IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and BOEHRINGER INGELHEIM FREMONT, INC.,	)	
Defendants.	)	

COMPLAINT

INTRODUCTION

1. This is an action for patent infringement arising from the desire of Boehringer Ingelheim International GmbH, Boehringer Ingelheim Pharmaceuticals, Inc., and Boehringer Ingelheim Fremont, Inc. ("Boehringer" or "Defendants") to reap the rewards of AbbVie's innovation. This innovation has resulted in more than 100 issued United States patents concerning the HUMIRA® product, 74 of which AbbVie has identified as infringed. While AbbVie has spent vast resources over decades developing HUMIRA®, Boehringer seeks to copy AbbVie's work and ignore AbbVie's patents. But while the Biosimilar Price Competition and Innovation Act ("BPCIA") gives Boehringer an abbreviated regulatory pathway for its biosimilar version of HUMIRA®, it does *not* give Boehringer license to infringe AbbVie's patents. AbbVie seeks an injunction to prevent this infringement.

2. HUMIRA® belongs to a category of drugs known as biologics. Biologics are complex proteins manufactured in living cells rather than by chemical synthesis. These are

critically important drugs that are difficult to develop, manufacture, formulate, and administer. Within the category of biologics, HUMIRA® is unique. HUMIRA® was the first fully human antibody approved by the Food and Drug Administration ("FDA"). In bringing HUMIRA® from the laboratory to patients, AbbVie operated in uncharted territory. In 1996, AbbVie invented the antibody in HUMIRA®. But that was only the first step. Since then, AbbVie has embarked on two decades of research, investment, and innovation.

3. As part of its commitment to improve patients' lives, AbbVie has dedicated substantial resources to an extensive clinical trial program. AbbVie's clinical research on HUMIRA® includes over 100 clinical trials and resulted in FDA approval for the treatment of ten different diseases, including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease (adult and pediatric), ulcerative colitis, hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis. To date, over one million patients have benefited from AbbVie's pioneering work on HUMIRA®. Boehringer seeks to copy the results of AbbVie's clinical development.

4. To further benefit patients, AbbVie also invested in and created a subcutaneous, high concentration, liquid formulation of the HUMIRA® antibody. Before AbbVie's launch of HUMIRA®, patients had to go to the hospital to receive their medicine intravenously or mix batches of their medicine at home (which was difficult for patients with inflamed joints) and inject themselves twice a week. As a result of AbbVie's dedication and innovation, patients can now inject the medicine at home, using pre-filled syringes, and take fewer injections. The added convenience and precision has improved patients' lives and increased compliance, all without sacrificing HUMIRA®'s outstanding efficacy. Here again, Boehringer seeks to copy the results of AbbVie's innovative formulation work.

5. AbbVie has also spent many years developing the complex manufacturing processes for HUMIRA®, and its active ingredient, adalimumab. As discussed above, unlike traditional drugs, HUMIRA® is a complex biologic created in living organisms. Even minor changes can impact the stability, purity, and efficacy of the drug. Again, Boehringer seeks to copy the results of AbbVie's innovative manufacturing work.

6. In attempting to copy the results of AbbVie's innovations, however, Boehringer is faced with two major hurdles: the United States Patent and Trademark Office ("USPTO") has granted AbbVie numerous patents that are valid and infringed by Boehringer, and the United States Congress has laid out a mechanism for AbbVie to bring litigation on these patents before Boehringer launches its biosimilar.

7. In the BPCIA, Congress recognized the need to protect an originator's patent rights and provided a multi-step process for identifying and litigating those patents. As part of that process, AbbVie identified 74 patents, but this lawsuit involves only eight of them. That is Boehringer's choice, not AbbVie's. The BPCIA gave Boehringer the ability to cap the number of patents at issue in this lawsuit, rather than litigate all of AbbVie's patents efficiently in a single wave and without delay. As spelled out in the law, Boehringer selected the number of patents (five) each side could litigate in this first wave, the parties exchanged lists of five patents each, and the eight patents-in-suit constitute the compilation of the two lists (two patents were on both lists). While AbbVie is only permitted to assert eight patents now, if and when Boehringer provides its 180-day Notice of Commercial Marketing, and as circumstances otherwise warrant, AbbVie will have the opportunity to assert the remainder of the patents. Therefore, there will be a second wave of litigation to adjudicate AbbVie's substantial patent rights relating to HUMIRA®.

8. AbbVie seeks an injunction to prevent Boehringer from engaging in widespread infringement of the eight patents in this Complaint. AbbVie also reserves its right to assert the remaining patents infringed by Boehringer in a second wave if and when Boehringer provides a Notice of Commercial Marketing, or as circumstances otherwise warrant.

NATURE OF THE ACTION

9. AbbVie Inc. and AbbVie Biotechnology Ltd ("ABL" and collectively with AbbVie Inc., "AbbVie" or "Plaintiffs") for their Complaint against Boehringer further allege as follows:

10. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, including 35 U.S.C. § 271(e)(2)(C). This is also a civil action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, seeking declaratory judgments that the asserted patents are infringed.

11. This lawsuit results from Boehringer's infringement of AbbVie patents that concern AbbVie's groundbreaking HUMIRA®.

12. AbbVie Inc. is the holder of Biologic License Application ("BLA") No. 125057 for HUMIRA®, whose active pharmaceutical ingredient is the antibody adalimumab.

13. In 1996, after many years of intense research, AbbVie's predecessor first created adalimumab. Adalimumab, a biologic, is a fully human, high-affinity, and neutralizing therapeutic antibody to human TNF-α, a protein made by the human body as part of the body's immune response. The mechanisms by which TNF-α affects the body are complex and not completely understood (even today).

14. The invention of adalimumab was particularly noteworthy in that it was the first fully human antibody approved by the FDA. This was hailed by the medical and scientific

community as a major breakthrough. Compared to other drugs that were available at the time, adalimumab offered patients substantial benefits. For example, REMICADE® (infliximab), which was a chimeric antibody, had numerous drawbacks, including, among others, the fact that it had to be administered by intravenous injection at an infusion center.

15. Inventing the adalimumab antibody itself, however, was only the first step in the process. Following the isolation and characterization of adalimumab, AbbVie and its predecessor Abbott Laboratories, spent more than a decade and hundreds of millions of dollars on scientific studies and clinical trials to determine how to use HUMIRA® to treat patients for different diseases, how to formulate HUMIRA® for administration to humans, and how to manufacture HUMIRA®. AbbVie's scientific and clinical investments in HUMIRA® continue to this day.

16. AbbVie's innovative work has been recognized by the medical and scientific community. For example, in 2007, HUMIRA® was awarded the Galien Prize, perhaps the most prestigious honor in the pharmaceutical and biotechnology world.

17. More importantly, AbbVie's work has benefited patients immensely. Children have gone from wheelchairs to playgrounds, and adults have gone from bed to work. AbbVie is very proud of the fact that HUMIRA® has improved the lives of more than one million patients to date.

18. The Patent Office has also recognized AbbVie's innovative work by granting it over 100 patents on HUMIRA® beyond the initial antibody patent, 74 of which AbbVie has identified as infringed.

19. Boehringer has chosen to allow AbbVie to bring this lawsuit on only eight of AbbVie's 74 patents at this time. While Boehringer can delay justice, it cannot prevent it.

Pursuant to the BPCIA, AbbVie can seek relief, including an injunction, on the remaining patents when Boehringer files a Notice of Commercial Marketing, which it must do at least 180 days prior to launching its biosimilar product.

20. In seeking approval for its biosimilar adalimumab product BI 695501 (the "Boehringer aBLA Product"), Boehringer seeks to benefit from AbbVie's substantial investment in HUMIRA® and the two decades of time, effort, investment, and innovation by AbbVie's scientists. Although the BPCIA allows Boehringer an abbreviated regulatory pathway, it does not give Boehringer a license to infringe AbbVie's intellectual property. At this time, AbbVie seeks an injunction to prevent infringement of at least 162 claims of the eight asserted AbbVie patents. If and when Boehringer files a Notice of Commercial Marketing or as circumstances otherwise warrant, AbbVie will assert additional patents from its estate.

PARTIES

21. Plaintiff AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie Inc. is engaged in the development, sale, and distribution of a broad range of pharmaceutical and biologic drugs.

22. Plaintiff ABL is a corporation organized and existing under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM1l, Bermuda. Through intermediate organizations, Plaintiff AbbVie Inc. owns Plaintiff ABL.

23. On information and belief, Defendant Boehringer Ingelheim International GmbH ("BII") is a company organized and existing under the laws of Germany with its principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.

24. On information and belief, BII, acting in concert with the other Defendants, is in the business of developing, manufacturing, marketing, and selling biologic drugs, including the proposed biosimilar version of AbbVie's HUMIRA® (adalimumab) product, BI 695501. On information and belief, these drugs are (or will be) distributed and sold in the State of Delaware and throughout the United States.

25. On information and belief, Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a corporation existing under the laws of Delaware with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

26. On information and belief, BIPI, acting in concert with the other Defendants, is in the business of developing, manufacturing, marketing, and selling biologic drugs, including the proposed biosimilar version of AbbVie's HUMIRA® (adalimumab) product, BI 695501. On information and belief, these drugs are (or will be) distributed and sold in the State of Delaware and throughout the United States.

27. On information and belief, Defendant Boehringer Ingelheim Fremont, Inc. ("BIFI") is a corporation existing under the laws of Delaware with its principal place of business at 6701 Kaiser Drive, Fremont, California 94555.

28. On information and belief, BIFI is in the business of manufacturing biologic drugs, including the proposed biosimilar version of AbbVie's HUMIRA® (adalimumab) product, BI 695501. On information and belief, these drugs are (or will be) distributed and sold in the State of Delaware and throughout the United States.

29. On information and belief, BIPI and BIFI are wholly-owned, indirect subsidiaries of BII.

30. On information and belief, Defendants are working in concert with respect to the U.S. regulatory approval of a proposed biosimilar version of AbbVie's HUMIRA® (adalimumab) product, and each Defendant intends to benefit directly from any approval of the proposed biosimilar version of AbbVie's HUMIRA® (adalimumab) product, including through sales of this product in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

31. This is an action for patent infringement under 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, 1338(a), 2201(a), and 2202.

32. This Court has personal jurisdiction over each of the Defendants for the reasons set forth below.

A. Boehringer Ingelheim Pharmaceuticals, Inc.

33. This Court has jurisdiction over BIPI because, *inter alia*, it is incorporated in the State of Delaware, and its contacts with the State of Delaware are sufficient for jurisdiction.

34. On information and belief, BIPI has collaborated with the other Defendants to develop, manufacture, and seek approval for the Boehringer aBLA Product, and on information and belief, BIPI, in concert with the other Defendants, intends to manufacture, market, and sell the Boehringer aBLA Product in the United States and in the State of Delaware if the Boehringer aBLA Product receives FDA approval.

B. Boehringer Ingelheim Fremont, Inc.

35. This Court has jurisdiction over BIFI because, *inter alia*, it is incorporated in the State of Delaware, and its contacts with the State of Delaware are sufficient for jurisdiction.

36. BIFI is the only biologic manufacturing facility identified on Boehringer's website that is located in the United States. Boehringer Ingelheim, "Fremont," https://www.bioxcellence.com/about_us/manufacturing_plants/fremont.html, attached hereto as Exhibit 1. According to Boehringer's website, "Boehringer Ingelheim's 300,000 square-foot multi-product manufacturing facility in Fremont, USA is dedicated to the manufacture of monoclonal antibody therapies and other proteins from mammalian cell culture technology. It includes process development labs, a pilot plant, and large-scale bioreactors for manufacturing biologics for clinical studies as well as for commercialization." *Id.* BIFI "specializes" in biologics and produces them "through a highly-sophisticated series of manufacturing steps." Jens Vogel, "Boehringer Ingelheim Fremont & Biosimilars," May 18, 2017, https://www.linkedin.com/pulse/boehringer-ingelheim-fremont-biosimilars-jens-h-vogel-ph-d-. In addition, Boehringer has confirmed that BIFI is "very active" in the biosimilars space. BoehringerUS, "BI Fremont – ft. Jens Vogel," Jun. 19, 2017, https://www.youtube.com/watch?v=6aryfRX9YtI. On information and belief, in an application for a sales and use tax exclusion to expand the BIFI manufacturing facility, BIFI disclosed that "[s]everal different biologics and biosimilars are expected to be produced by the facility, and the majority have already been approved by the Food and Drug Administration." Boehringer Ingelheim Fremont, Inc., Application No. 17-SM043, May 16, 2017, http://www.treasurer.ca.gov/caeatfa/meeting/staff/2017/20170516/4a2.pdf, attached hereto as Exhibit 2.

37. On information and belief, BIFI, in concert with the other Defendants, intends to manufacture the Boehringer aBLA Product for marketing and sale into the State of Delaware if the Boehringer aBLA Product receives FDA approval.

C. Boehringer Ingelheim International GmbH

38. This Court has jurisdiction over BII because BII's contacts with the State of Delaware and the United States are sufficient for jurisdiction.

39. On information and belief, BII intends to act in concert with, direct, and/or authorize the other Defendants to manufacture, market, and sell the Boehringer aBLA Product into the United States and the State of Delaware if the Boehringer aBLA Product receives FDA approval.

40. On information and belief, BII has acted in concert with, directed, and/or authorized the other Defendants to develop and seek approval for the Boehringer aBLA Product, including by sponsoring, directing, and/or authorizing clinical trials of the Boehringer aBLA Product in support of Boehringer's abbreviated Biologics License Application ("Boehringer's aBLA"). For example, Boehringer issued a press release on BII's website regarding Phase I and Phase III clinical trials comparing the Boehringer aBLA Product to the "U.S. licensed…reference product[]." *See* Press Release, Boehringer Ingelheim, "Boehringer Ingelheim Announces Completed Enrollment of Phase III Clinical Trial for Biosimilar Candidate to Adalimumab," Nov. 10, 2015, https://www.boehringer-ingelheim.com/press-release/boehringer-ingelheim-announces-completed-enrollment-phase-iii-clinical-trial, attached hereto as Exhibit 3. *See also* Press Release, Boehringer Ingelheim, "Boehringer Ingelheim's Biosimilar Candidate Demonstrated Pharmacokinetic Bioequivalence to Adalimumab," Oct. 28, 2015, https://www.boehringer-ingelheim.com/press-release/boehringer-ingelheim-s-biosimilar-candidate-demonstrated-pharmacokinetic, attached hereto as Exhibit 4.

41. On information and belief, BII is actively involved with filing the Boehringer aBLA and the strategy for obtaining FDA approval to market and sell the Boehringer aBLA

Product in the State of Delaware and throughout the United States, which directly gives rise to AbbVie's claims of patent infringement. For example, Boehringer issued a press release on BII's website regarding the Boehringer aBLA. *See* Press Release, Boehringer Ingelheim, "Boehringer Ingelheim biosimilar candidate to Humira® accepted for EMA and FDA regulatory review," Jan. 18, 2017, https://www.boehringer-ingelheim.com/press-release/boehringer-ingelheim-biosimilar-candidate-humira-accepted-ema-and-fda-regulatory, attached hereto as Exhibit 5.

42. On information and belief, BII exercises control over the other Defendants with respect to biosimilar products, and approves significant decisions of each, including controlling or otherwise directing and authorizing the preparation and filing of the Boehringer aBLA.

43. Furthermore, Defendants hold themselves out as a unitary entity and have represented to the public that their activities with respect to biosimilars are directed, controlled, and carried out as a single entity. For example, in the press release at Exhibit 5, BII states that "*Boehringer Ingelheim* is seeking approval for BI 695501 as a biosimilar to Humira®" (emphasis added).

44. In addition, on May 12, 2017, May 18, 2017, and July 6, 2017, BIPI and BII collectively provided statements pursuant to 42 U.S.C. § 262(*l*)(3)(B) and 42 U.S.C. § 262(*l*)(7)(B) related to the Boehringer aBLA and Boehringer aBLA Product. On July 31, 2017, BIPI and BII collectively identified five patents to AbbVie pursuant to 42 U.S.C. § 262(*l*)(5).

45. On information and belief, BII has also acted in concert with, directed, and/or authorized BIPI to communicate with AbbVie regarding the information exchange procedures under the BPCIA, as evidenced by the letters described in paragraph 44.

46. Furthermore, BII has availed itself of this Court by asserting claims in this judicial District in numerous legal proceedings. *See, e.g., Boehringer Ingelheim Pharma GmbH & Co. KG et al. v. Teva Pharm. USA Inc. et al.*, 1:15-cv-00048-SLR (Jan. 16, 2015); *Boehringer Ingelheim Pharma GmbH & Co. KG et al v. Barr Labs. et al.*, 1:07-cv-00432-GMS (Jul. 11, 2007); *Boehringer Ingelheim Int'l GmbH et al v. Mylan Pharm. Inc*., 1:05-cv-00854-JJF, (Dec. 12, 2005); *Boehringer Ingelheim Int'l GmbH et al. v. Barr Labs., Inc. et al.*, 1:05-cv-00700-JJF (Sept. 26, 2005).

47. Additionally, and alternatively, to the extent BII is not subject to the jurisdiction of the courts of general jurisdiction of the State of Delaware, BII is likewise not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is subject to jurisdiction based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Federal Rule of Civil Procedure 4(k)(2).

D. Venue

48. Venue lies in this District pursuant to 28 U.S.C. §§ 1391 and/or 1400, including because, *inter alia*, BIPI and BIFI are organized under the laws of Delaware and have regular and established places of business in this judicial District; Boehringer has committed an act of infringement and will commit further acts of infringement in this judicial District; and, as a foreign entity, BII is subject to suit in any jurisdiction in the United States including the District of Delaware. 28 U.S.C. § 1391(c).

THE PARTIES' EXCHANGES UNDER THE BPCIA

49. On information and belief, on October 27, 2016, Boehringer submitted an aBLA to the FDA pursuant to the BPCIA, specifically 42 U.S.C. § 262(k), requesting that its biosimilar adalimumab product BI 695501 be licensed for commercial sale by relying on AbbVie's

demonstration that HUMIRA® is safe, pure, and potent. The BPCIA provides an abbreviated pathway for approval of a biologic product that is "biosimilar" to a "reference product." Boehringer has demonstrated its intention to utilize AbbVie's data and work discovering and developing adalimumab through the use of the abbreviated BPCIA biosimilar pathway.

50. To facilitate the protection of biologic innovator's patent rights, Congress created an act of infringement related to the submission of an application under subsection 262(k), *see* 35 U.S.C. § 271(e)(2)(C), and enumerated a set of pre-litigation exchanges under the BPCIA that are outlined at 42 U.S.C. § 262(*l*). The subsection *(l*) procedures are intended to ensure that the maker of an innovative biologic product that is the subject of a biosimilar application will have sufficient time and opportunity to enforce its patent rights before a biosimilar product enters the market. The BPCIA also requires that a subsection (k) applicant give at least 180 days' notice before the first commercial marketing of a biosimilar licensed by the FDA. 42 U.S.C. § 262(*l*)(8)(A). The statute specifically contemplates injunctive relief, including preliminary injunctive relief, to prevent unlawful infringement.

51. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

52. On January 9, 2017, Boehringer contacted AbbVie and indicated that it had submitted an aBLA to the FDA and that the FDA accepted the aBLA.

53. In January 2017, the parties began exchanging information in accordance with the procedures outlined in the BPCIA. On or about January 13, 2017, Boehringer provided outside counsel for AbbVie and AbbVie's designated in-house attorney with access to Boehringer's aBLA. Although Boehringer provided its aBLA to AbbVie, it did not provide any "other information that describes the process or processes used to manufacture" the Boehringer aBLA

product, as required by the statute. 42 U.S.C. § 262(*l*)(2)(A). In the confidentiality agreements Boehringer required each recipient to sign before obtaining access to its aBLA, Boehringer has not permitted AbbVie attorneys to consult with outside experts regarding its aBLA.

54. On March 13, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(A), AbbVie provided Boehringer with its list of patents for which it believed a claim of patent infringement could be reasonably asserted against Boehringer's aBLA Product ("AbbVie's 3A List"). This list identified 72 patents from among the more than 100 patents in the HUMIRA® estate. AbbVie also asked, "in the event that Boehringer Ingelheim asserts that any of these patents are either not infringed or invalid pursuant to Section (*l*)(3)(B)(ii)(I), . . . that Boehringer Ingelheim identify and provide copies of any documentary evidence supporting those assertions, so that AbbVie may fully consider it."

55. On April 18, 2017, June 6, 2017, and June 20, 2017, pursuant to 42 U.S.C. § 262(*l*)(7), AbbVie provided supplemental patent lists to Boehringer, each adding a recently issued patent.

56. On May 12, 2017, Boehringer responded by providing AbbVie, pursuant to the confidentiality agreements referenced in paragraph 53 above, with statements pursuant to 42 U.S.C. § 262(*l*)(3)(B) contesting Boehringer's infringement of certain patents and the validity of those patents. On May 18, 2017, and July 6, 2017, Boehringer provided AbbVie, pursuant to the confidentiality agreements referenced in paragraph 53 above, with statements pursuant to 42 U.S.C. § 262(*l*)(3)(B) and 42 U.S.C. § 262(*l*)(7)(B) contesting Boehringer's infringement of supplemental patents identified by AbbVie pursuant to 42 U.S.C. § 262(*l*)(7) and the validity of those patents. Despite AbbVie's requests, Boehringer did not provide any additional evidence

(*e.g.*, additional manufacturing documents or product information, beyond what was in the aBLA) relating to its non-infringement contentions.

57. On July 11, 2017, AbbVie provided Defendants with its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C). AbbVie's nearly 1,500-page statement shows that AbbVie has reason to believe that Boehringer's biosimilar product, BI 695501, would infringe as many as 1,600 claims from among the following 71 AbbVie patents and that those patent claims are valid ("AbbVie's 3C Statement"):

	U.S. Patent No.	**Title**
1.	8,231,876	Purified Antibody Composition
2.	8,663,945	Methods of Producing Anti-TNF-Alpha Antibodies in Mammalian Cell Culture
3.	8,715,664	Use of Human TNFα Antibodies for Treatment of Erosive Polyarthritis
4.	8,802,100	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
5.	8,802,101	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
6.	8,808,700	Use of TNF Alpha Inhibitor for Treatment of Erosive Polyarthritis
7.	8,883,156	Purified Antibody Composition
8.	8,889,135	Methods of Administering Anti-TNFα Antibodies
9.	8,889,136	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
10.	8,895,009	Purified Antibody Composition
11.	8,906,372	Purified Antibody Composition
12.	8,906,373	Use of TNF-alpha Inhibitor for Treatment of Psoriasis
13.	8,906,646	Fed-batch Method of Making Human Anti-TNF-Alpha Antibody
14.	8,911,737	Methods of Administering Anti-TNFα Antibodies

	U.S. Patent No.	Title
15.	8,911,964	Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody
16.	8,916,153	Purified Antibody Composition
17.	8,916,157	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
18.	8,916,158	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
19.	8,926,975	Method of Treating Ankylosing Spondylitis
20.	8,946,395	Purification of Proteins Using Hydrophobic Interaction Chromatography
21.	8,961,973	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
22.	8,961,974	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
23.	8,974,790	Methods of Administering Anti-TNFα Antibodies
24.	8,986,693	Use of TNFα Inhibitor for Treatment of Psoriasis
25.	8,992,926	Methods of Administering Anti-TNFα Antibodies
26.	8,999,337	Methods for Treating Juvenile Idiopathic Arthritis by Inhibition of TNFα
27.	9,017,680	Methods of Administering Anti-TNFα Antibodies
28.	9,018,361	Isolation and Purification of Antibodies Using Protein A Affinity Chromatography
29.	9,061,005	Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease
30.	9,062,106	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
31.	9,067,992	Use of TNFα Inhibitor for Treatment of Psoriatic Arthritis
32.	9,073,987	Methods of Administering Anti-TNFα Antibodies
33.	9,073,988	Fed Batch Method of Making Anti-TNF-Alpha Antibodies
34.	9,085,618	Low Acidic Species Compositions and Methods for Producing and Using the Same
35.	9,085,620	Use of TNFα Inhibitor for Treatment of Psoriatic Arthritis

	U.S. Patent No.	Title
36.	9,090,688	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
37.	9,090,689	Use of TNFα Inhibitor for Treatment of Psoriasis
38.	9,090,867	Fed-Batch Method of Making Anti-TNF-Alpha Antibody
39.	9,096,666	Purified Antibody Composition
40.	9,102,723	Purified Antibody Composition
41.	9,114,166	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
42.	9,150,645	Cell Culture Methods to Reduce Acidic Species
43.	9,187,559	Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease
44.	9,193,787	Human Antibodies that Bind Human TNF-Alpha and Methods of Preparing the Same
45.	9,200,069	Low Acidic Species Compositions and Methods for Producing and Using the Same
46.	9,200,070	Low Acidic Species Compositions and Methods for Producing and Using the Same
47.	9,206,390	Methods to Control Protein Heterogeneity
48.	9,220,781	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
49.	9,234,032	Fed-Batch Methods for Producing Adalimumab
50.	9,234,033	Methods to Control Protein Heterogeneity
51.	9,249,182	Purification of Antibodies Using Hydrophobic Interaction Chromatography
52.	9,255,143	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
53.	9,266,949	Low Acidic Species Compositions and Methods for Producing and Using the Same
54.	9,272,041	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
55.	9,273,132	Purified Antibody Composition
56.	9,284,370	Methods for Treating Juvenile Idiopathic Arthritis

	U.S. Patent No.	Title
57.	9,284,371	Methods of Producing Adalimumab
58.	9,290,568	Methods to Control Protein Heterogeneity
59.	9,302,011	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
60.	9,315,574	Low Acidic Species Compositions and Methods for Producing and Using the Same
61.	9,328,165	Purified Antibody Composition
62.	9,334,319	Low Acidic Species Compositions
63.	9,346,879	Protein Purification Methods to Reduce Acidic Species
64.	9,359,434	Cell Culture Methods to Reduce Acidic Species
65.	9,365,645	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
66.	9,499,614	Methods for Modulating Protein Glycosylation Profiles of Recombinant Protein Therapeutics Using Monosaccharides and Oligosaccharides
67.	9,505,834	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
68.	9,512,214	Methods to Control Protein Heterogeneity
69.	9,512,216	Use of TNFα Inhibitor
70.	9,522,953	Low Acidic Species Compositions and Methods for Producing and Using the Same
71.	9,546,212	Methods of Administering Anti-TNFα Antibodies

58. On information and belief, Boehringer's biosimilar product, BI 695501, will also infringe one or more claims from among the following three AbbVie patents identified by AbbVie pursuant to 42 U.S.C. § 262(*l*)(7):

	U.S. Patent No.	Title
72.	9,624,295	Uses and Compositions for Treatment of Psoriatic Arthritis

	U.S. Patent No.	Title
73.	9,669,093	Methods for Treating Juvenile Idiopathic Arthritis
74.	9,683,033	Cell Culture Methods to Reduce Acidic Species

59. During the negotiation period that followed after AbbVie provided its 3C Statement, AbbVie provided Boehringer with its opening proposal that the parties litigate all the identified patents in this suit. Boehringer waited until the last day possible to provide AbbVie with the number of patents that it would agree to be sued on. That number was five. This meant that the maximum number of patents that could be part of this first lawsuit under the BPCIA was ten (five patents from each side), despite AbbVie's identification of 74 patents in the BPCIA exchange process.

60. On July 31, 2017, the parties exchanged their lists of five patents pursuant to 42 U.S.C. § 262(*l*)(5), which calls for the parties to exchange "the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6)" and "the list of patents . . . that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6)." AbbVie identified U.S. Patent No. 8,926,975; U.S. Patent No. 9,018,361; U.S. Patent No. 9,266,949; U.S. Patent No. 9,272,041; and U.S. Patent No. 9,546,212. Boehringer identified U.S. Patent No. 8,926,975; U.S. Patent No. 9,090,867; U.S. Patent No. 9,096,666; U.S. Patent No. 9,255,143; and U.S. Patent No. 9,272,041. Given there was overlap of two patents, there are eight patents in this suit.

61. At this time, and as a result of Boehringer's gamesmanship, AbbVie is limited to seeking redress on eight of its patents. But AbbVie will have a second opportunity, if and when

Boehringer provides a 180-day Notice of Commercial Marketing (or as circumstances otherwise warrant), to assert its remaining patents. So while Boehringer's tactics may create delay, it still must deal with AbbVie's patents before going to market.

BOEHRINGER'S aBLA PRODUCT

62. On information and belief, Boehringer has undertaken the development of a proposed biosimilar to AbbVie's HUMIRA® (adalimumab) product.

63. On information and belief, Boehringer has submitted an aBLA to the FDA seeking approval to market in the United States a biosimilar version of AbbVie's HUMIRA® adalimumab product.

64. On January 18, 2017, Boehringer announced that the FDA had accepted its submission of an aBLA with the FDA for BI 695501, a biosimilar candidate to HUMIRA® (adalimumab). *See* Exhibit 5.

65. Boehringer has stated that its "adalimumab biosimilar candidate delivers the same clinical benefits and safety profile as HUMIRA®." *See* Press Release, Boehringer Ingelheim, "Boehringer Ingelheim presents Phase III results demonstrating clinical equivalence of adalimumab biosimilar candidate to HUMIRA®," Jun. 14, 2017, https://www.boehringer-ingelheim.com/press-release/biosimilar-candidate-shows-clinical-equivalence-humira, attached hereto as Exhibit 6.

66. Boehringer has completed clinical trials with BI 695501, testing its use in subjects with moderate to severe rheumatoid arthritis. *See* Exhibit 6; *see also* Exhibit 3. On information and belief, the aBLA relies upon data from one or more of these studies to support Boehringer's application. *See* Exhibit 6. On information and belief, Boehringer has also sponsored ongoing clinical trials testing the use of BI 695501 in subjects with plaque psoriasis and Crohn's disease.

67. Boehringer has further indicated that it is "ultimately interested in obtaining labels for all the indications" of HUMIRA®. Scrip Intelligence, "Boehringer Ingelheim Limbering Up with Humira Biosimilar," Jun. 14, 2017, attached hereto as Exhibit 7.

68. On information and belief, the FDA has not yet approved Boehringer's proposed biosimilar product.

69. Boehringer has committed a statutory act of patent infringement under 35 U.S.C. § 271(e)(2)(C) by submitting an application seeking approval of a biological product with respect to patents identified by AbbVie pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i).

ABBVIE'S ADALIMUMAB PATENTS

70. In the course of developing HUMIRA®, AbbVie has obtained more than 100 patents related to HUMIRA®, including its administration, its formulation, and the processes for manufacturing it.

71. Because of Boehringer's actions, AbbVie is limited to asserting the following eight patents in the present lawsuit: U.S. Patent No. 8,926,975; U.S. Patent No. 9,018,361; U.S. Patent No. 9,090,867; U.S. Patent No. 9,096,666; U.S. Patent No. 9,255,143; U.S. Patent No. 9,266,949; U.S. Patent No. 9,272,041; and U.S. Patent No. 9,546,212 (the "AbbVie Patents").

72. AbbVie asserts the following eight patents in this suit.

U.S. Patent No. 8,926,975

73. U.S. Patent No. 8,926,975 (the "'975 patent"), titled "Method of Treating Ankylosing Spondylitis," was duly and legally issued by the USPTO on January 6, 2015. A true and correct copy of the '975 patent is attached as Exhibit 8.

74. ABL is the owner by assignment of the '975 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the

’975 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’975 patent.

U.S. Patent No. 9,018,361

75. U.S. Patent No. 9,018,361 (the “’361 patent”), titled “Isolation and Purification of Antibodies Using Protein A Affinity Chromatography,” was duly and legally issued by the USPTO on April 28, 2015. A true and correct copy of the ’361 patent is attached as Exhibit 9.

76. AbbVie Inc. is the owner by assignment of the ’361 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’361 patent in the United States. ABL and AbbVie Inc. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’361 patent.

U.S. Patent No. 9,090,867

77. U.S. Patent No. 9,090,867 (the “’867 patent”), titled “Fed-Batch Method of Making Anti-TNF-Alpha Antibody,” was duly and legally issued by the USPTO on July 28, 2015. A true and correct copy of the ’867 patent is attached as Exhibit 10.

78. AbbVie Inc. is the owner by assignment of the ’867 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’867 patent in the United States. ABL and AbbVie Inc. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’867 patent.

U.S. Patent No. 9,096,666

79. U.S. Patent No. 9,096,666 (the "'666 patent"), titled "Purified Antibody Composition," was duly and legally issued by the USPTO on August 4, 2015. A true and correct copy of the '666 patent is attached as Exhibit 11.

80. ABL is the owner by assignment of the '666 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '666 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '666 patent.

U.S. Patent No. 9,255,143

81. U.S. Patent No. 9,255,143 (the "'143 patent"), titled "Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins," was duly and legally issued by the USPTO on February 9, 2016. A true and correct copy of the '143 patent is attached as Exhibit 12.

82. AbbVie Inc. is the owner by assignment of the '143 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '143 patent in the United States. ABL and AbbVie Inc. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '143 patent.

U.S. Patent No. 9,266,949

83. U.S. Patent No. 9,266,949 (the "'949 patent"), titled "Low Acidic Species Compositions and Methods for Producing and Using the Same," was duly and legally issued by the USPTO on February 23, 2016. A true and correct copy of the '949 patent is attached as Exhibit 13.

84. AbbVie Inc. is the owner by assignment of the ’949 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’949 patent in the United States. ABL and AbbVie Inc. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’949 patent.

U.S. Patent No. 9,272,041

85. U.S. Patent No. 9,272,041 (the “’041 patent”), titled “Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders,” was duly and legally issued by the USPTO on March 1, 2016. A true and correct copy of the ’041 patent is attached as Exhibit 14.

86. ABL is the owner by assignment of the ’041 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’041 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’041 patent.

U.S. Patent No. 9,546,212

87. U.S. Patent No. 9,546,212 (the “’212 patent”), titled “Methods of Administering Anti-TNFα Antibodies,” was duly and legally issued by the USPTO on January 17, 2017. A true and correct copy of the ’212 patent is attached as Exhibit 15.

88. ABL is the owner by assignment of the ’212 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’212 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’212 patent.

89. AbbVie included in its disclosures to Boehringer, pursuant to 42 U.S.C. § 262(*l*)(3)(A), each of the patents described in Counts I-XVI below.

90. AbbVie has provided to Boehringer, pursuant to U.S.C. § 262(*l*)(3)(C), claim-by-claim infringement contentions for each of the claims described in Counts I-XVI below.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 8,926,975

91. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

92. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

93. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

94. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

95. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

96. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2), Boehringer's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the '975 patent is an act of infringement of one or more of the claims of the '975 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

97. Boehringer has provided information to AbbVie pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the indications, dosage, and methods of use for the Boehringer aBLA Product. Based on this confidential information and on information and belief, Boehringer's

commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will actively induce infringement by others of at least claims 1-6 of the ’975 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

98. On information and belief, Boehringer has an affirmative intent to actively induce infringement by others of one or more claims of the ’975 patent, either literally or under the doctrine of equivalents. On information and belief, Boehringer has filed an aBLA that includes a proposed package insert with directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Boehringer aBLA Product.

99. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Boehringer aBLA Product at least according to Boehringer’s proposed package insert and, therefore, will directly infringe at least one claim of the ’975 patent, either literally or under the doctrine of equivalents.

100. On information and belief, Boehringer will knowingly or with willful blindness induce another’s direct infringement of at least one of the claims of the ’975 patent, either literally or under the doctrine of equivalents, by at least Boehringer’s proposed package insert for the Boehringer aBLA Product.

101. Boehringer has knowledge of and is aware of the ’975 patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

102. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Boehringer is enjoined from infringing the claims of the ’975 patent.

103. AbbVie seeks an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Boehringer from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Boehringer aBLA Product.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 9,018,361

104. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

105. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

106. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

107. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

108. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

109. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the '361 patent is an act of infringement of one or more of the claims of the '361 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

110. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claims 1-2 and 6-13 of the '361 patent under 35 U.S.C. § 271(a) and/or § 271(g), either literally or under the doctrine of equivalents. For at least one claim, Boehringer's failure to provide sufficient manufacturing information, as required by the BPCIA, has prevented AbbVie from learning additional facts that would support AbbVie's allegation. In the absence of sufficient manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Boehringer infringes certain claims of the '361 patent. Boehringer has the burden of establishing that the Boehringer aBLA Product was not made by the process claimed in the '361 patent. *See* 35 U.S.C. § 295.

111. On information and belief, BIFI has manufactured and/or will manufacture the Boehringer aBLA Product once it is approved by the FDA. On information and belief, BIPI and/or BII act in concert with and/or direct BIFI to make the Boehringer aBLA Product, and thereby actively induce infringement of at least claims 1-2 and 6-13 of the '361 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

112. On information and belief, BIPI, by seeking licensure of a product manufactured using methods claimed in the '361 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the '361 patent, either literally or under the doctrine of equivalents.

113. On information and belief, BII, by acting in concert with, directing, and/or authorizing BIPI to file the Boehringer aBLA, has an affirmative intent to actively induce infringement by others of one or more claims of the ’361 patent, either literally or under the doctrine of equivalents.

114. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that BIFI’s manufacture of the Boehringer aBLA Product directly infringes at least one claim of the ’361 patent, either literally or under the doctrine of equivalents.

115. On information and belief, BIPI and BII knowingly or with willful blindness induce another’s direct infringement of at least one of the claims of the ’361 patent, either literally or under the doctrine of equivalents, by at least the fact that BIFI has manufactured and/or will manufacture the Boehringer aBLA Product for sale in the United States market using methods claimed in the ’361 patent.

116. Boehringer has knowledge of and is aware of the ’361 patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

117. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Boehringer is enjoined from infringing the claims of the ’361 patent.

118. AbbVie seeks an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Boehringer from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Boehringer aBLA Product and/or the use of the claimed methods of the ’361 patent.

COUNT III

INFRINGEMENT OF U.S. PATENT NO. 9,090,867

119. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

120. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

121. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

122. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

123. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

124. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the '867 patent is an act of infringement of one or more of the claims of the '867 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

125. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will

infringe at least claims 1-13, 15-27, and 29-30 of the ’867 patent under 35 U.S.C. § 271(a) and/or § 271(g), either literally or under the doctrine of equivalents. For at least one claim, Boehringer’s failure to provide sufficient manufacturing information, as required by the BPCIA, has prevented AbbVie from learning additional facts that would support AbbVie’s allegation. In the absence of sufficient manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Boehringer infringes certain claims of the ’867 patent. Boehringer has the burden of establishing that the Boehringer aBLA Product was not made by the process claimed in the ’867 patent. *See* 35 U.S.C. § 295.

126. On information and belief, BIFI has manufactured and/or will manufacture the Boehringer aBLA Product once it is approved by the FDA. On information and belief, BIPI and/or BII act in concert with and/or direct BIFI to make the Boehringer aBLA Product, and thereby actively induce infringement of at least claims 1-13, 15-27, and 29-30 of the ’867 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

127. On information and belief, BIPI, by seeking licensure of a product manufactured using methods claimed in the ’867 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the ’867 patent, either literally or under the doctrine of equivalents.

128. On information and belief, BII, by acting in concert with, directing, and/or authorizing BIPI to file the Boehringer aBLA, has an affirmative intent to actively induce infringement by others of one or more claims of the ’867 patent, either literally or under the doctrine of equivalents.

129. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that BIFI's manufacture of the Boehringer aBLA Product directly infringes at least one claim of the '867 patent, either literally or under the doctrine of equivalents.

130. On information and belief, BIPI and BII knowingly or with willful blindness induce another's direct infringement of at least one of the claims of the '867 patent, either literally or under the doctrine of equivalents, by at least the fact that BIFI has manufactured and/or will manufacture the Boehringer aBLA Product for sale in the United States market using methods claimed in the '867 patent.

131. Boehringer has knowledge of and is aware of the '867 patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

132. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Boehringer is enjoined from infringing the claims of the '867 patent.

133. AbbVie seeks an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Boehringer from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Boehringer aBLA Product and/or the use of the claimed methods of the '867 patent.

COUNT IV

INFRINGEMENT OF U.S. PATENT NO. 9,096,666

134. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

135. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or

sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

136. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

137. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

138. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

139. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the '666 patent is an act of infringement of one or more claims of the '666 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

140. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claims 1-30 of the '666 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. For at least one claim, Boehringer's failure to provide sufficient manufacturing information, as required by the BPCIA, has prevented AbbVie from learning additional facts that would support AbbVie's allegation. In the absence of sufficient manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to

obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Boehringer infringes certain claims of the ’666 patent.

141. On information and belief, BIFI has manufactured and/or will manufacture the Boehringer aBLA Product once it is approved by the FDA. On information and belief, BIPI and/or BII act in concert with and/or direct BIFI to make the Boehringer aBLA Product, and thereby actively induce infringement of at least claims 1-30 of the ’666 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

142. On information and belief, BIPI, by seeking licensure for a product manufactured by another for sale in the United States that infringes the ’666 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the ’666 patent, either literally or under the doctrine of equivalents.

143. On information and belief, BII, by acting in concert with, directing, and/or authorizing BIPI to file the Boehringer aBLA, has an affirmative intent to actively induce infringement by others of one or more claims of the ’666 patent, either literally or under the doctrine of equivalents.

144. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that BIFI’s manufacture of the Boehringer aBLA Product directly infringes at least one claim of the ’666 patent, either literally or under the doctrine of equivalents.

145. On information and belief, BIPI and BII knowingly or with willful blindness induce another’s direct infringement of at least one of the claims of the ’666 patent, either literally or under the doctrine of equivalents, by at least the fact that BIFI has manufactured and/or will manufacture the Boehringer aBLA Product for sale in the United States market.

146. Boehringer has knowledge of and is aware of the '666 patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

147. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Boehringer is enjoined from infringing the claims of the '666 patent.

148. AbbVie seeks an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Boehringer from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Boehringer aBLA Product.

COUNT V

INFRINGEMENT OF U.S. PATENT NO. 9,255,143

149. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

150. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

151. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

152. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

153. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

154. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's submission of its aBLA to

obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the ’143 patent is an act of infringement of one or more claims of the ’143 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

155. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer’s commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claims 1-15, 18, and 20-21 of the ’143 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. For at least one claim, Boehringer’s failure to provide sufficient manufacturing information, as required by the BPCIA, has prevented AbbVie from learning additional facts that would support AbbVie’s allegation. In the absence of sufficient manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Boehringer infringes certain claims of the ’143 patent.

156. On information and belief, BIFI has manufactured and/or will manufacture the Boehringer aBLA Product once it is approved by the FDA. On information and belief, BIPI and/or BII act in concert with and/or direct BIFI to make the Boehringer aBLA Product, and thereby actively induce infringement of at least claims 1-15, 18, and 20-21 of the ’143 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

157. On information and belief, BIPI, by seeking licensure for a product manufactured by another for sale in the United States that infringes the ’143 patent, has an affirmative intent to

actively induce infringement by others of one or more claims of the ’143 patent, either literally or under the doctrine of equivalents.

158. On information and belief, BII, by acting in concert with, directing, and/or authorizing BIPI to file the Boehringer aBLA, has an affirmative intent to actively induce infringement by others of one or more claims of the ’143 patent, either literally or under the doctrine of equivalents.

159. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that BIFI’s manufacture of the Boehringer aBLA Product directly infringes at least one claim of the ’143 patent, either literally or under the doctrine of equivalents.

160. On information and belief, BIPI and BII knowingly or with willful blindness induce another’s direct infringement of at least one of the claims of the ’143 patent, either literally or under the doctrine of equivalents, by at least the fact that BIFI has manufactured and/or will manufacture the Boehringer aBLA Product for sale in the United States market.

161. Boehringer has knowledge of and is aware of the ’143 patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

162. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Boehringer is enjoined from infringing the claims of the ’143 patent.

163. AbbVie seeks an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Boehringer from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Boehringer aBLA Product.

COUNT VI

INFRINGEMENT OF U.S. PATENT NO. 9,266,949

164. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

165. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

166. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

167. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

168. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

169. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the '949 patent is an act of infringement of one or more of the claims of the '949 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

170. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will

infringe at least claims 1-30 of the ’949 patent under 35 U.S.C. § 271(a) and/or § 271(g), either literally or under the doctrine of equivalents. For at least one claim, Boehringer’s failure to provide sufficient manufacturing information, as required by the BPCIA, has prevented AbbVie from learning additional facts that would support AbbVie’s allegation. In the absence of sufficient manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Boehringer infringes certain claims of the ’949 patent. Boehringer has the burden of establishing that the Boehringer aBLA Product was not made by the process claimed in the ’949 patent. *See* 35 U.S.C. § 295.

171. On information and belief, BIFI has manufactured and/or will manufacture the Boehringer aBLA Product once it is approved by the FDA. On information and belief, BIPI and/or BII act in concert with and/or direct BIFI to make the Boehringer aBLA Product, and thereby actively induce infringement of at least claims 1-30 of the ’949 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

172. On information and belief, BIPI, by seeking licensure of a product manufactured using methods claimed in the ’949 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the ’949 patent, either literally or under the doctrine of equivalents.

173. On information and belief, BII, by acting in concert with, directing, and/or authorizing BIPI to file the Boehringer aBLA, has an affirmative intent to actively induce infringement by others of one or more claims of the ’949 patent, either literally or under the doctrine of equivalents.

174. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that BIFI's manufacture of the Boehringer aBLA Product directly infringes at least one claim of the '949 patent, either literally or under the doctrine of equivalents.

175. On information and belief, BIPI and BII knowingly or with willful blindness induce another's direct infringement of at least one of the claims of the '949 patent, either literally or under the doctrine of equivalents, by at least the fact that BIFI has manufactured and/or will manufacture the Boehringer aBLA Product for sale in the United States market using methods claimed in the '949 patent.

176. Boehringer has knowledge of and is aware of the '949 patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

177. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Boehringer is enjoined from infringing the claims of the '949 patent.

178. AbbVie seeks an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Boehringer from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Boehringer aBLA Product and/or the use of the claimed methods of the '949 patent.

COUNT VII

INFRINGEMENT OF U.S. PATENT NO. 9,272,041

179. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

180. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or

sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

181. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

182. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

183. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

184. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2), Boehringer's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the '041 patent is an act of infringement of one or more of the claims of the '041 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents

185. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claims 1-2, 4-7, 16-19, 21-23, and 28-30 of the '041 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

186. On information and belief, BIFI has manufactured and/or will manufacture the Boehringer aBLA Product once it is approved by the FDA. On information and belief, BIPI and/or BII act in concert with and/or direct BIFI to make the Boehringer aBLA Product, and

thereby actively induces infringement of at least claims 1-2, 4-7, 16-19, 21-23, and 28-30 of the ’041 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

187. On information and belief, BIPI, by seeking licensure for a product manufactured by another for sale in the United States that infringes the ’041 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the ’041 patent, either literally or under the doctrine of equivalents.

188. On information and belief, BII, by acting in concert with, directing, and/or authorizing BIPI to file the Boehringer aBLA, has an affirmative intent to actively induce infringement by others of one or more claims of the ’041 patent, either literally or under the doctrine of equivalents.

189. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that BIFI’s manufacture of the Boehringer aBLA Product directly infringes at least one claim of the ’041 patent, either literally or under the doctrine of equivalents.

190. On information and belief, BIPI and BII knowingly or with willful blindness induce another’s direct infringement of at least one of the claims of the ’041 patent, either literally or under the doctrine of equivalents, by at least the fact that BIFI has manufactured and/or will manufacture the Boehringer aBLA Product for sale in the United States market.

191. Boehringer has knowledge of and is aware of the ’041 patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

192. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Boehringer is enjoined from infringing the claims of the ’041 patent.

193. AbbVie seeks an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Boehringer from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Boehringer aBLA Product.

COUNT VIII

INFRINGEMENT OF U.S. PATENT NO. 9,546,212

194. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

195. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

196. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

197. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

198. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

199. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2), Boehringer's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the '212 patent is an act of infringement of one or more of the claims of the '212 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

200. Boehringer has provided information to AbbVie pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the indications, dosage, and methods of use for the Boehringer aBLA

Product. Based on this confidential information and on information and belief, Boehringer's commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will actively induce infringement by others of at least claims 1-24 of the '212 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

201. On information and belief, Boehringer has an affirmative intent to actively induce infringement by others of one or more claims of the '212 patent, either literally or under the doctrine of equivalents. On information and belief, Boehringer has filed an aBLA that includes a proposed package insert with directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Boehringer aBLA Product.

202. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Boehringer aBLA Product at least according to Boehringer's proposed package insert and, therefore, will directly infringe at least one claim of the '212 patent, either literally or under the doctrine of equivalents.

203. On information and belief, Boehringer will knowingly or with willful blindness induce another's direct infringement of at least one of the claims of the '212 patent, either literally or under the doctrine of equivalents, by at least Boehringer's proposed package insert for the Boehringer aBLA Product.

204. Boehringer has knowledge of and is aware of the '212 patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

205. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Boehringer is enjoined from infringing the claims of the ’212 patent.

206. AbbVie seeks an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Boehringer from the commercial manufacture, use, sale, or offer for sale within and/or importation into the United States of the Boehringer aBLA Product.

COUNT IX

DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,926,975

207. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

208. AbbVie’s claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

209. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

210. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer’s aBLA.

211. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

212. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

213. On information and belief, Boehringer’s submission and the FDA’s acceptance of Boehringer’s aBLA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab, create an actual,

immediate, and real controversy within the Declaratory Judgment Act that Boehringer will directly and/or indirectly infringe one or more valid and enforceable claims of the '975 patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

214. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2), Boehringer's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the '975 patent is an act of infringement of one or more of the claims of the '975 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

215. Boehringer has provided information to AbbVie pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the indications, dosage, and methods of use for the Boehringer aBLA Product. Based on this confidential information and on information and belief, Boehringer's commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will actively induce infringement by others of at least claims 1-6 of the '975 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

216. On information and belief, Boehringer has an affirmative intent to actively induce infringement by others of one or more claims of the '975 patent, either literally or under the doctrine of equivalents. On information and belief, Boehringer has filed an aBLA that includes a proposed package insert with directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Boehringer aBLA Product.

217. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Boehringer aBLA Product at least according to Boehringer's

package insert and, therefore, will directly infringe at least one or more claims of the ’975 patent, either literally or under the doctrine of equivalents.

218. On information and belief, Boehringer will knowingly or with willful blindness induce another’s direct infringement of at least one or more of the claims of the ’975 patent, either literally or under the doctrine of equivalents, by at least Boehringer’s package insert for the Boehringer aBLA Product.

219. Boehringer has knowledge of and is aware of the ’975 patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

220. Plaintiffs seek a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product will infringe the ’975 patent.

221. Unless Boehringer is enjoined from directly and indirectly infringing the ’975 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT X

DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,018,361

222. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

223. AbbVie’s claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

224. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or

sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

225. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

226. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

227. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

228. On information and belief, Boehringer's submission and the FDA's acceptance of Boehringer's aBLA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Boehringer will directly and/or indirectly infringe one or more valid and enforceable claims of the '361 patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

229. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the '361 patent is an act of infringement of one or more of the claims of the '361 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

230. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or

through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claims 1-2 and 6-13 of the ’361 patent under 35 U.S.C. § 271(a) and/or § 271(g), either literally or under the doctrine of equivalents. For at least one claim, Boehringer’s failure to provide sufficient manufacturing information, as required by the BPCIA, has prevented AbbVie from learning additional facts that would support AbbVie’s allegation. In the absence of sufficient manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Boehringer infringes certain claims of the ’361 patent. Boehringer has the burden of establishing that the Boehringer aBLA Product was not made by the process claimed in the ’361 patent. *See* 35 U.S.C. § 295.

231. On information and belief, BIFI has manufactured and/or will manufacture the Boehringer aBLA Product once it is approved by the FDA. On information and belief, BIPI and/or BII act in concert with and/or direct BIFI to make the Boehringer aBLA Product, and thereby actively induce infringement of at least claims 1-2 and 6-13 of the ’361 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

232. On information and belief, BIPI, by seeking licensure of a product manufactured using methods claimed in the ’361 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the ’361 patent, either literally or under the doctrine of equivalents.

233. On information and belief, BII, by acting in concert with, directing, and/or authorizing BIPI to file the Boehringer aBLA, has an affirmative intent to actively induce infringement by others of one or more claims of the ’361 patent, either literally or under the doctrine of equivalents.

234. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that BIFI's manufacture of the Boehringer aBLA Product directly infringes at least one claim of the '361 patent, either literally or under the doctrine of equivalents.

235. On information and belief, BIPI and BII knowingly or with willful blindness induce another's direct infringement of at least one of the claims of the '361 patent, either literally or under the doctrine of equivalents, by at least the fact that BIFI has manufactured and/or will manufacture the Boehringer aBLA Product for sale in the United States market using methods claimed in the '361 patent.

236. Boehringer has knowledge of and is aware of the '361 patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

237. Plaintiffs seek a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product and/or use of the claimed methods will infringe the '361 patent.

238. Unless Boehringer is enjoined from directly and indirectly infringing the '361 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XI

DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,090,867

239. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

240. AbbVie's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

241. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

242. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

243. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

244. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

245. On information and belief, Boehringer's submission and the FDA's acceptance of Boehringer's aBLA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Boehringer will directly and/or indirectly infringe one or more valid and enforceable claims of the '867 patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

246. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the '867 patent is an act of infringement of one or more of the claims of the '867 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

247. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claims 1-13, 15-27, and 29-30 of the '867 patent under 35 U.S.C. § 271(a) and/or § 271(g), either literally or under the doctrine of equivalents. For at least one claim, Boehringer's failure to provide sufficient manufacturing information, as required by the BPCIA, has prevented AbbVie from learning additional facts that would support AbbVie's allegation. In the absence of sufficient manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Boehringer infringes certain claims of the '867 patent. Boehringer has the burden of establishing that the Boehringer aBLA Product was not made by the process claimed in the '867 patent. *See* 35 U.S.C. § 295.

248. On information and belief, BIFI has manufactured and/or will manufacture the Boehringer aBLA Product once it is approved by the FDA. On information and belief, BIPI and/or BII act in concert with and/or direct BIFI to make the Boehringer aBLA Product, and thereby actively induce infringement of at least claims 1-13, 15-27, and 29-30 of the '867 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

249. On information and belief, BIPI, by seeking licensure of a product manufactured using methods claimed in the '867 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the '867 patent, either literally or under the doctrine of equivalents.

250. On information and belief, BII, by acting in concert with, directing, and/or authorizing BIPI to file the Boehringer aBLA, has an affirmative intent to actively induce infringement by others of one or more claims of the ’867 patent, either literally or under the doctrine of equivalents.

251. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that BIFI’s manufacture of the Boehringer aBLA Product directly infringes at least one claim of the ’867 patent, either literally or under the doctrine of equivalents.

252. On information and belief, BIPI and BII knowingly or with willful blindness induce another’s direct infringement of at least one of the claims of the ’867 patent, either literally or under the doctrine of equivalents, by at least the fact that BIFI has manufactured and/or will manufacture the Boehringer aBLA Product for sale in the United States market using methods claimed in the ’867 patent.

253. Boehringer has knowledge of and is aware of the ’867 patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

254. Plaintiffs seek a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product and/or use of the claimed methods will infringe the ’867 patent.

255. Unless Boehringer is enjoined from directly and indirectly infringing the ’867 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XII

DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,096,666

256. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

257. AbbVie's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

258. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

259. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

260. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

261. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

262. On information and belief, Boehringer's submission and the FDA's acceptance of Boehringer's aBLA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Boehringer will directly and/or indirectly infringe one or more valid and enforceable claims of the '666 patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

263. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's submission of its aBLA to

obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the ’666 patent is an act of infringement of one or more claims of the ’666 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

264. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer’s commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claims 1-30 of the ’666 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. For at least one claim, Boehringer’s failure to provide sufficient manufacturing information, as required by the BPCIA, has prevented AbbVie from learning additional facts that would support AbbVie’s allegation. In the absence of sufficient manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Boehringer infringes certain claims of the ’666 patent.

265. On information and belief, BIFI has manufactured and/or will manufacture the Boehringer aBLA Product once it is approved by the FDA. On information and belief, BIPI and/or BII act in concert with and/or direct BIFI to make the Boehringer aBLA Product, and thereby actively induce infringement of at least claims 1-30 of the ’666 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

266. On information and belief, BIPI, by seeking licensure for a product manufactured by another for sale in the United States that infringes the ’666 patent, has an affirmative intent to

actively induce infringement by others of one or more claims of the ’666 patent, either literally or under the doctrine of equivalents.

267. On information and belief, BII, by acting in concert with, directing, and/or authorizing BIPI to file the Boehringer aBLA, has an affirmative intent to actively induce infringement by others of one or more claims of the ’666 patent, either literally or under the doctrine of equivalents.

268. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that BIFI’s manufacture of the Boehringer aBLA Product directly infringes at least one claim of the ’666 patent, either literally or under the doctrine of equivalents.

269. On information and belief, BIPI and BII knowingly or with willful blindness induce another’s direct infringement of at least one of the claims of the ’666 patent, either literally or under the doctrine of equivalents, by at least the fact that BIFI has manufactured and/or will manufacture the Boehringer aBLA Product for sale in the United States market.

270. Boehringer has knowledge of and is aware of the ’666 patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

271. Plaintiffs seek a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product will infringe the ’666 patent.

272. Unless Boehringer is enjoined from directly and indirectly infringing the ’666 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XIII

DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,255,143

273. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

274. AbbVie's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

275. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

276. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

277. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

278. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

279. On information and belief, Boehringer's submission and the FDA's acceptance of Boehringer's aBLA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Boehringer will directly and/or indirectly infringe one or more valid and enforceable claims of the '143 patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

280. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's submission of its aBLA to

obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the ’143 patent is an act of infringement of one or more claims of the ’143 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

281. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer’s commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claims 1-15, 18, and 20-21 of the ’143 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. For at least one claim, Boehringer’s failure to provide sufficient manufacturing information, as required by the BPCIA, has prevented AbbVie from learning additional facts that would support AbbVie’s allegation. In the absence of sufficient manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Boehringer infringes certain claims of the ’143 patent.

282. On information and belief, BIFI has manufactured and/or will manufacture the Boehringer aBLA Product once it is approved by the FDA. On information and belief, BIPI and/or BII act in concert with and/or direct BIFI to make the Boehringer aBLA Product, and thereby actively induce infringement of at least claims 1-15, 18, and 20-21 of the ’143 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

283. On information and belief, BIPI, by seeking licensure for a product manufactured by another for sale in the United States that infringes the ’143 patent, has an affirmative intent to

actively induce infringement by others of one or more claims of the ’143 patent, either literally or under the doctrine of equivalents.

284. On information and belief, BII, by acting in concert with, directing, and/or authorizing BIPI to file the Boehringer aBLA, has an affirmative intent to actively induce infringement by others of one or more claims of the ’143 patent, either literally or under the doctrine of equivalents.

285. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that BIFI’s manufacture of the Boehringer aBLA Product directly infringes at least one claim of the ’143 patent, either literally or under the doctrine of equivalents.

286. On information and belief, BIPI and BII knowingly or with willful blindness induce another’s direct infringement of at least one of the claims of the ’143 patent, either literally or under the doctrine of equivalents, by at least the fact that BIFI has manufactured and/or will manufacture the Boehringer aBLA Product for sale in the United States market.

287. Boehringer has knowledge of and is aware of the ’143 patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

288. Plaintiffs seek a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product will infringe the ’143 patent.

289. Unless Boehringer is enjoined from directly and indirectly infringing the ’143 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XIV

DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,266,949

290. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

291. AbbVie's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

292. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

293. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

294. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

295. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

296. On information and belief, Boehringer's submission and the FDA's acceptance of Boehringer's aBLA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Boehringer will directly and/or indirectly infringe one or more valid and enforceable claims of the '949 patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

297. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer's submission of its aBLA to

obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the ’949 patent is an act of infringement of one or more of the claims of the ’949 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

298. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer’s commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claims 1-30 of the ’949 patent under 35 U.S.C. § 271(a) and/or § 271(g), either literally or under the doctrine of equivalents. For at least one claim, Boehringer’s failure to provide sufficient manufacturing information, as required by the BPCIA, has prevented AbbVie from learning additional facts that would support AbbVie’s allegation. In the absence of sufficient manufacturing information, AbbVie resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to present to the Court additional evidence that Boehringer infringes certain claims of the ’949 patent. Boehringer has the burden of establishing that the Boehringer aBLA Product was not made by the process claimed in the ’949 patent. *See* 35 U.S.C. § 295.

299. On information and belief, BIFI has manufactured and/or will manufacture the Boehringer aBLA Product once it is approved by the FDA. On information and belief, BIPI and/or BII act in concert with and/or direct BIFI to make the Boehringer aBLA Product, and thereby actively induce infringement of at least claims 1-30 of the ’949 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

300. On information and belief, BIPI, by seeking licensure of a product manufactured using methods claimed in the ’949 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the ’949 patent, either literally or under the doctrine of equivalents.

301. On information and belief, BII, by acting in concert with, directing, and/or authorizing BIPI to file the Boehringer aBLA, has an affirmative intent to actively induce infringement by others of one or more claims of the ’949 patent, either literally or under the doctrine of equivalents.

302. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that BIFI’s manufacture of the Boehringer aBLA Product directly infringes at least one claim of the ’949 patent, either literally or under the doctrine of equivalents.

303. On information and belief, BIPI and BII knowingly or with willful blindness induce another’s direct infringement of at least one of the claims of the ’949 patent, either literally or under the doctrine of equivalents, by at least the fact that BIFI has manufactured and/or will manufacture the Boehringer aBLA Product for sale in the United States market using methods claimed in the ’949 patent.

304. Boehringer has knowledge of and is aware of the ’949 patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

305. Plaintiffs seek a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product and/or use of the claimed methods will infringe the ’949 patent.

306. Unless Boehringer is enjoined from directly and indirectly infringing the ’949 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XV

DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,272,041

307. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

308. AbbVie’s claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

309. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

310. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer’s aBLA.

311. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

312. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

313. On information and belief, Boehringer’s submission and the FDA’s acceptance of Boehringer’s aBLA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Boehringer will

directly and/or indirectly infringe one or more valid and enforceable claims of the ’041 patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

314. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2), Boehringer’s submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the ’041 patent is an act of infringement of one or more of the claims of the ’041 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

315. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Boehringer’s commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe at least claims 1-2, 4-7, 16-19, 21-23, and 28-30 of the ’041 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

316. On information and belief, BIFI has manufactured and/or will manufacture the Boehringer aBLA Product once it is approved by the FDA. On information and belief, BIPI and/or BII act in concert with and/or direct BIFI to make the Boehringer aBLA Product, and thereby actively induce infringement by others of at least claims 1-2, 4-7, 16-19, 21-23, and 28-30 of the ’041 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

317. On information and belief, BIPI, by seeking licensure for a product manufactured by another for sale in the United States that infringes the ’041 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the ’041 patent, either literally or under the doctrine of equivalents.

318. On information and belief, BII, by acting in concert with, directing, and/or authorizing BIPI to file the Boehringer aBLA, has an affirmative intent to actively induce infringement by others of one or more claims of the ’041 patent, either literally or under the doctrine of equivalents.

319. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that BIFI’s manufacture of the Boehringer aBLA Product directly infringes at least one claim of the ’041 patent, either literally or under the doctrine of equivalents.

320. On information and belief, BIPI and BII knowingly or with willful blindness induce another’s direct infringement of at least one of the claims of the ’041 patent, either literally or under the doctrine of equivalents, by at least the fact that BIFI has manufactured and/or will manufacture the Boehringer aBLA Product for sale in the United States market.

321. Boehringer has knowledge of and is aware of the ’041 patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

322. Plaintiffs seek a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product will infringe the ’041 patent.

323. Unless Boehringer is enjoined from directly and indirectly infringing the ’041 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT XVI

DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,546,212

324. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

325. AbbVie's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

326. On information and belief, on or about October 27, 2016, Boehringer submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

327. On information and belief, on or before January 9, 2017, the FDA accepted Boehringer's aBLA.

328. On January 13, 2017, Boehringer provided AbbVie with a copy of its aBLA.

329. On information and belief, Boehringer intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product promptly upon receiving FDA approval to do so.

330. On information and belief, Boehringer's submission and the FDA's acceptance of Boehringer's aBLA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Boehringer aBLA Product, a biosimilar version of adalimumab, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Boehringer will directly and/or indirectly infringe one or more valid and enforceable claims of the '212 patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

331. Based on confidential information disclosed to AbbVie by Boehringer pursuant to 42 U.S.C. § 262(*l*)(2), Boehringer's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Boehringer aBLA Product prior to the expiration of the '212 patent is an act of infringement of one or more of the claims of the '212 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

332. Boehringer has provided information to AbbVie pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the indications, dosage, and methods of use for the Boehringer aBLA Product. Based on this confidential information and on information and belief, Boehringer's commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will actively induce infringement by others of at least claims 1-24 of the '212 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

333. On information and belief, Boehringer has an affirmative intent to actively induce infringement by others of one or more claims of the '212 patent, either literally or under the doctrine of equivalents. On information and belief, Boehringer has filed an aBLA that includes a proposed package insert with directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Boehringer aBLA Product.

334. On information and belief, Boehringer is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Boehringer aBLA Product at least according to Boehringer's package insert and, therefore, will directly infringe at least one or more claims of the '212 patent, either literally or under the doctrine of equivalents.

335. On information and belief, Boehringer will knowingly or with willful blindness induce another's direct infringement of at least one or more of the claims of the '212 patent, either literally or under the doctrine of equivalents, by at least Boehringer's package insert for the Boehringer aBLA Product.

336. Boehringer has knowledge of and is aware of the ’212 patent, including due to AbbVie’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

337. Plaintiffs seek a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Boehringer aBLA Product will infringe the ’212 patent.

338. Unless Boehringer is enjoined from directly and indirectly infringing the ’212 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

PRAYER FOR RELIEF

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

a. a judgment and declaration that Boehringer has infringed or induced infringement of one or more claims of the AbbVie Patents under 35 U.S.C. § 271(e)(2)(C);

b. a judgment and declaration that Boehringer has or will infringe or has or will induce infringement of one or more claims of the AbbVie Patents by engaging in the manufacture, import, offer for sale, sale, or use within the United States of the Boehringer aBLA Product before the expirations of the AbbVie Patents;

c. preliminary and/or permanent equitable relief, including but not limited to a preliminary and permanent injunction that enjoins Boehringer, 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 them and/or their successors or assigns from infringing the AbbVie Patents, or contributing to or inducing anyone

to do the same, by acts including the manufacture, use, offer to sell, sale, or distribution within the United States, or importation into the United States, of any current or future versions of the Boehringer aBLA Product, the use or manufacturing of which infringes the AbbVie Patents;

d. 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

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

Respectfully submitted,

ROSS ARONSTAM & MORITZ LLP

/s/ Benjamin J. Schladweiler

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