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

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD Plaintiffs, v. SANDOZ INC., SANDOZ GMBH, and SANDOZ INTERNATIONAL GMBH Defendants.	)	Civil Action No. _____

COMPLAINT

INTRODUCTION

1. AbbVie's scientists and clinicians invested decades developing the groundbreaking drug HUMIRA®, the first fully human antibody ever approved by the U.S. Food and Drug Administration ("FDA"), and expanding its use into a variety of diseases and patient populations. Over one million patients have benefited from AbbVie's pioneering work. And the

United States Patent and Trademark ("USPTO") has recognized AbbVie's innovation, awarding over 100 patents relating to HUMIRA®.

2. Numerous biosimilar companies—including Defendants Sandoz Inc., Sandoz GmbH, and Sandoz International ("Sandoz" or "Defendants")—have taken note of AbbVie's success as well, attempting to make copycat versions of HUMIRA®. When confronted with AbbVie's patents, these companies took their best shots, filing 20 *inter partes* review ("IPR") proceedings at the Patent Trial and Appeal Board ("PTAB") of the USPTO. Despite the lower burden of proof (a preponderance of the evidence rather than clear and convincing evidence) and the high invalidation rate in IPRs, the PTAB has rejected the overwhelming majority of these challenges. Of particular relevance here, the PTAB has rejected eight challenges to AbbVie patents directed to formulating adalimumab (the active ingredient of HUMIRA®), and three challenges to patents directed to treatment of inflammatory bowel diseases, including the patent-in-suit.

3. Sandoz has itself lost six IPR proceedings at the PTAB on patents relating to HUMIRA®, including one of the patents-in-suit. In each case, the PTAB held that Sandoz failed to establish a reasonable likelihood that any challenged claim would be held unpatentable.[1] The PTAB's decisions not to institute IPRs on these patents confirms and supports their validity.

4. Despite its repeated, failed attacks, Sandoz has elected to put off confronting the vast majority of AbbVie's patents for another day, substantially delaying resolution of the parties' dispute. Under the Biosimilar Price Competition and Innovation Act ("BPCIA"), the

[1] *See Sandoz Inc. v. AbbVie Biotechnology Ltd*, Case Nos. IPR2017-01823, Decision Denying Institution of Inter Partes Review, Paper No. 16 (P.T.A.B. February 9, 2018); IPR2017-01824, Decision Denying Institution of Inter Partes Review, Paper No. 14 (P.T.A.B. February 9, 2018); IPR2017-01987, Decision Denying Institution of Inter Partes Review, Paper No. 15 (P.T.A.B. March 9, 2018); IPR2017-01988, Decision Denying Institution of Inter Partes Review, Paper No. 13 (P.T.A.B. March 9, 2018); IPR2018-0002, Decision Denying Institution of Inter Partes Review, Paper No. 13 (P.T.A.B. May 3, 2018); IPR2018-00156, Decision Denying Institution of Inter Partes Review, Paper No. 11 (P.T.A.B. June 5, 2018).

United States Congress laid out a process for AbbVie to bring litigation on its patents before Sandoz launches its biosimilar. As part of that process, AbbVie identified ***84*** patents, including those that Sandoz unsuccessfully challenged before the USPTO. But the BPCIA gives Sandoz, as the biosimilar applicant, the unilateral option to limit the number of patents that AbbVie can assert at this stage. Sandoz has chosen to take advantage of those provisions of the BPCIA to avoid litigating all but two of AbbVie's 84 patents at this time.

5. While Sandoz can delay justice, it cannot prevent it. Pursuant to the BPCIA, AbbVie can seek relief, including an injunction, on the remaining patents when Sandoz files a Notice of Commercial Marketing, which it must do at least 180 days prior to launching a biosimilar product, or as circumstances otherwise warrant. Sandoz's choice will result in a second wave of litigation.

6. AbbVie brings this first action for patent infringement to prevent Sandoz from reaping the rewards of AbbVie's innovation. While AbbVie has spent vast resources over decades developing HUMIRA®, Sandoz seeks to copy AbbVie's work and ignore AbbVie's patents. Sandoz had submitted an abbreviated Biologics License Application ("aBLA") to the FDA requesting that its biosimilar adalimumab product GP2017 be licensed for commercial sale by relying on AbbVie's demonstration that HUMIRA® is safe and effective. But while the BPCIA gives Sandoz an abbreviated regulatory pathway for its biosimilar version of HUMIRA®, it does *not* give Sandoz license to infringe AbbVie's patents. AbbVie seeks an injunction to prevent this infringement.

7. HUMIRA® belongs to a category of drugs known as biologics. Biologics are complex proteins manufactured in living cells rather than by chemical synthesis. This makes them more difficult to develop, manufacture, formulate, and administer. Whereas small molecule

drugs have been around for centuries, biologics are newer, larger, and more complex. Even within the category of biologics, HUMIRA® is unique. HUMIRA® is the first fully human antibody approved by the FDA. In bringing HUMIRA® from the laboratory to patients, AbbVie was in uncharted territory. In 1996, AbbVie's predecessor invented the antibody in HUMIRA® after years of intense research. But that was only the first step. Since then, AbbVie has embarked on two decades of research, investment, and innovation.

8. 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 that resulted in FDA approval for the treatment of ten different diseases: rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease (adult and pediatric), ulcerative colitis, hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis. Sandoz seeks to copy the results of AbbVie's clinical development.

9. To further benefit patients, AbbVie also invested in and invented subcutaneous, high concentration, liquid formulations 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 is 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, without sacrificing HUMIRA®'s safety and efficacy. Here again, Sandoz seeks to copy the results of AbbVie's innovative formulation work.

10. AbbVie seeks an injunction to prevent Sandoz from infringing two of the many patents that reflect AbbVie's years of innovation and research. AbbVie also reserves its right to

assert the remaining patents infringed by Sandoz in a second wave when Sandoz provides a Notice of Commercial Marketing, or as circumstances otherwise warrant.

NATURE OF THE ACTION

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

11. 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.

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

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

14. 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).

15. The invention of adalimumab was particularly noteworthy in that it is 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.

16. 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.

17. 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.

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

19. In seeking approval for its biosimilar adalimumab product GP2017 (the "Sandoz aBLA Product"), Sandoz 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 Sandoz an abbreviated FDA regulatory pathway, it does not give Sandoz a license to infringe AbbVie's intellectual property. At this time, AbbVie seeks an injunction to prevent infringement of the two asserted AbbVie patents. When Sandoz files a Notice of Commercial Marketing or as circumstances otherwise warrant, AbbVie will assert additional patents.

PARTIES

20. 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.

21. 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.

22. On information and belief, Defendant Sandoz Inc. is a company organized and existing under the laws of the state of Colorado with its principal place of business at 100 College Road West, Princeton, New Jersey 08540.

23. On information and belief, Sandoz Inc., 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, GP2017. On information and belief, these drugs are (or will be) distributed and sold in the State of New Jersey and throughout the United States. On information and belief, Sandoz Inc. is the United States agent for Sandoz International GmbH and Sandoz GmbH for purposes including, but not limited to, filing regulatory submissions to and corresponding with the FDA.

24. On information and belief, Sandoz Inc. operates as a subsidiary of Sandoz International GmbH.

25. On information and belief, Defendant Sandoz International GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany with its principal place of business at Industriestrasse 25, 83607 Holzkirchen, Germany.

26. On information and belief, Sandoz International GmbH, 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, GP2017. On information and belief, these drugs are (or will be) distributed and sold in the State of New Jersey and throughout the United States.

27. On information and belief, Defendant Sandoz GmbH is a corporation organized and existing under the laws of the Republic of Austria with its principal place of business at Biochemiestrasse 10, 6250 Kundl, Austria.

28. On information and belief, Sandoz GmbH, acting in concert with the other Defendants, is in the business of manufacturing biologic drugs, including the proposed biosimilar version of AbbVie's HUMIRA® (adalimumab) product, GP2017. On information and belief, these drugs are (or will be) distributed and sold in the State of New Jersey and throughout the United States.

29. On information and belief, Sandoz GmbH operates as a subsidiary of Sandoz International GmbH.

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 New Jersey 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. Sandoz Inc.

33. This Court has personal jurisdiction over Sandoz Inc. because, *inter alia*, Sandoz Inc.'s principal place of business is in the District of New Jersey and its contacts with the State of New Jersey are sufficient for jurisdiction. In addition, Sandoz Inc. has agreed that New Jersey would be an appropriate venue for this lawsuit.

34. This Court also has personal jurisdiction over Sandoz Inc. because Sandoz Inc. has directly or indirectly committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(c) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including in New Jersey.

35. For example, on information and belief, Sandoz Inc. has acted and/or intends to act in concert with the other Defendants to develop, manufacture, and seek approval for the Sandoz aBLA Product, and on information and belief, Sandoz Inc., in concert with the other Defendants, intends to market and sell the Sandoz aBLA Product in the United States and in the State of New Jersey if the Sandoz aBLA Product receives FDA approval.

36. On information and belief, Sandoz Inc. develops, manufactures, seeks regulatory approval for, markets, distributes, and sells biopharmaceuticals for sale and use throughout the United States, including in the State of New Jersey. On information and belief, Sandoz Inc. purposefully has conducted and continues to conduct business, directly or indirectly, in this

District. On information and belief, Sandoz Inc. is registered as a Manufacturer and Wholesaler in the State of New Jersey. On information and belief, Sandoz Inc. is registered to do business in New Jersey under entity identification number 0100097265.

B. Sandoz International GmbH

37. This Court has jurisdiction over Sandoz International GmbH because Sandoz International GmbH's contacts with the State of New Jersey and the United States are sufficient for jurisdiction.

38. On information and belief, Sandoz International GmbH, acting in concert with the other Defendants, has directly or indirectly committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(c) and intends a future course of conduct that includes acts of patent infringement in New Jersey and the United States. These acts have led and will lead to foreseeable harm and injury to AbbVie, including in New Jersey and the United States.

39. For example, on information and belief, Sandoz International GmbH has acted and/or intends to act in concert with, directed, and/or authorized the other Defendants to develop, manufacture, and seek approval for the Sandoz aBLA Product, and on information and belief, Sandoz International GmbH, in concert with the other Defendants, intends to market and sell the Sandoz aBLA Product in the United States and in the State of New Jersey if the Sandoz aBLA Product receives FDA approval.

40. On information and belief, Sandoz International GmbH has acted in concert with, directed, and/or authorized the other Defendants to develop and seek approval for the Sandoz aBLA Product by, *inter alia*, directing and/or authorizing clinical trials of the Sandoz aBLA Product in support of Defendant Sandoz Inc.'s abbreviated Biologics License Application ("Sandoz's aBLA").

41. On information and belief, Sandoz International GmbH exercises considerable control over Sandoz Inc. with respect to biosimilar products and approves significant decisions of Sandoz Inc. such as allowing Sandoz Inc. to act as the agent for Sandoz International GmbH in connection with preparing and filing Sandoz's aBLA and to act as Sandoz International GmbH's agent in the United States.

42. On information and belief, Sandoz International GmbH exercises control over Sandoz subsidiaries, including Sandoz Inc., through the Sandoz International GmbH leadership team, which includes "Carol Lynch, President of Sandoz US and Head of North America." On information and belief, Ms. Lynch is the President of Sandoz Inc. as well as the Global Head of Biopharmaceuticals at Sandoz International GmbH, and Ms. Lynch directly or indirectly reports to the head of Sandoz International GmbH.

43. On information and belief, Sandoz International GmbH is actively involved with filing Sandoz's aBLA and the strategy for obtaining FDA approval to market and sell the Sandoz aBLA Product in the State of New Jersey and throughout the United States, which directly gives rise to AbbVie's claims of patent infringement. For example, on March 6, 2017, Sandoz issued a press release regarding Sandoz's aBLA Product from Holzkirchen, Germany, the location of Sandoz International GmbH. *See* Press Release, Sandoz International GmbH, "New Data Demonstrate Sandoz Proposed Biosimilar Adalimumab Has Equivalent Efficacy to Reference Medicine," March 6, 2017, https://www.sandoz.com/news/media-releases/new-data-demonstrate-sandoz-proposed-biosimilar-adalimumab-has-equivalent, attached hereto as Exhibit 1. Sandoz International GmbH's press release discusses its "proposed biosimilar adalimumab (GP2017)." *Id.; see also* Press Release, Sandoz International GmbH, "Sandoz Proposed Biosimilar Adalimumab Matches Reference Biologic in Terms of Efficacy and Safety in Long-

Term Study," September 14, 2017, https://www.sandoz.com/news/media-releases/sandoz-proposed-biosimilar-adalimumab-matches-reference-biologic-terms-efficacy, attached hereto as Exhibit 2 ("Sandoz . . . today announces new data on its proposed biosimilar adalimumab.").

44. On January 16, 2018, Sandoz announced that the FDA accepted the aBLA for GP2017 from Holzkirchen, Germany. *See* Press Release, Sandoz International GmbH, "Sandoz Regulatory Submission for Proposed Biosimilar Adalimumab Accepted by FDA," January 16, 2018, https://www.sandoz.com/news/media-releases/sandoz-regulatory-submission-proposed-biosimilar-adalimumab-accepted-fda, attached hereto as Exhibit 3. That press release included the following quote from Mark Levick, MD, PhD: "The FDA's acceptance of the regulatory submission for our biosimilar adalimumab brings us one step closer to offering a portfolio of options to the millions of patients in the US who suffer from an inflammatory disease." On information and belief, Dr. Levick is Global Head of Development, Biopharmaceuticals based in Sandoz International GmbH's Holzkirchen, Germany headquarters. On information and belief, these press releases about the Sandoz aBLA Product and the Sandoz aBLA were on behalf of Sandoz International GmbH.

45. Sandoz Inc., Sandoz International GmbH, and Sandoz GmbH hold themselves out as a unitary entity and have represented to the public that their activities are directed, controlled, and carried out as a single entity. For example, Sandoz International GmbH maintains an Internet website at the URL www.sandoz.com, which states that "the name Sandoz" encompasses "a single global brand." *See* Sandoz International GmbH, "The Sandoz Brand," https://www.sandoz.com/about-us/who-we-are/sandoz-brand, attached hereto as Exhibit 4.

46. Sandoz International GmbH has previously submitted to the jurisdiction of this Court and availed itself of the legal protections of the State of New Jersey by asserting

affirmative defenses in the United States District Court for the District of New Jersey. *See, e.g.*, *Immunex Corp., et al. v. Sandoz Inc., et al*., No. 16-cv-1118, ECF No. 106 (D.N.J. Sept. 21, 2016).

47. Additionally and alternatively, to the extent Sandoz International GmbH is not subject to the jurisdiction of the courts of general jurisdiction of the State of New Jersey, Sandoz International GmbH 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).

C. Sandoz GmbH

48. This Court has jurisdiction over Sandoz GmbH because Sandoz GmbH's contacts with the State of New Jersey and the United States are sufficient for jurisdiction.

49. On information and belief, Sandoz GmbH, acting in concert with the other Defendants, has directly or indirectly committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(c) and intends a future course of conduct that includes acts of patent infringement in New Jersey and the United States. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including in New Jersey and the United States.

50. For example, on information and belief, Sandoz GmbH has acted and/or intends to act in concert with the other Defendants to develop, manufacture, and seek approval for the Sandoz aBLA Product, and on information and belief, Sandoz GmbH, in concert with the other Defendants, intends to market and sell the Sandoz aBLA Product in the United States and in the State of New Jersey if the Sandoz aBLA Product receives FDA approval.

51. On information and belief, Sandoz GmbH has acted and/or intends to act in

concert with the other Defendants to develop and seek approval for the Sandoz aBLA Product, including by sponsoring and/or participating in clinical trials of the Sandoz aBLA Product in support of Sandoz's aBLA, including a "Study to Demonstrate Equivalent Efficacy and to Compare Safety of Biosimilar Adalimumab (GP2017) and Humira (ADACCESS)." A publication describing the study and its results stated that "Sandoz GmbH designed and sponsored the study; participated in the collection, analysis and interpretation of the data, and in the writing, reviewing and approval of the abstract." Blauvelt, Andrew et al., "A randomized, double-blind, multicenter study to compare the efficacy, safety, and immunogenicity of a proposed adalimumab biosimilar (GP2017) with originator adalimumab in patients with moderate-to-severe chronic plaque-type psoriasis," J. Am. Acad. Dermatol., June 2007, at AB22, attached hereto as Exhibit 5.

52. On information and belief, the Sandoz aBLA Product is or will be manufactured at Sandoz GmbH facilities. On information and belief, Sandoz GmbH's facilities include biosimilar manufacturing facilities located in Schaftenau, Austria and Kundl, Austria. Sandoz describes its plant in Schaftenau as the "facility that will be used to manufacture pre-filled syringes and devices for . . . Sandoz's biosimilars." *See* Sandoz International GmbH, "Sandoz Inaugurates BioInject – a new state-of-the-art biopharmaceutical manufacturing facility in Schaftenau, Austria," September 17, 2015, https://www.sandoz.com/news/media-releases/sandoz-inaugurates-bioinject-new-state-art-biopharmaceutical-manufacturing, attached hereto as Exhibit 6. Therefore, on information and belief, Sandoz GmbH actively participated in the preparation of Sandoz's aBLA, for example by providing information regarding the facilities in which the Sandoz biosimilar product is manufactured, processed, packaged, or held. *See* 42 U.S.C. § 262(k)(2)(A)(v).

53. On information and belief, the acts of Sandoz Inc. complained of herein were and will be done, in part, for the benefit of Sandoz GmbH, which has or will directly or indirectly manufacture, export, and sell the Sandoz aBLA Product into New Jersey and the United States.

54. Additionally and alternatively, to the extent Sandoz GmbH is not subject to the jurisdiction of the courts of general jurisdiction of the State of New Jersey, Sandoz GmbH 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

55. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and/or 1400.

56. On information and belief, Sandoz Inc. has its principal place of business in New Jersey and, as set forth above, is subject to personal jurisdiction in this district. Sandoz Inc. has committed an act of infringement and intends a future course of conduct that includes acts of patent infringement in New Jersey, as set forth above. In addition, Sandoz Inc. has agreed that New Jersey would be an appropriate venue for this lawsuit.

57. On information and belief, Sandoz Inc. has a regular and established place of business in this judicial District because, *inter alia*, its principal place of business is in New Jersey. On information and belief, Sandoz Inc. maintains regular and established places of business at One Health Plaza, Bldg. 435, East Hanover, NJ 07936 and 100 College Road West, Princeton, NJ 08540.

58. As foreign entities, Sandoz International GmbH and Sandoz GmbH are subject to suit in any jurisdiction in the United States, including the District of New Jersey. 28 U.S.C.

§ 1391(c).

59. For these reasons, and for other reasons that will be presented to the Court if jurisdiction and/or venue is challenged, the Court has personal jurisdiction over Sandoz, and venue in this judicial district is proper.

THE PARTIES' EXCHANGES UNDER THE BPCIA

60. On information and belief, prior to January 2018, Sandoz submitted an aBLA to the FDA pursuant to the BPCIA, specifically 42 U.S.C. § 262(k).

61. The BPCIA was enacted on March 23, 2010, and created for the first time an abbreviated pathway for approval of follow-on biologic products. 42 U.S.C. § 262(k) provides a pathway for approval of a product that is "biosimilar" to a "reference product." A "biosimilar" product is defined by the BPCIA as a biological product that (1) "is highly similar to the reference product notwithstanding minor differences in clinically inactive components" and (2) has "no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product." 42 U.S.C. § 262(i)(2). The BPCIA defines a "reference product" to be a "single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." 42 U.S.C. § 262(i)(4).

62. Sandoz has demonstrated its intention to utilize AbbVie's data and work discovering and developing adalimumab through the use of the abbreviated BPCIA biosimilar pathway.

63. To facilitate the protection of a 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.

64. The BPCIA includes a mechanism for Sandoz to provide AbbVie a copy of its aBLA submission and relevant manufacturing information within 20 days of the FDA accepting the application for review. 42 U.S.C. § 262(*l*)(2)(A).

65. On January 12, 2018, Sandoz contacted AbbVie and indicated that it "has been pursuing the filing of a 42 U.S.C. § 262(*k*) application" for FDA approval of "a Sandoz biosimilar adalimumab product," and indicating Sandoz "will make disclosure pursuant to the exchanges discussed in 42 U.S.C. § 262(*l*)" to AbbVie.

66. On information and belief, on or before January 16, 2018, the FDA accepted Sandoz's aBLA.

67. In January 2018, the parties began exchanging information in accordance with the procedures outlined in the BPCIA. On or about January 17, 2018, Sandoz provided outside counsel for AbbVie and AbbVie's designated in-house attorney with access to Sandoz's aBLA. Although Sandoz provided its aBLA to AbbVie, it did not at that time provide the relevant "other information that describes the process or processes used to manufacture" the Sandoz aBLA product, as required by the statute. 42 U.S.C. § 262(*l*)(2)(A). AbbVie attorneys are not permitted under the statutory provisions of the BPCIA to consult with independent experts regarding

Sandoz's confidential information. 42 U.S.C. § 262(*l*)(1)(C).

68. On March 18, 2018, pursuant to 42 U.S.C. § 262(*l*)(3)(A), AbbVie provided Sandoz with its list of patents for which it believed a claim of patent infringement could be reasonably asserted against Sandoz's aBLA Product ("AbbVie's 3A List"). AbbVie also asked, "in the event that Sandoz asserts that any of these patents are either not infringed or invalid pursuant to Section (*l*)(3)(B)(ii)(I), . . . that Sandoz identify and provide copies of any documentary evidence supporting those assertions, so that AbbVie may fully consider it."

69. On April 24, 2018 and May 1, 2018, pursuant to 42 U.S.C. § 262(*l*)(7), AbbVie provided supplemental patent lists to Sandoz, each adding a recently issued patent.

70. On May 16, 2018, Sandoz responded by providing AbbVie, pursuant to the confidentiality restrictions under 42 U.S.C. § 262(*l*)(1), with statements pursuant to 42 U.S.C. § 262(*l*)(3)(B) and 42 U.S.C. § 262(*l*)(7)(B) contesting Sandoz's infringement of certain patents and the validity of those patents ("Sandoz's 3B Statement"). Although Sandoz provided certain additional information regarding its manufacturing process with its 3B Statement, it did not provide information sufficient to confirm that it does not infringe each of the claims of the patents identified by AbbVie, as AbbVie requested.

71. On July 15, 2018, AbbVie provided Sandoz with a detailed, approximately 1,200-page statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) responding to Sandoz's allegations and concerning the following 84 AbbVie patents ("AbbVie's 3C Statement"):

	U.S. Patent No.	**Title**
1.	6,805,686	Autoinjector with Extendable Needle Protector Shroud
2.	8,216,583	Formulation of Human Antibodies for Treating TNF-α Associated Disorders

	U.S. Patent No.	Title
3.	8,231,876	Purified Antibody Composition
4.	8,663,945	Methods of Producing Anti-TNF-Alpha Antibodies in Mammalian Cell Culture
5.	8,715,664	Use of Human TNFα Antibodies for Treatment of Erosive Polyarthritis
6.	8,795,670	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
7.	8,802,100	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
8.	8,802,101	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
9.	8,802,102	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
10.	8,808,700	Use of TNF Alpha Inhibitor for Treatment of Erosive Polyarthritis
11.	8,883,156	Purified Antibody Composition
12.	8,889,135	Methods of Administering Anti-TNFα Antibodies
13.	8,889,136	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
14.	8,895,009	Purified Antibody Composition
15.	8,906,372	Purified Antibody Composition
16.	8,906,373	Use of TNF-alpha Inhibitor for Treatment of Psoriasis
17.	8,906,646	Fed-batch Method of Making Human Anti-TNF-Alpha Antibody
18.	8,911,737	Methods of Administering Anti-TNFα Antibodies
19.	8,911,741	Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody
20.	8,911,964	Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody
21.	8,916,153	Purified Antibody Composition
22.	8,916,157	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
23.	8,916,158	Formulation of Human Antibodies for Treating TNF-α Associated Disorders

	U.S. Patent No.	Title
24.	8,926,975	Method of Treating Ankylosing Spondylitis
25.	8,932,591	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
26.	8,940,305	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
27.	8,961,973	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
28.	8,961,974	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
29.	8,974,790	Methods of Administering Anti-TNFα Antibodies
30.	8,986,693	Use of TNFα Inhibitor for Treatment of Psoriasis
31.	8,992,926	Methods of Administering Anti-TNFα Antibodies
32.	8,999,337	Methods for Treating Juvenile Idiopathic Arthritis by Inhibition of TNFα
33.	9,017,680	Methods of Administering Anti-TNFα Antibodies
34.	9,018,361	Isolation and Purification of Antibodies Using Protein A Affinity Chromatography
35.	9,061,005	Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease
36.	9,067,992	Use of TNFα Inhibitor for Treatment of Psoriatic Arthritis
37.	9,073,987	Methods of Administering Anti-TNFα Antibodies
38.	9,073,988	Fed Batch Method of Making Anti-TNF-Alpha Antibodies
39.	9,085,618	Low Acidic Species Compositions and Methods for Producing and Using the Same
40.	9,085,620	Use of TNFα Inhibitor for Treatment of Psoriatic Arthritis
41.	9,090,689	Use of TNFα Inhibitor for Treatment of Psoriasis
42.	9,090,867	Fed-Batch Method of Making Anti-TNF-Alpha Antibody
43.	9,096,666	Purified Antibody Composition
44.	9,102,723	Purified Antibody Composition

	U.S. Patent No.	Title
45.	9,114,166	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
46.	9,150,645	Cell Culture Methods to Reduce Acidic Species
47.	9,187,559	Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease
48.	9,193,787	Human Antibodies that Bind Human TNF-Alpha and Methods of Preparing the Same
49.	9,200,069	Low Acidic Species Compositions and Methods for Producing and Using the Same
50.	9,200,070	Low Acidic Species Compositions and Methods for Producing and Using the Same
51.	9,220,781	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
52.	9,234,032	Fed-Batch Methods for Producing Adalimumab
53.	9,255,143	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
54.	9,266,949	Low Acidic Species Compositions and Methods for Producing and Using the Same
55.	9,272,041	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
56.	9,272,042	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
57.	9,273,132	Purified Antibody Composition
58.	9,284,370	Methods for Treating Juvenile Idiopathic Arthritis
59.	9,284,371	Methods of Producing Adalimumab
60.	9,289,497	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
61.	9,290,568	Methods to Control Protein Heterogeneity
62.	9,295,725	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
63.	9,302,011	Formulation of Human Antibodies for Treating TNF-α Associated Disorders
64.	9,315,574	Low Acidic Species Compositions and Methods for Producing and Using the Same
65.	9,327,032	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders

	U.S. Patent No.	Title
66.	9,334,319	Low Acidic Species Compositions
67.	9,346,879	Protein Purification Methods to Reduce Acidic Species
68.	9,359,434	Cell Culture Methods to Reduce Acidic Species
69.	9,365,645	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
70.	9,505,833	Human Antibodies that Bind Human TNF-Alpha and Methods of Preparing the Same
71.	9,505,834	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
72.	9,512,216	Use of TNFα Inhibitor
73.	9,522,953	Low Acidic Species Compositions and Methods for Producing and Using the Same
74.	9,546,212	Methods of Administering Anti-TNFα Antibodies
75.	9,550,826	Glycoengineered Binding Protein Compositions
76.	9,624,295	Uses and Compositions for Treatment of Psoriatic Arthritis
77.	9,669,093	Methods for Treating Juvenile Idiopathic Arthritis
78.	9,683,033	Cell Culture Methods to Reduce Acidic Species
79.	9,732,152	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
80.	9,738,714	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
81.	9,750,808	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
82.	9,913,902	Purified Antibody Composition
83.	9,950,066	Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders
84.	9,957,318	Protein Purification Methods to Reduce Acidic Species

72. During the negotiation period that followed after AbbVie provided its 3C Statement, AbbVie engaged in good faith discussions with Sandoz. Sandoz refused to accept any

of AbbVie's proposals and, on August 5, 2018, provided AbbVie with the number of patents that it would agree to be sued on. That number was one. This meant that the maximum number of patents that could be part of this first lawsuit under the BPCIA was two, despite AbbVie's identification of 84 patents in the BPCIA exchange process.

73. On August 10, 2018, each party identified its one patent 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)." The parties identified U.S. Patent No. 9,187,559 and U.S. Patent No. 9,750,808.

74. At this time, and as a result of Sandoz's gamesmanship, AbbVie is limited to seeking redress on two of its patents. But AbbVie will have a second opportunity, when Sandoz provides a 180-day Notice of Commercial Marketing (or as circumstances otherwise warrant), to assert its remaining patents. So while Sandoz's tactics may create delay, it still must deal with AbbVie's patents before going to market.

SANDOZ'S aBLA PRODUCT

75. On information and belief, Sandoz has undertaken the development of a proposed biosimilar to AbbVie's HUMIRA® adalimumab product.

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

77. Sandoz has made statements regarding its clinical testing of the Sandoz aBLA Product. For example, Sandoz International GmbH has stated "Data from a long-term study of

patients continuously treated with the proposed biosimilar or the reference medicine show that efficacy and safety profiles of the two medicines match throughout 51 weeks of treatment in patients with moderate-to-severe chronic plaque psoriasis." *See* Exhibit 2. Sandoz has also claimed that the "Sandoz proposed biosimilar adalimumab (GP2017) [was] shown to have equivalent efficacy and a similar safety profile as reference medicine, Humira®." *See* Exhibit 1.

78. In Europe, Sandoz received approval from the European Commission to market its biosimilar adalimumab for use all indications of Humira®. *See* Sandoz International GmbH, "Sandoz Receives European Commission Approval for Biosimilar Hyrimoz® (adalimumab)," July 27, 2018, https://www.sandoz.com/news/media-releases/sandoz-receives-european-commission-approval-biosimilar-hyrimozr-adalimumab, attached as Exhibit 7.

79. On information and belief, Sandoz's aBLA seeks approval for indications for which HUMIRA® is approved (the "Sandoz ABLA Product Indications"). *See* Sandoz International GmbH, Sandoz Biosimilar Pipeline, https://www.sandoz.com/our-work/biopharmaceuticals/sandoz-biosimilar-pipeline, attached as Exhibit 8.

80. On information and belief, Sandoz completed a clinical trial with the Sandoz aBLA Product, testing its use in subjects with chronic plaque-type psoriasis, and has completed a pharmacokinetic study. *See* Sandoz International GmbH, "Sandoz Regulatory Submission for Proposed Biosimilar Adalimumab Accepted by FDA," January 16, 2018, https://www.sandoz.com/news/media-releases/sandoz-regulatory-submission-proposed-biosimilar-adalimumab-accepted-fda, attached as Exhibit 9.

81. On information and belief, Sandoz relies upon data from this study to support its aBLA.

82. On January 16, 2018, Sandoz announced that it had submitted its aBLA to the

FDA and the FDA accepted the aBLA. *See* Exhibit 9.

83. On information and belief, the FDA has not yet decided whether to approve Sandoz's proposed biosimilar product or what indications to approve it for.

84. Sandoz 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 that could be identified by AbbVie pursuant to 42 U.S.C. § 262(*l*)(3)(A)(i).

ABBVIE'S ADALIMUMAB PATENTS

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

86. Sandoz itself has unsuccessfully challenged the validity of some of these patents, as the PTAB declined to institute *inter partes* review petitions brought by Sandoz directed to five patents identified on AbbVie's list of patents pursuant to 42 U.S.C. §262(*l*)(3)(A), including U.S. Patent Nos. 9,187,559; 9,512,216; 8,974,790; 8,911,737; and 8,802,100.

87. Because of Sandoz's actions, AbbVie is limited to asserting the following two patents in the present lawsuit: U.S. Patent No. 9,187,559 and U.S. Patent No. 9,750,808 (the "AbbVie Patents").

88. AbbVie asserts the following two patents in this suit.

U.S. Patent No. 9,187,559

89. U.S. Patent No. 9,187,559 (the "'559 patent"), titled "Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease," was duly and legally issued by the USPTO on November 17, 2015. A true and correct copy of the '559 patent is attached as Exhibit 10.

90. ABL is the owner by assignment of the ’559 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’559 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 ’559 patent.

U.S. Patent No. 9,750,808

91. U.S. Patent No. 9,750,808 (the “’808 patent”), titled “Formulation of Human Antibodies for Treating TNF-α Associated Disorders,” was duly and legally issued by the USPTO on September 5, 2017. A true and correct copy of the ’808 patent is attached as Exhibit 11.

92. ABL is the owner by assignment of the ’808 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’808 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 ’808 patent.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 9,187,559

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

94. On information and belief, prior to January 2018, Sandoz submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Sandoz aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

95. On information and belief, on or before January 16, 2018, the FDA accepted Sandoz’s aBLA.

96. On January 17, 2018, Sandoz provided AbbVie with a copy of its aBLA.

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

98. On information and belief, Sandoz is actively seeking FDA approval to sell the Sandoz aBLA Product for the Sandoz aBLA Product Indications, and for the dosages and methods of use approved for the HUMIRA® product sold by AbbVie.

99. Based on confidential information disclosed to AbbVie by Sandoz pursuant to 42 U.S.C. § 262(*l*)(2), Sandoz's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Sandoz aBLA Product prior to the expiration of the '559 patent is an act of infringement of one or more claims of the '559 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

100. Based on confidential information disclosed to AbbVie by Sandoz pursuant to 42 U.S.C. § 262(*l*)(2) relating to the indications, dosage, and methods of use for the Sandoz aBLA Product, and on information and belief, Sandoz's commercial manufacture, use, sale, offer for sale, and/or importation of the Sandoz aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once its aBLA is approved by the FDA, will actively induce infringement by others of claims 1-30 of the '559 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

101. On information and belief, Sandoz has an affirmative intent to actively induce infringement by others of one or more claims of the '559 patent, either literally or under the doctrine of equivalents. On information and belief, Sandoz 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 Sandoz aBLA Product.

102. On information and belief, Sandoz 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 Sandoz aBLA Product at least according to Sandoz's proposed package insert and, therefore, will directly infringe claims 1-30 of the '559 patent, either literally or under the doctrine of equivalents.

103. Sandoz has knowledge of and is aware of the '559 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.

104. On information and belief, Sandoz knowingly or with willful blindness has induced or will induce another's direct infringement of one or more of the claims of the '559 patent, either literally or under the doctrine of equivalents, by at least Sandoz's proposed package insert for the Sandoz aBLA Product.

105. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Sandoz is enjoined from infringing the claims of the '559 patent.

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

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 9,750,808

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

108. On information and belief, prior to January 2018, Sandoz submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the

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

109. On information and belief, on or before January 16, 2018, the FDA accepted Sandoz's aBLA.

110. On January 17, 2018, Sandoz provided AbbVie with a copy of its aBLA.

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

112. Based on confidential information disclosed to AbbVie by Sandoz pursuant to 42 U.S.C. § 262(*l*)(2), Sandoz's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Sandoz aBLA Product prior to the expiration of the '808 patent is an act of infringement of one or more claims of the '808 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

113. Based on confidential information disclosed to AbbVie by Sandoz pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Sandoz's commercial manufacture, use, sale, offer for sale, and/or importation of the Sandoz aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once its aBLA is approved by the FDA, will directly infringe at least claims 1-10, 14-17, and 24-27 of the '808 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

114. On information and belief, Sandoz GmbH has manufactured the Sandoz aBLA Product for use in clinical trials, the results of which were submitted as part of Sandoz's aBLA, and will manufacture the Sandoz aBLA Product once it is approved by the FDA. On information and belief, Sandoz Inc. and/or Sandoz International GmbH act in concert with and/or direct

Sandoz GmbH to make the Sandoz aBLA Product, and thereby actively induce infringement of at least claims 1-10, 14-17, and 24-27 of the '808 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

115. On information and belief, Sandoz Inc., by seeking licensure for a product manufactured by another for sale in the United States that infringes the '808 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the '808 patent, either literally or under the doctrine of equivalents.

116. On information and belief, Sandoz International GmbH, by acting in concert with, directing, and/or authorizing Sandoz Inc. to file the Sandoz aBLA, has an affirmative intent to actively induce infringement by others of one or more of the claims of the '808 patent, either literally or under the doctrine of equivalents.

117. On information and belief, Sandoz is aware, has knowledge, and/or is willfully blind to the fact that Sandoz GmbH's manufacture of the Sandoz aBLA Product directly infringes one or more of the claims of the '808 patent, either literally or under the doctrine of equivalents.

118. Sandoz has knowledge of and is aware of the '808 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.

119. On information and belief, Sandoz Inc. and Sandoz International GmbH knowingly or with willful blindness has induced or will induce another's direct infringement of one or more of the claims of the '808 patent, either literally or under the doctrine of equivalents, by at least the fact that Sandoz GmbH has manufactured and/or will manufacture the Sandoz aBLA Product for sale in the United States market.

120. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Sandoz is enjoined from infringing the claims of the '808 patent.

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

COUNT III
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,187,559

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

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

124. On information and belief, prior to January 2018, Sandoz submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Sandoz aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

125. On information and belief, on or before January 16, 2018, the FDA accepted Sandoz's aBLA.

126. On January 17, 2018, Sandoz provided AbbVie with a copy of its aBLA.

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

128. On information and belief, Sandoz's submission and FDA acceptance of Sandoz's aBLA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Sandoz aBLA Product, a biosimilar version of adalimumab, create an actual, immediate, and real

controversy within the Declaratory Judgment Act that Sandoz will directly and/or indirectly infringe one or more valid and enforceable claims of the '559 patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

129. On information and belief, Sandoz is actively seeking FDA approval to sell the Sandoz aBLA Product for the Sandoz aBLA Product Indications, and for the dosages and methods of use approved for the HUMIRA® product sold by AbbVie.

130. Based on confidential information disclosed to AbbVie by Sandoz pursuant to 42 U.S.C. § 262(*l*)(2), Sandoz's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Sandoz aBLA Product prior to the expiration of the '559 patent is an act of infringement of one or more claims of the '559 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

131. Based on confidential information disclosed to AbbVie by Sandoz pursuant to 42 U.S.C. § 262(*l*)(2) relating to the indications, dosage, and methods of use for the Sandoz aBLA Product, and on information and belief, Sandoz's commercial manufacture, use, sale, offer for sale, and/or importation of the Sandoz aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once its aBLA is approved by the FDA, will actively induce infringement by others of claims 1-30 of the '559 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

132. On information and belief, Sandoz has an affirmative intent to actively induce infringement by others of one or more claims of the '559 patent, either literally or under the doctrine of equivalents. On information and belief, Sandoz 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 Sandoz aBLA Product.

133. Sandoz has knowledge of and is aware of the '559 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.

134. On information and belief, Sandoz 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 Sandoz aBLA Product at least according to Sandoz's proposed package insert and, therefore, will directly infringe claims 1-30 of the '559 patent, either literally or under the doctrine of equivalents.

135. On information and belief, Sandoz knowingly or with willful blindness has induced or will induce another's direct infringement of one or more of the claims of the '559 patent, either literally or under the doctrine of equivalents, by at least Sandoz's proposed package insert for the Sandoz aBLA Product.

136. Plaintiffs seek a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Sandoz aBLA Product will infringe the '559 patent.

137. Unless Sandoz is enjoined from directly and indirectly infringing the '559 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,750,808

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

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

140. On information and belief, prior to January 2018, Sandoz submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Sandoz aBLA Product, a biosimilar version of adalimumab. Adalimumab is subject to BLA No. 125057 to AbbVie Inc.

141. On information and belief, on or before January 16, 2018, the FDA accepted Sandoz's aBLA.

142. On January 17, 2018, Sandoz provided AbbVie with a copy of its aBLA.

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

144. On information and belief, Sandoz's submission and FDA acceptance of Sandoz's aBLA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Sandoz aBLA Product, a biosimilar version of adalimumab, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Sandoz will directly and/or indirectly infringe one or more valid and enforceable claims of the '808 patent. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

145. Based on confidential information disclosed to AbbVie by Sandoz pursuant to 42 U.S.C. § 262(*l*)(2), Sandoz's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Sandoz aBLA Product prior to the expiration of the '808 patent is an act of infringement of one or more claims of the '808 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

146. Based on confidential information disclosed to AbbVie by Sandoz pursuant to 42 U.S.C. § 262(*l*)(2) and on information and belief, Sandoz's commercial manufacture, use, sale,

offer for sale, and/or importation of the Sandoz aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once its aBLA is approved by the FDA, will directly infringe at least claims 1-10, 14-17, and 24-27 of the ’808 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

147. On information and belief, Sandoz GmbH has manufactured the Sandoz aBLA Product for use in clinical trials, the results of which were submitted as part of Sandoz’s aBLA, and will manufacture the Sandoz aBLA Product. On information and belief, Sandoz Inc. and/or Sandoz International GmbH act in concert with and/or direct Sandoz GmbH to make the Sandoz aBLA Product, and thereby actively induce infringement of at least claims 1-10, 14-17, and 24-27 of the ’808 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

148. On information and belief, Sandoz Inc., by seeking licensure for a product manufactured by another for sale in the United States that infringes the ’808 patent, has an affirmative intent to actively induce infringement by others of one or more claims of the ’808 patent, either literally or under the doctrine of equivalents.

149. On information and belief, Sandoz International GmbH, by acting in concert with, directing, and/or authorizing Sandoz Inc. to file the Sandoz aBLA, has an affirmative intent to actively induce infringement by others of one or more of the claims of the ’808 patent, either literally or under the doctrine of equivalents.

150. Sandoz has knowledge of and is aware of the ’808 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.

151. On information and belief, Sandoz is aware, has knowledge, and/or is willfully blind to the fact that Sandoz GmbH's manufacture of the Sandoz aBLA Product directly infringes one or more claim of the '808 patent, either literally or under the doctrine of equivalents.

152. On information and belief, Sandoz Inc. and Sandoz International GmbH knowingly or with willful blindness has induced or will induce another's direct infringement of one or more of the claims of the '808 patent, either literally or under the doctrine of equivalents, by at least the fact that Sandoz GmbH has manufactured and/or will manufacture the Sandoz aBLA Product for sale in the United States market.

153. Plaintiffs seek a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Sandoz aBLA Product will infringe the '808 patent.

154. Unless Sandoz is enjoined from directly and indirectly infringing the '808 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 that Sandoz 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 that Sandoz 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 Sandoz 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 Sandoz, 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, distribution, or importation of any current or future versions of the Sandoz aBLA Product, or the use or manufacturing of which infringes the AbbVie Patents;

e. 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

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

Respectfully submitted,

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Dated: August 10, 2018

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, Plaintiffs hereby certify that the matter in controversy is related to the subject matter in the following actions and proceedings:

- *AbbVie Inc., et al. v. Boehringer Ingelheim International GmbH*, Civil Action No. 17-1065-MSG-RL (D. Del.)
- *Sandoz Inc. v. AbbVie Biotechnology Ltd*, IPR2017-01824 (P.T.A.B.), *appeal pending*, Case No. 2018-2142 (Fed. Cir.)
- *Sandoz Inc. v. AbbVie Biotechnology Ltd*, IPR2017-01987 (P.T.A.B.)
- *Sandoz Inc. v. AbbVie Biotechnology Ltd*, IPR2017-01988 (P.T.A.B.)
- *Sandoz Inc. v. AbbVie Biotechnology Ltd*, IPR2017-02105 (P.T.A.B.)
- *Sandoz Inc. v. AbbVie Biotechnology Ltd*, IPR2017-02106 (P.T.A.B.)
- *Sandoz Inc. v. AbbVie Biotechnology Ltd*, IPR2018-00002 (P.T.A.B.), *appeal pending*, Case No. 2018-2143 (Fed. Cir.)

Dated: August 10, 2018

Respectfully,

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CERTIFICATION PURSUANT TO L. CIV. R. 201.1

Pursuant to Local Civil Rule 201.1, Plaintiffs hereby certify that the matter in controversy is not subject to compulsory arbitration in that Plaintiffs seek, *inter alia*, injunctive relief.

Dated: August 10, 2018

Respectfully,

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