

32. On September 3, 2018, Bioepis agreed to litigate each of the 21 patents addressed in Genentech's Aug. 17, 2018 Response.

BIOEPIS'S aBLA PRODUCT

33. Bioepis has publicly stated that its aBLA product is biosimilar to Herceptin®. For example, Bioepis has issued a press release claiming that SB3 is "a biosimilar candidate referencing Herceptin®" and describing SB3 as a "Trastuzumab Biosimilar Candidate."[4]

34. Given Bioepis's claim of biosimilarity, Bioepis's aBLA product must "utilize the same mechanism or mechanisms of action [as Herceptin®] for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling." 42 U.S.C. § 262(k)(2)(A)(i)(II).

35. Under 35 U.S.C. § 271(e)(2)(C), Bioepis has committed a statutory act of patent infringement with respect to the each patent asserted in this action because Bioepis submitted an application seeking approval of a biological product for which each such patent could have been identified by Genentech pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided the application and information required under 42 U.S.C. § 262(*l*)(2)(A) and because Genentech identified each such patent on its Apr. 28, 2018 List based on its review of the limited information that Bioepis produced to Genentech.

[4] http://www.samsungbioepis.com/en/newsroom/detail/Samsung-Bioepis-SB3-Trastuzumab-Biosimilar-Candidate.html.

GENENTECH'S ASSERTED PATENTS

36. Genentech has spent over two decades and significant resources developing Herceptin®, and the USPTO has awarded to Genentech numerous patents on innovations resulting from this massive undertaking. These patents cover the antibody trastuzumab, along with its manufacture and use.

37. Upon information and belief, Bioepis's aBLA product will infringe at least the following patents, which Genentech has asserted in this lawsuit: U.S. Patent No. 6,331,415, U.S. Patent No. 7,923,221, U.S. Patent No. 6,407,213, U.S. Patent No. 7,846,441, U.S. Patent No. 7,892,549, U.S. Patent No. 6,627,196, U.S. Patent No. 7,371,379, U.S. Patent No. 6,339,142, U.S. Patent No. 6,417,335, U.S. Patent No. 9,249,218, U.S. Patent No. 8,574,869, U.S. Patent No. 7,993,834, U.S. Patent No. 8,076,066, U.S. Patent No. 8,425,908, U.S. Patent No. 8,440,402, U.S. Patent No. 6,610,516, U.S. Patent No. 7,390,660, U.S. Patent No. 7,485,704, U.S. Patent No. 7,807,799, U.S. Patent No. 8,512,983, and U.S. Patent No. 9,714,293.

The Cabilly Patents

38. U.S. Patent Nos. 6,331,415 and 7,923,221 (collectively, the "Cabilly Patents") describe and claim a process for producing monoclonal antibodies, such as Herceptin®, from recombinant DNA. This effective and efficient process applies a novel co-expression technique to produce antibody heavy and light chains in a single host cell and has given rise to an entire industry of therapeutic monoclonal antibodies.

39. U.S. Patent No. 6,331,415 ("the '415 patent"), titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein," was duly and legally issued by the Patent Office on December 18, 2001. A true and correct copy of the '415 patent is

attached as Exhibit A. Genentech and the City of Hope are the owners by assignment of the '415 patent.

40. U.S. Patent No. 7,923,221 ("the '221 patent"), titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen," was duly and legally issued by the Patent Office on April 12, 2011. A true and correct copy of the '221 patent is attached as Exhibit B. Genentech and the City of Hope are the owners by assignment of the '221 patent.

The '213 Patent

41. U.S. Patent No. 6,407,213 ("the '213 patent") claims the Herceptin® antibody itself, along with other humanized monoclonal antibodies. The inventors of the '213 patent discovered that by grafting the key parts of a mouse antibody onto a human antibody consensus sequence, they could create antibodies that were both tolerated by the immune system and effective to treat diseases like HER2-positive breast cancer. The techniques described in the '213 patent allowed scientists to efficiently design antibodies for specific disease targets by modifying mouse antibodies produced in the laboratory in specific ways so that they are compatible with a human immune system.

42. The '213 patent, titled "Method for Making Humanized Antibodies," was duly and legally issued by the Patent Office on June 18, 2002. A true and correct copy of the '213 patent is attached as Exhibit C. Genentech is the owner by assignment of the '213 patent.

The Combination Chemotherapy Patents

43. U.S. Patent No. 7,846,441 ("the '441 patent"), claims the administration of Herceptin® in combination with a chemotherapy agent known as a taxoid, in the absence of an anthracycline derivative (another chemotherapy agent) in an amount effective to extend time to

disease progression without overall increase in severe adverse events. This specific method of treatment unexpectedly resulted in a significant improvement in patient outcomes. It nearly doubled the time until disease progression compared to treatment using a taxoid alone, and it also avoided the serious cardiotoxicity associated with Herceptin® in combination with anthracycline derivatives that unexpectedly presented during the Herceptin® clinical trials.

44. The ’441 patent, titled “Treatment with Anti-ErbB2 Antibodies,” was duly and legally issued by the Patent Office on December 7, 2010. A true and correct copy of the ’441 patent is attached as Exhibit D. Genentech is the owner by assignment of the ’441 patent.

45. U.S. Patent No. 7,892,549 (“the ’549 patent”) is a continuation to the ’441 patent that claims a method of treating a patient with HER2-positive breast cancer by administering Herceptin® in combination with a taxoid and a further growth inhibitory agent or further therapeutic agent.

46. The ’549 patent, titled “Treatment with Anti-ErbB2 Antibodies,” was duly and legally issued by the Patent Office on February 22, 2011. A true and correct copy of the ’549 patent is attached as Exhibit E. Genentech is the owner by assignment of the ’549 patent.

47. U.S. Patent No. 8,425,908 (“the ’908 patent”), claims priority to the same provisional application as the ’441 and ’549 patents. The ’908 patent claims a method of treating a patient with HER2-positive gastric cancer by administering Herceptin® in combination with chemotherapy and in the absence of an anthracycline derivative.

48. The ’908 patent, titled “Treatment with Anti-ErbB2 Antibodies,” was duly and legally issued by the Patent Office on April 23, 2013. A true and correct copy of the ’908 patent is attached as Exhibit F. Genentech is the owner by assignment of the ’908 patent.

The Method of Administration Patents

49. U.S. Patent Nos. 6,627,196 and 7,371,379 (collectively, the "Method of Administration Patents") generally cover the most common administration method for Herceptin®: an initial dose of 8 mg/kg, followed by 6 mg/kg doses once every three weeks. Herceptin® was initially approved for administration on a weekly regimen, but Genentech discovered that the drug could be dosed only once every three weeks without reducing safety or effectiveness. The discovery of three-weekly dosing has had a marked impact on patients' quality of life by providing the same life-saving effects of Herceptin® while allowing patients to receive treatment less frequently.

50. U.S. Patent No. 6,627,196 ("the '196 patent"), titled "Dosages for Treatment with Anti-ErbB2 Antibodies," was duly and legally issued by the Patent Office on September 30, 2003. A true and correct copy of the '196 patent is attached as Exhibit G. Genentech is the owner by assignment of the '196 patent.

51. U.S. Patent No. 7,371,379 ("the '379 patent"), titled "Dosages for Treatment with Anti-ErbB2 Antibodies," was duly and legally issued by the Patent Office on May 13, 2008. A true and correct copy of the '379 patent is attached as Exhibit H. Genentech is the owner by assignment of the '379 patent.

The Acidic Variants Patents

52. U.S. Patent Nos. 6,339,142, 6,417,335, and 9,249,218 (collectively, the "Acidic Variants Patents") cover compositions with reduced amounts of more acidic structural variants of trastuzumab ("acidic variants") and chromatographic processes for removing these acidic variants during purification. Some trastuzumab acidic variants have lower potency than

trastuzumab itself. The Acidic Variants Patents describe and claim chromatographic processes and compositions that ensure the Herceptin® drug product is uniformly pure and effective.

53. U.S. Patent No. 6,339,142 ("the '142 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on January 15, 2002. A true and correct copy of the '142 patent is attached as Exhibit I. Genentech is the owner by assignment of the '142 patent.

54. U.S. Patent No. 6,417,335 ("the '335 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on July 9, 2002. A true and correct copy of the '335 patent is attached as Exhibit J. Genentech is the owner by assignment of the '335 patent.

55. U.S. Patent No. 9,249,218 ("the '218 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on February 2, 2016. A true and correct copy of the '218 patent is attached as Exhibit K. Genentech is the owner by assignment of the '218 patent.

HER2 Diagnostic Patents

56. U.S. Patent Nos. 7,993,834, 8,076,066, and 8,440,402 claim novel techniques for identifying patients who might benefit from trastuzumab therapy using gene amplification techniques even where immunohistochemistry techniques suggest that the patient may not overexpress HER2.

57. U.S. Patent No. 7,993,834 ("the '834 patent"), titled "Detection of ErbB2 Gene Amplification to Increase the Likelihood of the Effectiveness of ErbB2 Antibody Breast Cancer Therapy," was duly and legally issued by the Patent Office on August 9, 2011. A true and correct copy of the '834 patent is attached as Exhibit L. Genentech is the owner by assignment of the '834 patent.

58. U.S. Patent No. 8,076,066 ("the '066 patent"), titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," was

duly and legally issued by the Patent Office on December 13, 2011. A true and correct copy of the ’066 patent is attached as Exhibit M. Genentech is the owner by assignment of the ’066 patent.

59. U.S. Patent No. 8,440,402 (“the ’402 patent”), titled “Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy,” was duly and legally issued by the Patent Office on May 14, 2013. A true and correct copy of the ’402 patent is attached as Exhibit N. Genentech is the owner by assignment of the ’402 patent.

Cell Culture, Purification, and Antibody Manufacturing Patents

60. U.S. Patent Nos. 6,610,516, 7,390,660, 7,485,704, 7,807,799, 8,512,983, 8,574,869, and 9,714,293, and claim novel techniques developed by Genentech relating to various aspects of cell culture, purification, and antibody purification.

61. U.S. Patent No. 6,610,516 (“the ’516 patent”), titled “Cell Culture Process,” was duly and legally issued by the Patent Office on August 26, 2003. A true and correct copy of the ’516 patent is attached as Exhibit O. Genentech is the owner by assignment of the ’516 patent.

62. U.S. Patent No. 7,390,660 (“the ’660 patent”), titled “Methods for Growing Mammalian Cells In Vitro,” was duly and legally issued by the Patent Office on June 24, 2008. A true and correct copy of the ’660 patent is attached as Exhibit P. The ’660 patent is assigned to Hoffmann La-Roche Inc., and Genentech, Inc. is the exclusive licensee with the sole right to enforce the ’660 patent.

63. U.S. Patent No. 7,485,704 (“the ’704 patent”), titled “Reducing Protein A Leaching During Protein A Affinity Chromatography,” was duly and legally issued by the Patent Office on February 3, 2009. A true and correct copy of the ’704 patent is attached as Exhibit Q. Genentech is the owner by assignment of the ’704 patent.

64. U.S. Patent No. 7,807,799 ("the '799 patent"), titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," was duly and legally issued by the Patent Office on October 5, 2010. A true and correct copy of the '799 patent is attached as Exhibit R. Genentech is the owner by assignment of the '799 patent.

65. U.S. Patent No. 8,512,983 ("the '983 patent"), titled "Production of Proteins in Glutamine-Free Cell Culture Media," was duly and legally issued by the Patent Office on August 20, 2013. A true and correct copy of the '983 patent is attached as Exhibit S. Genentech is the owner by assignment of the '983 patent.

66. U.S. Patent No. 8,574,869 ("the '869 patent"), titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," was duly and legally issued by the Patent Office on November 5, 2013. A true and correct copy of the '869 patent is attached as Exhibit T. Genentech is the owner by assignment of the '869 patent.

67. U.S. Patent No. 9,714,293 ("the '293 patent"), titled "Production of Proteins in Glutamine-Free Cell Culture Media," was duly and legally issued by the Patent Office on July 25, 2017. A true and correct copy of the '293 patent is attached as Exhibit U. Genentech is the owner by assignment of the '293 patent.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 6,331,415

68. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

69. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '415 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that

Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '415 patent on that list.

70. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '415 patent is a technical act of infringement of one or more claims of the '415 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

71. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '415 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '415 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

72. Bioepis has knowledge of and is aware of the '415 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '415 patent is willful.

73. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '415 patent. Plaintiffs have

no adequate remedy at law.

74. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 7,923,221

75. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

76. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '221 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '221 patent on that list.

77. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '221 patent is a technical act of infringement of one or more claims of the '221 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

78. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will

infringe the ’221 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech’s Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis’s proposed SB3 drug product will infringe the ’221 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

79. Bioepis has knowledge of and is aware of the ’221 patent, including due to Genentech’s Apr. 23, 2018 List and the filing of this Complaint. Bioepis’s infringement of the ’221 patent is willful.

80. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the ’221 patent. Plaintiffs have no adequate remedy at law.

81. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 6,407,213

82. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

83. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the ’213 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required

information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '213 patent on that list.

84. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '213 patent is a technical act of infringement of one or more claims of the '213 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

85. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '213 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '213 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

86. Bioepis has knowledge of and is aware of the '213 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '213 patent is willful.

87. Plaintiffs will suffer irreparable injury for which damages are an inadequate

remedy unless Bioepis is enjoined from infringing the claims of the ’213 patent. Plaintiffs have no adequate remedy at law.

88. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 7,846,441

89. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

90. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the ’441 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the ’441 patent on that list.

91. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the ’441 patent is a technical act of infringement of one or more claims of the ’441 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

92. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '441 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '441 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

93. Bioepis has knowledge of and is aware of the '441 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '441 patent is willful.

94. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Bioepis aBLA product, Bioepis has an affirmative intent to actively induce infringement by others of one or more claims of the '441 patent, either literally or under the doctrine of equivalents.

95. Upon information and belief, Bioepis is aware, have knowledge, and/or are willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Bioepis aBLA product according to Bioepis's proposed package insert and, therefore, will directly infringe at least one claim of the '441 patent, either literally or under the doctrine of equivalents.

96. Upon information and belief, Bioepis knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '441 patent, either literally or under the doctrine of equivalents, by at least Bioepis's proposed package insert for the Bioepis aBLA product.

97. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '441 patent. Plaintiffs have no adequate remedy at law.

98. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 7,892,549

99. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

100. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '549 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '549 patent on that list.

101. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale

of the Bioepis aBLA product prior to the expiration of the ’549 patent is a technical act of infringement of one or more claims of the ’549 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

102. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the ’549 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech’s Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis’s proposed SB3 drug product will infringe the ’549 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

103. Bioepis has knowledge of and is aware of the ’549 patent, including due to Genentech’s Apr. 23, 2018 List and the filing of this Complaint. Bioepis’s infringement of the ’549 patent is willful.

104. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Bioepis aBLA product, Bioepis has an affirmative intent to actively induce infringement by others of one or more claims of the ’549 patent, either literally or under the doctrine of equivalents.

105. Upon information and belief, Bioepis is aware, have knowledge, and/or are willfully blind to the fact that patients will administer and/or use and medical practitioners will

prescribe and/or administer the Bioepis aBLA product according to Bioepis's proposed package insert and, therefore, will directly infringe at least one claim of the '549 patent, either literally or under the doctrine of equivalents.

106. Upon information and belief, Bioepis knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '549 patent, either literally or under the doctrine of equivalents, by at least Bioepis's proposed package insert for the Bioepis aBLA product.

107. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '549 patent. Plaintiffs have no adequate remedy at law.

108. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT VI
INFRINGEMENT OF U.S. PATENT NO. 8,425,908

109. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

110. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '908 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '908 patent on that list.

111. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '908 patent is a technical act of infringement of one or more claims of the '908 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

112. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '908 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '908 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

113. Bioepis has knowledge of and is aware of the '908 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '908 patent is willful.

114. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Bioepis aBLA product, Bioepis has an

affirmative intent to actively induce infringement by others of one or more claims of the '908 patent, either literally or under the doctrine of equivalents.

115. Upon information and belief, Bioepis is aware, have knowledge, and/or are willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Bioepis aBLA product according to Bioepis's proposed package insert and, therefore, will directly infringe at least one claim of the '908 patent, either literally or under the doctrine of equivalents.

116. Upon information and belief, Bioepis knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '908 patent, either literally or under the doctrine of equivalents, by at least Bioepis's proposed package insert for the Bioepis aBLA product.

117. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '908 patent. Plaintiffs have no adequate remedy at law.

118. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT VII
INFRINGEMENT OF U.S. PATENT NO. 6,627,196

119. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

120. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '196 patent could

have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '196 patent on that list.

121. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '196 patent is a technical act of infringement of one or more claims of the '196 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

122. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '196 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '196 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

123. Bioepis has knowledge of and is aware of the '196 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '196 patent is willful.

124. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Bioepis aBLA product, Bioepis has an affirmative intent to actively induce infringement by others of one or more claims of the '196 patent, either literally or under the doctrine of equivalents.

125. Upon information and belief, Bioepis is aware, have knowledge, and/or are willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Bioepis aBLA product according to Bioepis's proposed package insert and, therefore, will directly infringe at least one claim of the '196 patent, either literally or under the doctrine of equivalents.

126. Upon information and belief, Bioepis knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '196 patent, either literally or under the doctrine of equivalents, by at least Bioepis's proposed package insert for the Bioepis aBLA product.

127. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '196 patent. Plaintiffs have no adequate remedy at law.

128. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT VIII
INFRINGEMENT OF U.S. PATENT NO. 7,371,379

129. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

130. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '379 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '379 patent on that list.

131. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '379 patent is a technical act of infringement of one or more claims of the '379 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

132. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '379 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '379 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

133. Bioepis has knowledge of and is aware of the '379 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '379 patent is willful.

134. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Bioepis aBLA product, Bioepis has an affirmative intent to actively induce infringement by others of one or more claims of the '379 patent, either literally or under the doctrine of equivalents.

135. Upon information and belief, Bioepis is aware, have knowledge, and/or are willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Bioepis aBLA product according to Bioepis's proposed package insert and, therefore, will directly infringe at least one claim of the '379 patent, either literally or under the doctrine of equivalents.

136. Upon information and belief, Bioepis knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '379 patent, either literally or under the doctrine of equivalents, by at least Bioepis's proposed package insert for the Bioepis aBLA product.

137. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '379 patent. Plaintiffs have no adequate remedy at law.

138. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the

commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT IX
INFRINGEMENT OF U.S. PATENT NO. 6,339,142

139. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

140. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '142 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '142 patent on that list.

141. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '142 patent is a technical act of infringement of one or more claims of the '142 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

142. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '142 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's

Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '142 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

143. Bioepis has knowledge of and is aware of the '142 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '142 patent is willful.

144. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '142 patent. Plaintiffs have no adequate remedy at law.

145. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT X
INFRINGEMENT OF U.S. PATENT NO. 6,417,335

146. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

147. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '335 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '335 patent on that list.

148. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '335 patent is a technical act of infringement of one or more claims of the '335 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

149. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '335 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '335 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

150. Bioepis has knowledge of and is aware of the '335 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '335 patent is willful.

151. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '335 patent. Plaintiffs have no adequate remedy at law.

152. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT XI
INFRINGEMENT OF U.S. PATENT NO. 9,249,218

153. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

154. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '218 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '218 patent on that list.

155. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '218 patent is a technical act of infringement of one or more claims of the '218 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

156. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '218 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its

activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '218 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

157. Bioepis has knowledge of and is aware of the '218 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '218 patent is willful.

158. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '218 patent. Plaintiffs have no adequate remedy at law.

159. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT XII
INFRINGEMENT OF U.S. PATENT NO. 7,993,834

160. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

161. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '834 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that

Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '834 patent on that list.

162. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '834 patent is a technical act of infringement of one or more claims of the '834 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

163. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '834 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '834 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

164. Bioepis has knowledge of and is aware of the '834 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '834 patent is willful.

165. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '834 patent. Plaintiffs have

no adequate remedy at law.

166. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT XIII
INFRINGEMENT OF U.S. PATENT NO. 8,076,066

167. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

168. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '066 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '066 patent on that list.

169. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '066 patent is a technical act of infringement of one or more claims of the '066 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

170. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will

infringe the ’066 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech’s Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis’s proposed SB3 drug product will infringe the ’066 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

171. Bioepis has knowledge of and is aware of the ’066 patent, including due to Genentech’s Apr. 23, 2018 List and the filing of this Complaint. Bioepis’s infringement of the ’066 patent is willful.

172. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the ’066 patent. Plaintiffs have no adequate remedy at law.

173. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT XIV
INFRINGEMENT OF U.S. PATENT NO. 8,440,402

174. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

175. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the ’402 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required

information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '402 patent on that list.

176. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '402 patent is a technical act of infringement of one or more claims of the '402 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

177. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '402 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '402 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

178. Bioepis has knowledge of and is aware of the '402 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '402 patent is willful.

179. Plaintiffs will suffer irreparable injury for which damages are an inadequate

remedy unless Bioepis is enjoined from infringing the claims of the '402 patent. Plaintiffs have no adequate remedy at law.

180. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT XV
INFRINGEMENT OF U.S. PATENT NO. 6,610,516

181. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

182. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '516 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '516 patent on that list.

183. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '516 patent is a technical act of infringement of one or more claims of the '516 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

184. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '516 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '516 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

185. Bioepis has knowledge of and is aware of the '516 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '516 patent is willful.

186. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '516 patent. Plaintiffs have no adequate remedy at law.

187. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT XVI
INFRINGEMENT OF U.S. PATENT NO. 7,390,660

188. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

189. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C.

§ 262(*l*)(2)(A). Based on the information currently available to Genentech, the '660 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '660 patent on that list.

190. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '660 patent is a technical act of infringement of one or more claims of the '660 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

191. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '660 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '660 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

192. Bioepis has knowledge of and is aware of the '660 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '660 patent is willful.

193. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '660 patent. Plaintiffs have no adequate remedy at law.

194. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT XVII
INFRINGEMENT OF U.S. PATENT NO. 7,485,704

195. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

196. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '704 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '704 patent on that list.

197. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '704 patent is a technical act of

infringement of one or more claims of the '704 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

198. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '704 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '704 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

199. Bioepis has knowledge of and is aware of the '704 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '704 patent is willful.

200. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '704 patent. Plaintiffs have no adequate remedy at law.

201. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT XVIII
INFRINGEMENT OF U.S. PATENT NO. 7,807,799

202. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

203. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '799 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '799 patent on that list.

204. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '799 patent is a technical act of infringement of one or more claims of the '799 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

205. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '799 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale,

use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '799 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

206. Bioepis has knowledge of and is aware of the '799 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '799 patent is willful.

207. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '799 patent. Plaintiffs have no adequate remedy at law.

208. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT XIX
INFRINGEMENT OF U.S. PATENT NO. 8,512,983

209. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

210. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '983 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '983 patent on that list.

211. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of

the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '983 patent is a technical act of infringement of one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

212. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '983 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '983 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

213. Bioepis has knowledge of and is aware of the '983 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '983 patent is willful.

214. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '983 patent. Plaintiffs have no adequate remedy at law.

215. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the

commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT XX
INFRINGEMENT OF U.S. PATENT NO. 8,574,869

216. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

217. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '869 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '869 patent on that list.

218. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '869 patent is a technical act of infringement of one or more claims of the '869 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

219. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '869 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's

Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '869 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

220. Bioepis has knowledge of and is aware of the '869 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '869 patent is willful.

221. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '869 patent. Plaintiffs have no adequate remedy at law.

222. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

COUNT XXI
INFRINGEMENT OF U.S. PATENT NO. 9,714,293

223. Plaintiffs incorporate by reference paragraphs 1-67 as if fully set forth herein.

224. Bioepis failed to provide Genentech with its aBLA and other information that describes the process or processes used to manufacture SB3, as required by 42 U.S.C. § 262(*l*)(2)(A). Based on the information currently available to Genentech, the '293 patent could have been identified pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i) had Bioepis provided this required information. Alternatively, to the extent that Bioepis contends that the list of patents that Genentech provided to Bioepis on April 23, 2018, constitutes a list pursuant to 42 U.S.C. § 262(*l*)(3)(A), Genentech identified the '293 patent on that list.

225. Based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Bioepis aBLA product prior to the expiration of the '293 patent is a technical act of infringement of one or more claims of the '293 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech provided detailed, claim-by-claim infringement contentions to Bioepis in its Aug. 17, 2018 Response.

226. Likewise, based on publicly available information and/or information provided by Bioepis pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Bioepis will infringe the '293 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and its proposed SB3 drug product, as explained in Genentech's Aug. 17, 2018 Response. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Bioepis's manufacture, importation, sale, offer for sale, use, and promotion of the use of the SB3 drug substance and Bioepis's proposed SB3 drug product will infringe the '293 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

227. Bioepis has knowledge of and is aware of the '293 patent, including due to Genentech's Apr. 23, 2018 List and the filing of this Complaint. Bioepis's infringement of the '293 patent is willful.

228. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Bioepis is enjoined from infringing the claims of the '293 patent. Plaintiffs have no adequate remedy at law.

229. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Bioepis from the commercial manufacture, use, offer to sell, or sale within the United States of the Bioepis aBLA product.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor against Bioepis and grant the following relief:

a. a judgment that Bioepis has infringed or induced infringement of one or more claims of the asserted patents under 35 U.S.C. § 271(e)(2)(C);

b. a judgment that Bioepis has infringed or will infringe, or has induced or will induce infringement, of one or more claims of the asserted patents by engaging in the manufacture, import, offer for sale, sale, or use within the United States of the Bioepis aBLA product before the expirations of the asserted patents;

c. preliminary and/or permanent equitable relief, including but not limited to a preliminary and permanent injunction that enjoins Bioepis, its officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with Bioepis and/or its successors or assigns from infringing the asserted patents, or contributing to or inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacturing of which infringes the asserted patents;

d. monetary damages in the event that Bioepis imports, manufactures, or launches its biosimilar product and/or otherwise practices the patented inventions in the United States prior to

the expiration of the asserted patents, including lost profits and/or a reasonable royalty, and an accounting and/or ongoing royalty for any post-judgment infringement;

e. a judgment that Bioepis's infringement was willful and enhancement of any monetary damages pursuant to 35 U.S.C. § 284;

f. a declaration that this is an exceptional case and an award to Plaintiffs of their attorneys' fees, costs, and expenses pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

g. such other relief as this Court may deem just and proper.

/s/ Frederick L. Cottrell, III
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