IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AbbVie Inc. and AbbVie Biotechnology Ltd, Plaintiffs/Counterclaim-Defendants, v. Boehringer Ingelheim International GmbH, Boehringer Ingelheim Fremont, Inc., and Boehringer Ingelheim Pharmaceuticals, Inc. Defendants/Counterclaim-Plaintiffs.	C.A. No. 17-1065-MSG-RL [redacted] [redacted] REDACTED VERSION

BOEHRINGER'S CORRECTED MOTION TO COMPEL PRODUCTION OF DOCUMENTS AND THINGS CONCERNING UNCLEAN HANDS

Boehringer Ingelheim Int'l GmbH et al. ("Boehringer") respectfully request that the Court compel AbbVie Inc. et al. ("AbbVie") to produce documents and things related to Boehringer's unclean hands defense (D.I. 20, Boehringer's Answer at 39, ¶ 23), as requested in Request Nos. 36-37 and 40-43 of Boehringer's Second Set of Requests for Production of Documents and Things (Exhibit "Ex." 1).[1] Our argument is simple: Boehringer pled the affirmative defense of unclean hands in its Answer almost eight months ago, the defense remains in the case today, and our discovery requests are tailored to that defense. This defense is not just important to this case, but is a matter of public interest. Under all applicable standards, there has been and continues to be no legitimate basis for AbbVie to avoid production. *See* Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any nonprivileged matter that is relevant to

[1] This motion has been corrected to remove a reference to a document that AbbVie produced in discovery and now claims is privileged. Boehringer disputes that the document is privileged and will address it in a separate motion to compel.

any party's claim or defense and proportional to the needs of the case."); *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Anti. Litig.*, No. 13-2445, 2016 WL 3519618, at *3 (E.D. Pa. June 28, 2016).

In the teleconference with Your Honor on May 7, 2018, AbbVie argued the affirmative defense was not sufficiently pled. (5/7/18 Hr'g Tr. at 52:2-54:2.) AbbVie is wrong. AbbVie has been on notice of the defense since September 11, 2017 and never moved to strike it. Nor could AbbVie now. AbbVie has waived its right, and Boehringer has pled the defense sufficiently. AbbVie's refusal to promptly produce documents relating to its unclean hands furthers its pattern of delay—the very strategy AbbVie's executives have touted to investors as its plan to stall biosimilar competition.

I. Background

A. Boehringer's Unclean Hands Defense

1. Legal Standard

Unclean hands is an equitable defense that grants the Court wide discretion to refuse to aid a litigant seeking affirmative relief. *E.g., Gilead Scis., Inc. v. Merck & Co.*, No. 2016-2302, 2018 WL 1936686, at *5 (Fed. Cir. Apr. 25, 2018). The doctrine applies where, as here, a party's misconduct involving "fraud, deceit, unconscionability, or bad faith"—directly related to the matter in issue—injures another party and affects the balance of equities between the litigants. *Sun Microsystems, Inc. v. Versata Enterprises, Inc.*, 630 F. Supp. 2d 395, 410 (D. Del. 2009). The "extent of actual harm caused by the conduct in question, either to the defendant or to the public interest, is [] highly relevant." *Merisant Co. v. McNeil Nutritionals, LLC*, 515 F. Supp. 2d 509, 531 (E.D. Pa. 2007). The lack of actual damages, however, does not preclude application of the doctrine. *The Medicines Co. v. Teva Parenteral Med. Inc.*, No. 09-750, 2011 WL 13135647, *23 (D. Del. Aug. 26, 2011), *report and recommendation adopted*, 2011 WL

13141923 (D. Del. Oct. 6, 2011).

2. Boehringer's Original Pleading

Boehringer's September 11, 2017 Answer and Counterclaims set forth the basis for its unclean hands defense. Boehringer alleged AbbVie's patents were unenforceable due to its "global effort to improperly delay competition with respect to adalimumab" (D.I. 20 at 47, ¶ 34.), that AbbVie had "engaged in a pattern of pursuing numerous overlapping and non-inventive patents for the purpose of developing a 'patent thicket,'" and had "us[ed] the patenting process itself," rather than meritorious patents, "as a means to seek to delay competition," (*id.* at 44-47, ¶¶ 21-34). AbbVie has powerful financial incentives to delay competition for Humira®. (*Id.* at 43, ¶ 16.) AbbVie sells roughly $50 million worth of Humira® each day, including $32 million in the United States (over $12 billion a year).[2] Each day that AbbVie delays competition adds extraordinarily value to the company and harms the public by blocking lower cost alternatives.

AbbVie's public statements highlight its improper motive. (*Id.* at 44-45, ¶ 24.) As AbbVie's CEO explained: "Any company seeking to market a biosimilar version of Humira will have to contend with this extensive patent estate." (*Id.* at 44-45, ¶ 24.) AbbVie's abuse of the patent system delayed (and continues to delay) Boehringer's efforts to market an adalimumab biosimilar (*id.* at 47, ¶ 34), harming Boehringer and the public at large (*id.* at 43, ¶ 16). The United Kingdom's High Court has found that the "object and cumulative consequence of" AbbVie's patent thicket "is intended to delay the entry of competing biosimilars." (*Id.* at 46-47, ¶ 33 (quoting the United Kingdom High Court in *Fujifilm Kyowa Kirin Biologics Co. v. AbbVie Biotech. Ltd*).) The balance of equities support Boehringer's affirmative defense.

Boehringer seeks by these pleadings discovery supporting its unclean hands defense,

[2] AbbVie Inc.'s Full-Year and Fourth Quarter 2017 Financial Results (http://investors.abbvie.com/news-releases/news-release-details/abbvie-reports-full-year-and-fourth-quarter-2017-financial) (accessed on May 9, 2018).

including documents concerning AbbVie's Humira® patent estate, intellectual property strategy, and presentations regarding the same. (Ex. 1 at 8-10.)

3. Boehringer's Interrogatory Response

Boehringer elaborated the defense of unclean hands in its May 3, 2018 responses to AbbVie's contention interrogatory. By way of example, Boehringer cited evidence that [redacted] (Ex. 2, Boehringer's First Supplemental Objections and Responses to AbbVie's Interrogatories (Nos. 19-20) at 7-8.) AbbVie's shotgun approach (*e.g.*, filing hundreds of patent applications nearly a decade after Humira®'s first sale) to create a morass of patents to use in litigation to delay competition (*id.* at 8-10, 13-16), to claim as inventions mere observations (*id.* at 10), and to engage in bad faith patent prosecution (*id.* at 10-13) exemplifies misconduct worthy of the Court's equitable intervention. This misconduct delays the efforts of parties, like Boehringer, to market biosimilar drug products and harms American patients, doctors, and third-party payers. (*Id.* at 10.)

B. Boehringer's Requested Discovery

Boehringer's requested discovery is directly relevant and tailored to its unclean hands defense. For example:

- Request Nos. 36,[3] 37, and 40 seek documents and things concerning "marketing," "financial analyses . . . and projections" and "the economic or market impact . . . to AbbVie or any Third Party resulting from AbbVie's enforcement of the patents-in-suit." These cover at least the following relevant evidence:
    - AbbVie's incentive to construct a thicket of patents to protect its "prized moneymaker" (Ex. 2 at 8); and
    - Injury to Boehringer and the public that result from AbbVie's abuses of the patent

[3] Request Nos. 36-37 are also relevant to secondary considerations of obviousness.

system (D.I. 20 at 43, ¶ 16 and 47, ¶ 34).

- Request No. 41 seeks documents and things concerning AbbVie's adalimumab "patent estate," which would cover at least the following relevant evidence:
  - [redacted] (Ex. 2 at 7);
  - [redacted] (*id.*); and
  - AbbVie's strategy for filing of at least 140 patent applications purportedly related to Humira® since 2013 (*id.* at 8).
- Request Nos. 42-43 seek documents and things concerning, *inter alia*, presentations given at any conference relating to AbbVie's intellectual property strategy for Humira®, which would cover at least the following relevant evidence:
  - AbbVie's Chief Financial Officer statements regarding the "thicket of patents" (Ex. 2 at 9);
  - AbbVie's Long-Term Strategy Presentation concerning its "Broad U.S. Humira® Patent Estate" (*id.* at 8); and
  - AbbVie's statement that its patent portfolio will "cover not only our commercial formulation but also other related formulations that biosimilar companies might employ" (*id.* at 9).

II. AbbVie Should Be Ordered to Produce the Requested Documents

A. Unclean Hands Is an Active Defense and the Requests Are Proportional to the Needs of the Case

Boehringer has pleaded the affirmative defense of unclean hands and it has been a defense in this case for the last eight months. Each of Boehringer's requests are directed to evidence of AbbVie misconduct that would support the defense. The evidence is highly relevant to the litigation; indeed, it may determine the matter. *See Gilead Scis.*, No. 2016-2302, 2018 WL 1936686, at *1 (barring patent owner from asserting its patents in light of unclean hands).

The party challenging discovery must demonstrate undue burden. *See, e.g., Inventio AG*

v. ThyssenKrupp Elevator Ams. Corp., No. 08-874, 2009 WL 2408422, at *2 (D. Del. Aug. 3, 2009). AbbVie cannot meet this test. Boehringer's request is proportional to the needs of the case. As this Court has already found, "there is a substantial amount in controversy in this litigation," "the issues at stake in this case are important, both to the parties and to the public," and "the parties have substantial economic and other resources." (D.I. 58, Order Concerning Discovery at 1.) AbbVie cannot credibly contest this. Its Chief Financial Officer appears to agree, stating that, "with a product as important and as attractive as [Humira®], you do everything you can on the IP front." (Ex. 2 at 9.)

B. AbbVie's Claim That Unclean Hands Is Not Properly Pled Is Incorrect and Must Fail

Boehringer pleaded unclean hands in its Answer almost eight months ago. In that Answer, Boehringer recited the overarching bases for its defense, including harm and equity. (*See* Section I.A.2 above.) AbbVie was on notice of the defense. (Ex. 3, 2/23/18 letter from Park to Stern at 7 (explaining that Request Nos. 40-43 [redacted]; Ex. 4, 4/13/18 letter from Park to Stern at 4 [redacted].) AbbVie now challenges the sufficiency of the pleading as a last-ditch effort to delay discovery further, almost eight months after Boehringer filed its Answer. AbbVie's objection is untimely. *See, e.g.*, *Cintron Beverage Grp., LLC v. Depersia*, No. 07-3043, 2008 WL 1776430, at *2 (E.D. Pa. Apr. 15, 2008) (finding motion to strike affirmative defenses filed over two months after the pleading as untimely); Fed. R. Civ. P. 12(f) ("motion [to strike is timely if made] within 21 days after being served with the pleading"). In any event, Boehringer is entitled to prove the merits of its defenses at trial—rather than

discovery. Memorandum Order at 5, *Sandvik Intellectual Property AB v. Kennametal Inc.*, No. 10-654, D.I. 283 (W.D. Pa. Sept. 25, 2012) (granting motion to compel discovery on unclean hands and inequitable conduct because the "the merits of those claims" need not be decided in discovery).

AbbVie's argument at the teleconference that it did not understand the true nature of the defense until it received Boehringer's interrogatory response lacks credibility. (5/7/18 Hr'g Tr. at 53:14-17.) While the interrogatory response provides details, as contention discovery should, the overarching claim is the same—AbbVie engaged in a "global effort to improperly delay competition with respect to adalimumab," a scheme which involved numerous components including "using the patenting process itself," rather than meritorious patents, "as a means to seek to delay competition." (D.I. 20 at 44-47, ¶¶ 21-34; Ex. 3 at 7; Ex. 4 at 4.)

AbbVie misconstrues Boehringer's unclean hands defense as inequitable conduct, a legally distinct defense directed to an "intent to deceive the [Patent and Trademark Office]," which thus includes deceptive conduct as an essential element. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011).[4] Fraud, however, "is not a requirement in an unclean hands defense." *See Knit With v. Knitting Fever, Inc.*, Nos. 08-4221, 4775, 2009 WL 973492, at *11 n.12 (E.D. Pa. Apr. 8, 2009) (declining to apply Rule 9(b) unless the "affirmative defense involves fraud"). And where, as here, the unclean hands defense does not "necessarily allege fraud" (*see* D.I. 20 at 44-47, ¶¶ 21-34; Ex. 2 at 6-10, 13-16), Rule 9(b)'s particularity requirement is not applicable, *see Petedge, Inc. v. Fortress Secure Sols.*, LLC, No. 15-11988, 2016 WL 407065, at *4 n.1 (D. Mass. Feb. 2, 2016) (applying rule 9(b) to inequitable conduct, but not unclean hands, because the defense, as pleaded, does not explicitly allege

[4] The deadline to amend pleadings has not passed, and continuing discovery may support additional defenses.

fraud); *see also Lexington Luminance LLC v. TCL Multimedia Tech. Holdings, Ltd.*, No. 16-11458, 2017 WL 3795769, at *8 (D. Mass. Aug. 30, 2017) (declining to apply Rule 9(b) to equitable affirmative defenses to patent infringement claims). In any event, AbbVie did not move to strike under Rule 9(b) and is on notice of significant particularity in the pleading and contention interrogatory response.

For the foregoing reasons, Boehringer respectfully requests that the Court grant this motion.

Dated: May 10, 2018

Respectfully submitted,

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EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD, Plaintiffs/Counterclaim-Defendants, -against- BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and BOEHRINGER INGELHEIM FREMONT, INC., Defendants/Counterclaim-Plaintiffs.	C.A. No. 17-1065 (MSG)

BOEHRINGER'S SECOND SET OF REQUESTS
FOR PRODUCTION OF DOCUMENTS AND THINGS

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, Boehringer Ingelheim International GmbH, Boehringer Ingelheim Pharmaceuticals, Inc., and Boehringer Ingelheim Fremont, Inc. hereby request that AbbVie Inc. and AbbVie Biotechnology Ltd produce documents and things in response to the following requests in accordance with the following Definitions and Instructions.

DEFINITIONS AND INSTRUCTIONS

1. Boehringer hereby incorporates by reference the Definitions and Instructions set forth in Boehringer's First Set of Requests for the Production of Documents and Things, dated November 22, 2017.

2. The term "adalimumab BLA" includes any and all Biologics License Applications concerning adalimumab submitted by or on behalf of AbbVie, including, but not limited to, BLA No. 125057, and any amendments or supplements thereto.

3. The term "adalimumab IND" includes any and all Investigational New Drug Applications concerning adalimumab submitted by or on behalf of AbbVie, and any amendments or supplements thereof.

4. The term "FDA" means the United States Food and Drug Administration.

5. The term "the '975 patent" means U.S. Patent No. 8,926,975, titled "Method of treating ankylosing spondylitis."

6. The term "the '361 patent" means U.S. Patent No. 9,018,361, titled "Isolation and purification of antibodies using protein A affinity chromatography."

7. The term "the '867 patent" means U.S. Patent No. 9,090,867, titled "Fed-batch method of making anti-TNF-alpha antibody."

8. The term "the '666 patent" means U.S. Patent No. 9,096,666, titled "Purified antibody composition."

9. The term "the '143 patent" means U.S. Patent No. 9,255,143, titled "Methods for controlling the galactosylation profile of recombinantly-expressed proteins."

10. The term "the '949 patent" means U.S. Patent No. 9,266,949, titled "Low acidic species compositions and methods for producing and using the same."

11. The term "the '041 patent" shall mean U.S. Patent No. 9,272,041, titled "Formulation of human antibodies for treating TNF-alpha associated disorders."

12. The term "the '212 patent" means U.S. Patent No. 9,546,212, titled "Methods of administering anti-TNFα antibodies."

13. The term "priority application" means any patent application to which any of the patents-in-suit claim priority, either in whole or in part, through a continuation, continuation-in-part, divisional, or provisional application.

14. The term "related application" means any patent application that claims priority, either in whole or in part, to a priority application through a continuation, continuation-in-part, divisional, or provisional application.

15. The term "related U.S. patent" means any patent issuing from a related application.

16. The term "related foreign patent" means any patent issuing outside of the U.S. from a patent application that claims priority to a priority application.

REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS

Request No. 10

The prosecution history for each of the patents-in-suit, including the prosecution history for the priority applications.

Request No. 11

The prosecution history for each related U.S. patent and any related application.

Request No. 12

The prosecution history for each related foreign patent.

Request No. 13

Documents and things concerning any data, including any figures, tables, or examples, included or referenced in any of the patents-in-suit, including, but not limited to, documents and things concerning the design, planning, execution, results, and analysis of, or support for, any of the foregoing.

Request No. 14

Executed, filed, or recorded documents and things concerning any rights to any of the patents-in-suit or any priority application, including, but not limited to, any license, assignment, or transfer of interest of any of the foregoing.

Request No. 15

Documents and things concerning the decision to file the patent applications resulting in the patents-in-suit, including the priority applications.

Request No. 16

Documents and things concerning any opposition to any related foreign patent.

Request No. 17

Documents and things concerning the preparation or submission of any declaration submitted during the prosecution of the patents-in-suit (including the prosecution of the priority applications) and any related applications and foreign patents, including, but not limited to, declarations filed by: (a) Diane Dong; (b) John Ponzo; (c) Stephen Cramer; (d) Janet E. Pope; (e) Michael Weinblatt; (f) Diane Mould; (g) Hartmut Kupper; (h) Medgar Williams; and (i) Donald L. Jarvis; (j) Cornelia T. Bengea; and (k) Lisa M. Rives.

Request No. 18

Documents and things concerning the preparation or submission of any declaration submitted during the prosecution of the following patents: (1) U.S. Patent Nos. 9,334,319 and 9,346,879 (by Christopher Chumsae and Zehra Kaymakcalan); (2) U.S. Patent No. 9,193,787 (by Li-Hong Malmberg and Frank W.R. Chaplen); and (3) U.S. Patent 9,150,645 (by John Ponzo).

Request No. 19

Any adalimumab BLA and any submission or communication between AbbVie and the FDA concerning the foregoing.

Request No. 20

Any adalimumab IND and any submission or communication between AbbVie and the FDA concerning the foregoing.

Request No. 21

Documents and things from February 9, 1996, to February 9, 2016, sufficient to show the corporate and organizational structure of AbbVie and any other entity involved in the research, development, importation, manufacture, testing, distribution, sale, offer for sale, use, marketing, or promotion of adalimumab or a formulation containing adalimumab, or involved in the prosecution of any of the patents-in-suit and/or any related patents, including their relationship to one another as well as to their respective parents, subsidiaries, and affiliates.

Request No. 22

Batch records for each batch of adalimumab or a formulation containing adalimumab sold or offered for sale between February 9, 1996, and December 18, 2014.

Request No. 23

Documents and things sufficient to identify the following information for each batch of adalimumab or a formulation containing adalimumab sold or offered for sale between February 9, 1996, and December 18, 2014: (1) the lot number; (2) the manufacturing entity; (3) the site(s) of manufacture; and (4) the manufacturing processes used to prepare each batch.

Request No. 24

Documents and things sufficient to identify the following information for each batch of adalimumab or a formulation containing adalimumab sold or offered for sale between February 9, 1996, and December 18, 2014: (1) when each batch was first sold or offered for sale; (2) the entities involved in each such sale or offer for sale; (3) the terms of each sale or offer for sale; and (4) the physical transfer of each batch that was sold or offered for sale from one entity to the other.

Request No. 25

Documents and things concerning the testing or analysis of each batch of adalimumab or a formulation containing adalimumab sold, or offered for sale, between February 9, 1996, and December 18, 2014.

Request No. 26

Batch records for each batch of adalimumab or a formulation containing adalimumab used in clinical trials between February 9, 1996, and December 18, 2014.

Request No. 27

Documents and things sufficient to identify the following information for each batch of adalimumab or a formulation containing adalimumab used in clinical trials between February 9, 1996, and December 18, 2014: (1) the lot number; (2) the manufacturing entity; (3) the site(s) of manufacture; and (4) the manufacturing processes used to prepare each batch.

Request No. 28

Documents and things sufficient to identify the following information for each batch of adalimumab or a formulation containing adalimumab used in clinical trials between February 9, 1996, and December 18, 2014: (1) where and when each batch was used; and (2) the entities involved in such use.

Request No. 29

Documents and things concerning the testing or analysis of each batch of adalimumab or a formulation containing adalimumab used in clinical trials between February 9, 1996, and December 18, 2014.

Request No. 30

Documents and things from February 9, 1996, to December 18, 2014, concerning any supply, distribution, or manufacturing agreements concerning adalimumab or a formulation containing adalimumab, including, but not limited to, proposed and executed agreements.

Request No. 31

Documents and things concerning communications between AbbVie and any Third Party concerning the subject matter of any of the alleged inventions of the patents-in-suit, including, but not limited to: (a) reports or presentations; (b) data; (c) transfer of technology/know how; or (d) agreements between AbbVie and the Third Party.

Request No. 32

Documents and things concerning the research and development of the alleged invention(s) of the patents-in-suit, including, but not limited to, documents concerning the conception and reduction to practice of any of the alleged inventions of the patents-in-suit.

Request No. 33

Publications, manuscripts submitted for publication, press releases, and presentations by AbbVie or any named inventor of the patents-in-suit concerning the subject matter of any of the alleged inventions of the patents-in-suit.

Request No. 34

Documents and things concerning any literature search concerning the subject matter of any of the alleged inventions of the patents-in-suit.

Request No. 35

Document and things concerning public disclosures, including, but not limited to patents, patent applications, publications, and presentations concerning the subject matter of any of the alleged inventions of the patents-in-suit, including, but not limited to, the documents and things identified in Boehringer's statements pursuant to 42 U.S.C. § 262(*l*)(3)(B) with respect to the patents-in-suit, and any data referenced therein and communications between and among AbbVie and the authors or named inventors of any of the foregoing.

Request No. 36

Documents and things concerning the marketing and promotion by AbbVie of any formulation containing adalimumab, including Humira®, including, but not limited to, U.S. marketing or promotional materials and brand plans.

Request No. 37

Documents and things concerning financial analyses, sales, revenues, costs, profits, and projections concerning any AbbVie adalimumab or any formulation containing adalimumab, including Humira®.

Request No. 38

Documents and things regarding comparisons between AbbVie's adalimumab or any formulation containing adalimumab, including Humira®, on the one hand, and any FDA-approved products, on the other hand, including comparisons of safety, efficacy, mechanisms of action, marketing activities, sales, and price.

Request No. 39

Documents and things concerning the identity of products that compete with AbbVie's adalimumab or any formulation containing adalimumab, including Humira®, in the United States, including any documents and things generated by or on behalf of AbbVie concerning similarities or differences between the products and marketing strategies with respect to competitive products.

Request No. 40

Documents and things concerning the economic or market impact (whether actual, anticipated, direct, or indirect) to AbbVie or any Third Party resulting from AbbVie's enforcement of the patents-in-suit or any related U.S. patent.

Request No. 41

Documents and things concerning AbbVie's adalimumab "patent estate" (*see, e.g.,* Andrew Pollack, *Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions*, N.Y. TIMES, (July 16, 2016), https://www.nytimes.com/2016/07/16/business/makers-of-humira-and-enbrel-using-new-drug-patents-to-delay-generic-versions.html).

Request No. 42

Documents and things concerning the October 30, 2015 presentation by AbbVie's Chairman and Chief Executive Officer titled "AbbVie Long Term Strategy," including, but not limited to, any documents referenced or used to prepare the foregoing or any drafts thereof.

Request No. 43

Documents and things concerning any presentation given at any conference or materials provided to AbbVie shareholders relating to AbbVie's intellectual property strategy for Humira®.

Request No. 44

Documents and things concerning the use of a TNFα inhibitor, including, but not limited to, adalimumab, infliximab, and etanercept, on the one hand, and any American College of Rheumatology ("ACR") response (including ACR20, ACR50, and ACR70), or any component thereof, on the other.

Request No. 45

Documents and things concerning a TNFα inhibitor, including, but not limited to, adalimumab, infliximab, and etanercept, on the one hand, and ankylosing spondylitis, including, but not limited to, the use of a TNFα inhibitor to treat ankylosing spondylitis (including total spinal ankylosis) or in an ankylosing spondylitis patient (including patients with total spinal ankylosis), on the other.

Request No. 46

Documents and things concerning clinical studies where adalimumab or a formulation containing adalimumab was administered to patients having rheumatoid arthritis, including, but not limited to, any documents and things concerning the design, planning, execution, results, protocols, informed consents, and analysis of any clinical studies, and any presentation, publication, public communication, or non-public communication with Third Parties concerning any of the foregoing.

Request No. 47

Documents and things concerning clinical studies where adalimumab or a formulation containing adalimumab was administered to patients having ankylosing spondylitis (including patients with total spinal ankylosis), including, but not limited to, any documents and things concerning the design, planning, execution, results, protocols, informed consents, and analysis of any clinical studies, and any presentation, publication, public communication, or non-public communication with Third Parties concerning any of the foregoing.

Request No. 48

Documents and things concerning AbbVie's recruitment of patients, investigators, or clinical sites for any clinical studies involving adalimumab or a formulation containing adalimumab and patients having rheumatoid arthritis.

Request No. 49

Documents and things concerning AbbVie's recruitment of patients, investigators, or clinical sites for any clinical studies involving adalimumab or a formulation containing adalimumab and patients having ankylosing spondylitis (including patients with total spinal ankylosis).

Request No. 50

Documents and things concerning the dosing of adalimumab or a formulation containing adalimumab in patients having rheumatoid arthritis.

Request No. 51

Documents and things concerning the dosing of adalimumab or a formulation containing adalimumab in patients having ankylosing spondylitis (including patients with total spinal ankylosis).

Request No. 52

Documents and things concerning the immunogenicity of adalimumab and the impact of such immunogenicity, including, but not limited to, documents and things concerning the purification of host cell proteins, contaminants, dosing selection, efficacy, and safety.

Request No. 53

Documents and things concerning the design, research, development, testing, evaluation, and use of purification processes for adalimumab, including, but not limited to, documents and things concerning filtration steps, monomer levels, the harvesting of cell cultures, performing protein chromatography (including protein A chromatography), and performing low pH viral inactivation.

Request No. 54

Documents and things concerning the use of viral inactivation during any downstream process for the purification of adalimumab.

Request No. 55

Documents and things concerning the selection of the cell expression system used to express any adalimumab, including, but not limited to, the cell line and clone used to express such adalimumab, and any testing concerning the effect of any change in the cell expression system on the expression of adalimumab.

Request No. 56

Documents and things concerning processes for culturing CHO cells used for making adalimumab, including, but not limited to: (1) the glucose levels in the CHO cell culture media, including, but not limited to, documents describing the concentration of glucose in the cell culture media, any monitoring of glucose levels and addition of glucose when the glucose concentration decreases below a pre-defined level, and documents reflecting real-time monitoring of glucose levels in the cell culture media; (2) the pH and temperature of the cell culture media, including, but not limited to, documents describing the pH and temperature in the cell culture media, any methods used to adjust or control the pH and temperature in the cell culture media, and documents reflecting the monitoring or measurement of pH and temperature in the cell culture media; (3) components of any cell culture media and concentrations of those components, including, but not limited to, amino acid concentrations; and (4) titer or antibody titer targets made by said methods.

Request No. 57

Documents and things concerning the measurement of glucose in any cell culture media used in connection with the making of each batch of adalimumab.

Request No. 58

Documents and things concerning the measurement of pH in any cell culture media used in connection with the making of each batch of adalimumab.

Request No. 59

Documents and things concerning the measurement of temperature in any cell culture media used in connection with the making of each batch of adalimumab.

Request No. 60

Documents and things concerning any steps taken by AbbVie or any Third Party to increase the antibody titer of adalimumab.

Request No. 61

Documents and things concerning any affinity chromatography method used in connection with the making of adalimumab, including, but not limited to, documents and things describing the purpose of using affinity chromatography methods.

Request No. 62

Documents and things concerning the development of methods for measuring cathepsin L or procathepsin L, or any activity associated with the foregoing, in a batch of adalimumab or a formulation containing adalimumab, including, but not limited to, kinetic assays, endpoint assays, or assays measuring cathepsin L activity that utilize substrates incorporating leucine-arginine and/or phenylalanine-arginine dipeptides.

Request No. 63

Documents and things concerning the identification, measurement, and attempted measurement of host cell protein(s), protease(s), procathepsin L or cathepsin L, or any activity associated with the foregoing, including, but not limited to, kinetic activity associated therewith, in each batch of adalimumab or a formulation containing adalimumab.

Request No. 64

Documents and things concerning the specification for adalimumab or a formulation containing adalimumab with respect to the concentrations of procathepsin L, cathepsin L, or activity levels of cathepsin L or other cathepsins in any kinetic assay.

Request No. 65

Documents and things concerning the removal or inactivation of cathepsin L, procathepsin L, other cathepsins, proteases, or host cell proteins in a batch of adalimumab or a formulation containing adalimumab.

Request No. 66

Documents and things concerning the catalysis of procathepsin L to cathepsin L in a batch of adalimumab or a formulation containing adalimumab.

Request No. 67

Documents and things concerning the instruments used to measure the conversion of procathepsin L to cathepsin L, or activity levels of cathepsin L or other cathepsins in any kinetic assay, in a batch of adalimumab or a formulation containing adalimumab, including, but not limited to, any calibration information to account for fluorescence from other proteases or proteins or any background fluorescence.

Request No. 68

Documents and things concerning the specificity of any kinetic assay for cathepsin L and/or other cathepsins in a batch of adalimumab or a formulation containing adalimumab.

Request No. 69

Documents and things concerning the stability of cathepsin L in a batch of adalimumab or a formulation containing adalimumab.

Request No. 70

Documents and things concerning the activity of procathepsins or cathepsins during any purification or low pH viral inactivation step, including, but not limited to, any impact or effect of procathepsins or cathepsins on adalimumab structure or activity.

Request No. 71

Documents and things concerning the impact of any process choices on the N-linked oligosaccharides present on adalimumab, including, but not limited to, cell line used and composition of the cell culture media.

Request No. 72

Documents and things concerning the identification, measurement, and attempted measurement of N-linked oligosaccharides present on adalimumab that are of: (1) a galactose-containing fucosylated biantennary oligosaccharide form; or (ii) an agalactosyl fucosylated biantennary oligosaccharide form.

Request No. 73

Documents and things concerning the composition and development of the cell culture media used in each step of making adalimumab, including, but not limited to, documents describing the components and concentrations of each media, the absolute and relative amounts of each media, and the concentrations of amino acids.

Request No. 74

Documents and things concerning the identification, characterization, measurement, and attempted measurement of all charge variants of adalimumab in each batch of adalimumab or a formulation containing adalimumab, including, but not limited to, documents describing the acidic species content of each batch of adalimumab or a formulation containing adalimumab, and any cation exchange or weak cation exchange chromatography data or analysis of such batches using cation exchange or weak cation exchange chromatography.

Request No. 75

Documents and things concerning any efforts to alter or control the charge variant composition of adalimumab obtained from CHO cells, including, but not limited to, documents describing any efforts to control or reduce the levels of acidic species and the reasons for doing so, and any protocols, tests, results, and/or analysis concerning the foregoing.

Request No. 76

Documents and things concerning any specification for adalimumab or a formulation containing adalimumab relating to the charge variant profile, including, but not limited to, any acceptance criteria for the acidic peak group(s), main peak, and basic peak group(s) as measured by cation exchange or weak cation exchange chromatography, documents describing the reasons

for the selection of such acceptance criteria, and any communications with regulatory authorities regarding such acceptance criteria.

Request No. 77

Documents and things concerning the research and development of the formulation containing adalimumab described in Abbott Laboratories' December 2002 Humira® label.

Request No. 78

Documents and things concerning the stability or projected stability of adalimumab or a formulation containing adalimumab, whether or not the antibody or formulation was ultimately made or commercialized, including any protocols, testing, results, or analysis performed by AbbVie or a Third Party during the development of any formulation containing adalimumab, the reasons for such testing or analysis, and any experimental data.

Request No. 79

Documents and things concerning the design, research, development, testing, or analysis of any formulation containing adalimumab, whether or not the formulation was ultimately made or commercialized, including documents and things concerning the selection, function, and concentration of each component thereof, and documents concerning the selection of pH.

Request No. 80

Documents and things concerning any alleged secondary consideration of nonobviousness with respect to the claims of the patents-in-suit, including, but not limited to, any alleged commercial success, long-felt need, acquiescence, expressions of skepticism, copying, teaching away, successful or failed attempts by others, or simultaneous development.

Request No. 81

Documents and things that AbbVie intends to rely upon, or that concern the information AbbVie intends to rely upon, with respect to AbbVie's assertion that the claims of the patents-in-suit are valid, enforceable, and infringed by Boehringer.

Request No. 82

Documents and things produced to AbbVie by any Third Party in response to a subpoena, or other formal or informal request for documents, in connection with the Amgen Action.

Request No. 83

Documents and things concerning any patent or intellectual property policy in place at AbbVie at any time between February 9, 1995, and the present, including, but not limited to, documents concerning AbbVie's strategy, or approach to filing patent applications or maintaining patents or patent applications.

Request No. 84

Documents and things referred to, relied upon, or identified in response to any interrogatory served by Boehringer in this case.

Request No. 85

Documents and things that were consulted in connection with, or in any way form a basis for, AbbVie's response to any interrogatory served by Boehringer in this case.

Request No. 86

A current curriculum vitae for each named inventor of each patent-in-suit.

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Dated: December 27, 2017

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CERTIFICATE OF SERVICE

I, Selena E. Molina, hereby certify that a copy of the foregoing was served this 27th day of December 2017, as follows:

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EXHIBIT 2

REDACTED IN ITS ENTIRETY

EXHIBIT 3

REDACTED IN ITS ENTIRETY

EXHIBIT 4

REDACTED IN ITS ENTIRETY