IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN BIOTECH, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
AMGEN INC.,	)	
	)	
Defendant.	)	
	)	

COMPLAINT

INTRODUCTION

1. Janssen's scientists and clinicians spent decades developing STELARA® (ustekinumab), a complex biological product and a first-in-kind anti-IL-12/IL-23 fully human antibody medicine. Janssen invested many millions of dollars and countless research hours, and sponsored over 100 clinical trials to expand STELARA®'s use into a variety of diseases and patient populations. Hundreds of thousands of patients have benefited from Janssen's innovative work to date. Currently, STELARA® is prescribed in the United States to treat plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis ("UC").

2. Amgen Inc. ("Amgen" or "Defendant") is preparing to commercialize ABP 654, a "biosimilar" copy of STELARA®—that is, a copy designed to have the same amino acid sequence as the active ingredient (ustekinumab) and highly similar physical and biological properties, so it can be sold as a substitute for STELARA®.

3. The Biosimilar Price Competition and Innovation Act of 2009 ("BPCIA") established an abbreviated regulatory pathway for biosimilar applicants to seek FDA approval. 42 U.S.C. § 262 *et seq*. Importantly however, the BPCIA does *not* give biosimilar applicants like

Amgen license to infringe Janssen's patents; rather, it sets forth an intricate process, colloquially called the "patent dance," by which the parties can identify relevant patents and, if need be, litigate their infringement and validity in Court *before* the biosimilar launches.

4. On November 7, 2022, Amgen informed Janssen of its intention, pursuant to 42 U.S.C. § 262(l)(8)(A), to begin marketing its biosimilar version of STELARA® in 180 days (i.e., on May 6, 2023) or immediately upon receiving FDA approval thereafter. Ex. A. Amgen further stated that it intends to market ABP 654 for all indications for which STELARA® is approved. *Id.*

5. If Amgen carries through with its stated plan, it will infringe at least two Janssen patents that cover STELARA®. Specifically, Amgen's launch of ABP 654 will infringe at least U.S. Patent No. 6,902,734 ("the '734 patent") covering ustekinumab (the active compound in STELARA®), and U.S. Patent No. 10,961,307 ("the '307 patent") covering methods of treating ulcerative colitis with this medicine.

6. Janssen files this action seeking a declaratory judgment of infringement, and to preliminarily and permanently enjoin Amgen from infringing at least the '734 and '307 patents.

NATURE OF THE ACTION

7. Janssen Biotech, Inc. ("Janssen" or "Plaintiff"), for its Complaint against Amgen, further alleges as follows:

8. This civil action arises under the Patent Laws of the United States, 35 U.S.C. §§ 1, *et seq.*, including 35 U.S.C. § 271(a)-(c) & (e), the BPCIA, including 42 U.S.C. § 262(*l*), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

9. This lawsuit results from Amgen's planned and/or ongoing manufacture, use, offer to sell, sale, and import/export of its biosimilar to STELARA® (ustekinumab), called ABP 654—

which will infringe Janssen's patents concerning its innovative biologic drug, STELARA®, including at least the '734 and '307 patents.

PARTIES

10. Janssen is a Pennsylvania corporation with its principal place of business at 800 Ridgeview Road, Horsham, Pennsylvania, 19044.

11. Upon information and belief, Amgen is a Delaware corporation with a principal place of business at One Amgen Center Drive, Thousand Oaks, California, 91320.

12. Upon information and belief, Amgen is a biopharmaceutical company in the business of developing, manufacturing, marketing, and selling both biologic and biosimilar drugs, including the proposed biosimilar version of Janssen's STELARA® (ustekinumab) product, ABP 654.

JURISDICTION AND VENUE

13. This is an action for patent infringement under the Patent Laws of the United States, 35 U.S.C. §§ 1, *et seq.*, including 35 U.S.C. § 271(a)-(c) & (e), the BPCIA, including 42 U.S.C. § 262(*l*), 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.

14. The Court has personal jurisdiction over Amgen because Amgen is a corporation organized and existing under the laws of Delaware, and has availed itself of the rights and benefits of Delaware law, including by engaging in patent litigation in this District. *See, e.g.*, *Amgen Inc. v. USV Private Ltd.*, No. 22-387-MN (D. Del.); *Amgen Inc. v. Aurobindo Pharm. Ltd.*, No. 22-227-MN (D. Del.); *Amgen Inc. v. MSN Lab'ys Private Ltd.*, 21-662-MN (D. Del.); *Amgen Inc. v. Alembic Pharm. Ltd.*, No. 21-61-CFC (D. Del.); *Amgen Inc. v. Hospira*, Inc., No. 20-561-CFC (D. Del.). Furthermore, on information and belief, Amgen has regularly and systematically transacted

business in Delaware, has engaged in substantial and continuing contacts with Delaware, and through its intended launch will commit acts of patent infringement in Delaware.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)-(c) and 28 U.S.C. § 1400 because Amgen, a Delaware corporation subject to personal jurisdiction in the judicial district of Delaware, resides in the District. Furthermore, on information and belief, Amgen has regularly and systematically transacted business in Delaware and through its intended launch will commit acts of patent infringement in Delaware.

STELARA®

16. STELARA® is a fully human antibody biologic medicine with the active ingredient ustekinumab, which is a fully human isolated anti-IL-12 antibody.[1]

17. STELARA® was first approved by the FDA in September 2009 for the treatment of adults with moderate to severe plaque psoriasis. Today, STELARA® is approved to treat a number of different conditions and patient populations: both adult patients and pediatric patients six years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; both adult patients and pediatric patients six years and older with active psoriatic arthritis; adult patients with moderately to severely active Crohn's disease; and adult patients with moderately to severely active UC.

18. The FDA approved STELARA®'s use to treat UC, the most recent indication, in October 2019. For this indication, STELARA® is prescribed, recommended, or suggested in its label for administration to subjects with moderately to severely active ulcerative colitis as a

[1] Ustekinumab, the antibody that is the active ingredient in STELARA®, binds both IL-12 and IL-23 in the body; it can thus be characterized as an anti-IL-12 antibody, as well as an anti-IL-12/IL-23 antibody.

pharmaceutical composition comprising a clinically proven safe and clinically proven effective amount of ustekinumab.

ABP 654, THE AMGEN BIOSIMILAR PRODUCT

19. Amgen has developed a proposed biosimilar to Janssen's STELARA® product, called ABP 654. Amgen has publicly announced that "ABP 654 is being developed as a biosimilar candidate to STELARA," and further that "ABP 654 has the same pharmaceutical form, dosage strength, route of administration and dosing regimen as" STELARA®. Ex. B at 2-3.

20. On November 11, 2020, Amgen initiated a Phase 3 study evaluating the efficacy and safety of ABP 654 compared with STELARA®. *See* Ex. C. Amgen has publicly stated that this Phase 3 study "evaluating the efficacy and safety of ABP 654 compared to STELARA® … demonstrat[ed] no clinically meaningful differences between ABP 654 and STELARA." *See* Ex. B at 1; *see also* Ex. D at 41 ("Preliminary results from a Phase 3 study evaluating the efficacy and safety compared to STELARA® in adult patients with moderate to severe plaque psoriasis met the primary efficacy endpoint.").

21. Amgen is also conducting a separate Phase 3 study to investigate interchangeability of ABP 654 for STELARA®. *See* Ex. E; *see also* Ex. F at 40 ("A Phase 3 study to support an interchangeability designation in the U.S. is ongoing.").

22. Amgen has made several public statements regarding the development of ABP 654 at numerous scientific and healthcare investor conferences. *See, e.g.*, Exs. G-I.

23. The FDA has not yet approved Amgen's proposed ABP 654 biosimilar product.

AMGEN'S aBLA

24. On information and belief, on or before November 3, 2022, Amgen submitted an aBLA to the FDA seeking approval to market in the United States a biosimilar version of Janssen's

STELARA® product. On November 3, 2022, Amgen publicly announced that Phase 3 data had been "submitted to the FDA to support U.S. approval" of its biosimilar copy of STELARA® (ustekinumab). *See* Ex. J at 42. Amgen's aBLA submission to the FDA[2] constitutes an act of infringement under the BPCIA. *See* 42 U.S.C. § 271(e)(2)(C)(ii).

25. On November 11, 2022, counsel for Janssen asked Amgen's counsel whether Amgen had filed its aBLA with FDA, whether and when FDA had accepted Amgen's aBLA application, whether Amgen intends to participate in the BPCIA "patent dance," and whether Amgen would provide its aBLA to Janssen. *See* Ex. K. Amgen refused to disclose when it filed its aBLA, whether the FDA has accepted it, whether Amgen intends to participate in the BPCIA "patent dance," or whether the BPCIA's deadline by which Amgen must provide Janssen with a copy of its aBLA has passed. Amgen also refused to provide Janssen with either a copy of its aBLA or any other requested information.

26. Amgen's submission of an aBLA is an act of artificial infringement. 35 U.S.C. § 271(e)(2)(C). Because Amgen has refused to provide its aBLA, Janssen has identified patents that "could be identified pursuant to section 351(l)(3)(A)(i)." 35 U.S.C. § 271(e)(2)(C)(ii); *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1674–75 (2017) (failure to provide aBLA "does not define the act of artificial infringement itself" but "merely assists in identifying which patents will be the subject of the artificial infringement suit").

[2] Amgen's Notice of Commercial Marketing further supports that Amgen has already submitted its aBLA, since Amgen informed Janssen that it provided that notice "[p]ursuant to 42 U.S.C. § 262(l)(8)(A)." Ex. A. The cited statutory section, 42 U.S.C. § 262(*l*)(8)(A), provides that "[t]he *subsection (k) applicant shall provide notice* to the reference product sponsor not later than 180 days before the date of the first commercial marketing…" (emphasis added). By providing notice "pursuant to" § 262(*l*)(8)(A), Amgen confirms it is a "subsection (k) applicant"—an aBLA submitter under 42 U.S.C. § 262(k).

27. Based on Amgen's failure to disclose its aBLA, the BPCIA also authorizes Janssen to "bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of *any patent that claims the biological product or a use of the biological product*." 42 U.S.C. § 262(l)(9)(C) (emphasis added).

AMGEN'S NOTICE OF COMMERCIAL MARKETING

28. On November 7, 2022, Amgen provided its 180-day notice of commercial marketing to Janssen, stating:

> Pursuant to 42 U.S.C. § 262(*l*)(8)(A), Amgen hereby provides this notice of commercial marketing not later than 180 days before the date of the first commercial marketing of Amgen's ABP 654 drug products that are biosimilar candidates to the drug products covered by Biologics License Application Nos. 125261 and 761044 ("Stelara® drug products"). Amgen intends to commercially market its ABP 654 drug products with a full label that includes all the FDA approved indications for the Stelara® drug products. Amgen will decide on a specific date to commence U.S. commercial marketing of its ABP 654 drug products and intends to be ready to commence commercial marketing upon receiving FDA approval.

Ex. A.

29. This notice signals Amgen's stated intent to begin selling its infringing biosimilar product after 180 days, i.e., on May 6, 2023 (or as soon thereafter as it receives FDA approval to do so). Ex. A (Amgen "intends to be ready to commence commercial marketing upon receiving FDA approval"). Amgen informed Janssen it intends to market ABP 654 for all indications and patient groups for which STELARA® is approved. Ex. A ("Amgen intends to commercially market its ABP 654 drug products with a full label that includes all the FDA approved indications for the Stelara® drug products.").

30. Further, Amgen's stated intention to launch its ABP 654 biosimilar product as soon as possible presents a controversy of sufficient immediacy to support declaratory judgment of patent infringement under 35 U.S.C. § 271(a)-(c) and (e).

31. On information and belief, the FDA's approval of Amgen's aBLA is imminent.[3] The FDA has expressed its intention to "[r]eview and act on 90 percent of original biosimilar biological product application submissions within 10 months of the 60 day filing date." Ex. L at 4. Although Amgen has refused to disclose its aBLA filing date, the fact that Amgen has filed its aBLA indicates that it could gain FDA approval of ABP 654 in the second or third quarter of 2023.

32. Amgen's submission of its aBLA, combined with its stated intention to begin commercial manufacture, use, sale, offers for sale, and/or importation of ABP 654 in 180 days or immediately upon FDA approval thereafter, creates an actual, immediate, and real controversy within the Declaratory Judgment Act that Amgen will infringe one or more of the claims of the '734 patent and/or the '307 patent, literally or under the doctrine of equivalents.

33. As set forth below, Amgen's ABP 654 biosimilar product will infringe Janssen's patents, including at least the '734 and '307 patents, either literally or under the doctrine of equivalents. *See* 35 U.S.C. §§ 271(a)-(c) & (e).

34. These facts show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

JANSSEN'S ASSERTED PATENTS

35. In the course of developing STELARA®, Janssen obtained patents related to ustekinumab (the fully human monoclonal anti-IL-12 antibody that is the active compound in STELARA®), as well as its administration to treat UC.

[3] Unlike the Hatch-Waxman Act, filing a lawsuit under the BPCIA does not trigger an automatic 30-month stay of FDA approval for the biosimilar. Instead, the FDA approval process continues regardless of any patent infringement.

36. Janssen asserts the ’734 and ’307 patents in this suit (together, the “Asserted Patents”).

The ’734 Patent

37. The ’734 patent is titled “Anti-IL-12 antibodies and compositions thereof,” and was duly and legally issued on June 7, 2005. A true and correct copy of the ’734 patent is attached hereto as Ex. M. Janssen is the owner by assignment of the ’734 patent. Broadly speaking, the ’734 patent is directed to and claims compositions of ustekinumab, the antibody that is the active ingredient in STELARA®. The ’734 patent includes four claims, two of which are independent. Claim 1 recites:

> 1. An isolated anti-IL-12 antibody, comprising a heavy chain variable region (V_H) of the amino acid sequence set forth in SEQ ID NO:7 and a light chain variable region (V_L) of the amino acid sequence set forth in SEQ ID NO:8.

The ’307 Patent

38. The ’307 patent is titled “Methods of Treating Moderately to Severely Active Ulcerative Colitis by Administering an Anti-IL12/IL23 Antibody,” and was duly and legally issued on March 30, 2021. A true and correct copy of the ’307 patent is attached hereto as Ex. N. Janssen is the owner by assignment of the ’307 patent. In general, the ’307 patent is directed to and claims methods of treating ulcerative colitis with ustekinumab, the antibody that is the active ingredient in STELARA®. The ’307 patent includes 34 claims, four of which are independent. Claim 3 (which depends from Claim 1) recites:

> 1. A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising a clinically proven safe and clinically proven effective amount of an anti-IL-12/IL-23p40 antibody, wherein the antibody comprises a heavy chain variable region and a light chain variable region, the heavy chain variable region comprising: a complementarity determining region heavy chain 1 (CDRH1) amino acid sequence of SEQ ID NO:1; a CDRH2 amino acid sequence of SEQ ID

NO:2; and a CDRH3 amino acid sequence of SEQ ID NO:3; and the light chain variable region comprising: a complementarity determining region light chain 1 (CDRL1) amino acid sequence of SEQ ID NO:4; a CDRL2 amino acid sequence of SEQ ID NO:5; and a CDRL3 amino acid sequence of SEQ ID NO:6, wherein after treating with the antibody, the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤2 points with no individual subscore >1 and the US definition of clinical remission with absolute stool number ≤3, rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) clinical response based on the Mayo endoscopy subscore, (iv) improvements from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) mucosal healing, (vi) decrease from baseline in Mayo score, and (vii) clinical response as determined by a decrease from baseline in the Mayo score by ≥30% and ≥3 points and a decrease from baseline in the rectal bleeding subscore ≥1 points or a rectal bleeding subscore of 0 or 1.

3. … wherein the antibody comprises a heavy chain of the amino acid sequence of SEQ ID NO:10 and a light chain of the amino acid sequence of SEQ ID NO:11.

COUNT I
Infringement of the '734 Patent Under 35 U.S.C. § 271(e)(2)(C)(ii)

39. Janssen incorporates by reference the allegations set forth in paragraphs 1 through 38 as though fully set forth herein.

40. On information and belief, on or before November 3, 2022, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of ABP 654, its biosimilar version of STELARA® (ustekinumab). Ex. J at 42. The reference products for ustekinumab are BLA Nos. 125261 and 761044. Janssen is the holder of BLA Nos. 125261 and 761044.

41. Amgen has not provided Janssen a copy of its aBLA. But to be marketed as biosimilar to STELARA® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), ABP 654 must be highly similar to STELARA® with only minor differences in clinically inactive components, and with no clinically meaningful difference between ABP 654 and STELARA® in terms of safety,

purity, and potency. Ustekinumab is the active ingredient in STELARA®. Accordingly, ABP 654 must contain either ustekinumab or a human monoclonal antibody identical or highly similar in amino acid sequence to ustekinumab, and also highly similar in other characteristics (*e.g.*, post-translational modifications, carbohydrate profile, etc.).

42. On information and belief, the active ingredient in ABP 654 is an isolated anti-IL-12 antibody having an amino acid sequence identical to ustekinumab. Such an antibody meets multiple claims of the '734 patent. For example, Claim 1 recites:

> 1. An isolated anti-IL-12 antibody, comprising a heavy chain variable region (V_H) of the amino acid sequence set forth in SEQ ID NO:7 and a light chain variable region (V_L) of the amino acid sequence set forth in SEQ ID NO:8.

43. On information and belief, as a biosimilar to STELARA®, the active ingredient in ABP 654 is an isolated anti-IL-12 antibody.

44. The heavy chain variable region (V_H) of SEQ ID NO:7 recited in Claim 1 is the heavy chain variable region sequence of ustekinumab. The light chain variable region (V_L) of SEQ ID NO:8 is the light chain variable region sequence of ustekinumab. On information and belief, as a biosimilar to STELARA®, the active ingredient in ABP 654 has the same heavy chain variable region sequence as ustekinumab and SEQ ID NO:7, and the same light chain variable region sequence as ustekinumab and SEQ ID NO:8.

45. Moreover, pursuant to 42 U.S.C. § 262(k)(2)(A)(i), the active ingredient in ABP 654 and ustekinumab must utilize the same mechanism or mechanisms of action for the condition or conditions of use. Amgen has publicly stated that its Phase 3 study "evaluating the efficacy and safety of ABP 654 compared to STELARA® … demonstrat[ed] no clinically meaningful differences between ABP 654 and STELARA." *See* Ex. B at 1.

46. Thus, on information and belief, Amgen's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, sale, offer to sell, and/or importation of ABP 654 prior to the expiration of the '734 patent is an act of infringement of one or more of the claims of the '734 patent under 35 U.S.C. § 271(e)(2)(C)(ii), either literally or under the doctrine of equivalents.

47. On information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of ABP 654 directly infringes at least one claim of the '734 patent, either literally or under the doctrine of equivalents.

48. On information and belief, Amgen will knowingly or with willful blindness induce or contribute to another's direct infringement of at least one claim of the '734 patent, either literally or under the doctrine of equivalents.

49. Amgen has knowledge of and is aware of the '734 patent, including due to both Janssen's counsel's November 11, 2022 email, *see* Ex. K, and the filing of this Complaint, and on information and belief, has been aware of the '734 patent for months, if not years, before then.

50. Janssen will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '734 patent.

51. Janssen seeks an injunction preventing Amgen from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of ABP 654.

COUNT II
Declaratory Judgment of Infringement of the '734 Patent

52. Janssen incorporates by reference the allegations set forth in paragraphs 1 through 38 as though fully set forth herein.

53. This declaratory judgment action is authorized by, *inter alia*, the BPCIA due to Amgen's provision of a notice of commercial marketing, and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(8)(A-B), 262(*l*)(9)(C); 35 U.S.C. § 271(e); 28 U.S.C. §§ 2201, 2202. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

54. On information and belief, on or before November 3, 2022, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of ABP 654, its biosimilar version of STELARA® (ustekinumab). Ex. J at 42. The reference products for ustekinumab are BLA Nos. 125261 and 761044. Janssen is the holder of BLA Nos. 125261 and 761044.

55. On November 7, 2022, Amgen provided Janssen a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Ex. A.

56. On information and belief, Amgen has made substantial preparations and intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of ABP 654 after 180 days, i.e., on May 6, 2023 (or as soon thereafter as it receives FDA approval to do so). Ex. A (Amgen "intends to be ready to commence commercial marketing upon receiving FDA approval"). Amgen informed Janssen it intends to market ABP 654 for all indications and patient groups for which STELARA® is approved. Ex. A ("Amgen intends to commercially market its ABP 654 drug products with a full label that includes all the FDA approved indications for the Stelara® drug products."). Amgen's stated intention to launch its ABP 654 biosimilar product as soon as possible presents a controversy of sufficient immediacy to support declaratory judgment of patent infringement under 35 U.S.C. § 271(a)-(c) and (e).

57. Amgen's submission of its aBLA, combined with its stated intention in its Notice of Commercial Marketing to begin commercial manufacture, use, sale, offers for sale, and/or

importation of ABP 654 prior to the expiration of the ’734 patent (i.e., on May 6, 2023 or immediately upon FDA approval thereafter), creates an actual, immediate, and real controversy within the Declaratory Judgment Act that Amgen will infringe one or more of the claims of the ’734 patent, literally or under the doctrine of equivalents.

58. Amgen has not provided Janssen a copy of its aBLA. But to be marketed as biosimilar to STELARA® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), ABP 654 must be highly similar to STELARA® with only minor differences in clinically inactive components, and with no clinically meaningful difference between ABP 654 and STELARA® in terms of safety, purity, and potency. Ustekinumab is the active ingredient in STELARA®. Accordingly, ABP 654 must contain either ustekinumab or a human monoclonal antibody identical or highly similar in amino acid sequence to ustekinumab, and also highly similar in other characteristics (*e.g.*, post-translational modifications, carbohydrate profile, etc.).

59. On information and belief, the active ingredient in ABP 654 is an isolated anti-IL-12 antibody and has an amino acid sequence identical to ustekinumab. Such an antibody meets multiple claims of the ’734 patent. For example, Claim 1 recites:

> 1. An isolated anti-IL-12 antibody, comprising a heavy chain variable region (V_H) of the amino acid sequence set forth in SEQ ID NO:7 and a light chain variable region (V_L) of the amino acid sequence set forth in SEQ ID NO:8.

60. On information and belief, as a biosimilar to STELARA®, the active ingredient in ABP 654 is an isolated anti-IL-12 antibody.

61. The heavy chain variable region (V_H) of SEQ ID NO:7 recited in Claim 1 is the heavy chain variable region sequence of ustekinumab. The light chain variable region (V_L) of SEQ ID NO:8 is the light chain variable region sequence of ustekinumab. On information and belief, as a biosimilar to STELARA®, the active ingredient in ABP 654 has the same heavy chain variable

region sequence as ustekinumab and SEQ ID NO:7, and the same light chain variable region sequence as ustekinumab and SEQ ID NO:8.

62. Moreover, pursuant to 42 U.S.C. § 262(k)(2)(A)(i), the active ingredient in ABP 654 and ustekinumab must utilize the same mechanism or mechanisms of action for the condition or conditions of use. Amgen has publicly stated that its Phase 3 study "evaluating the efficacy and safety of ABP 654 compared to STELARA® … demonstrat[ed] no clinically meaningful differences between ABP 654 and STELARA." *See* Ex. B at 1.

63. On information and belief, Amgen has directly infringed or will directly infringe at least one claim of the '734 patent by making, using, offering for sale, selling within and/or importing into the United States ABP 654, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a).

64. On information and belief, Amgen has an affirmative intent to actively induce or contribute to infringement by others of at least one claim of the '734 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b)-(c).

65. On information and belief, through submitting its aBLA to FDA, Amgen has infringed or will infringe at least one claim of the '734 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(e).

66. On information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of ABP 654 directly infringes at least one claim of the '734 patent, either literally or under the doctrine of equivalents.

67. On information and belief, Amgen will knowingly or with willful blindness induce or contribute to another's direct infringement of at least one claim of the '734 patent, either literally or under the doctrine of equivalents.

68. Amgen has knowledge of and is aware of the '734 patent, including due to both Janssen's counsel's November 11, 2022 email, *see* Ex. K, and the filing of this Complaint, and on information and belief, has been aware of the '734 patent for months, if not years, before then.

69. Janssen will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '734 patent.

70. Janssen seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of ABP 654 will infringe the '734 patent.

71. Janssen seeks an injunction preventing Amgen from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of ABP 654.

COUNT III
Infringement of the '307 Patent Under 35 U.S.C. § 271(e)(2)(C)(ii)

72. Janssen incorporates by reference the allegations set forth in paragraphs 1 through 38 as though fully set forth herein.

73. On information and belief, on or before November 3, 2022, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of ABP 654, its biosimilar version of STELARA® (ustekinumab). Ex. J at 42. The reference products for ustekinumab are BLA Nos. 125261 and 761044. Janssen is the holder of BLA Nos. 125261 and 761044.

74. Amgen has not provided Janssen a copy of its aBLA. But to be marketed as biosimilar to STELARA® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), ABP 654 must be highly similar to STELARA® with only minor differences in clinically inactive components, and

with no clinically meaningful difference between ABP 654 and STELARA® in terms of safety, purity, and potency. Ustekinumab is the active ingredient in STELARA®. Accordingly, ABP 654 must contain either ustekinumab or a human monoclonal antibody identical or highly similar in amino acid sequence to ustekinumab, and also highly similar in other characteristics (*e.g.*, post-translational modifications, carbohydrate profile, etc.).

75. Moreover, pursuant to 42 U.S.C. § 262(k)(2)(A)(i), the active ingredient in ABP 654 and ustekinumab must utilize the same mechanism or mechanisms of action for the condition or conditions of use. Amgen has publicly stated that its Phase 3 study "evaluating the efficacy and safety of ABP 654 compared to STELARA® … demonstrat[ed] no clinically meaningful differences between ABP 654 and STELARA." *See* Ex. B at 1.

76. Furthermore, ABP 654 must be prescribed, recommended, or suggested for the condition or conditions previously approved for STELARA® with the same route of administration, dosage form, and strength as STELARA®. STELARA® is approved for treatment of, among other things, moderately to severely active ulcerative colitis, with recommended dosing comprising: (1) a single intravenous infusion using weight-based dosing of 260 mg for patients up to 55 kg, 390 mg for patients greater than 55 kg to 85 kg, and 520 mg for patients greater than 85 kg, followed by (2) a subcutaneous 90 mg dose 8 weeks after the initial intravenous dose, and every 8 weeks thereafter. Accordingly, on information and belief, ABP 654 will be prescribed, recommended, or suggested in its labeling for treatment of moderately to severely active ulcerative colitis, with recommended dosing the same as STELARA®.

77. Use of ABP 654 as directed on its label for the treatment of moderately to severely active ulcerative colitis meets each limitation of representative Claim 3 of the '307 patent, which depends from Claim 1 and recites:

> 1. A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising a clinically proven safe and clinically proven effective amount of an anti-IL-12/IL-23p40 antibody, wherein the antibody comprises a heavy chain variable region and a light chain variable region, the heavy chain variable region comprising: a complementarity determining region heavy chain 1 (CDRH1) amino acid sequence of SEQ ID NO:1; a CDRH2 amino acid sequence of SEQ ID NO:2; and a CDRH3 amino acid sequence of SEQ ID NO:3; and the light chain variable region comprising: a complementarity determining region light chain 1 (CDRL1) amino acid sequence of SEQ ID NO:4; a CDRL2 amino acid sequence of SEQ ID NO:5; and a CDRL3 amino acid sequence of SEQ ID NO:6, wherein after treating with the antibody, the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤2 points with no individual subscore >1 and the US definition of clinical remission with absolute stool number ≤3, rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) clinical response based on the Mayo endoscopy subscore, (iv) improvements from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) mucosal healing, (vi) decrease from baseline in Mayo score, and (vii) clinical response as determined by a decrease from baseline in the Mayo score by ≥30% and ≥3 points and a decrease from baseline in the rectal bleeding subscore ≥1 points or a rectal bleeding subscore of 0 or 1.
>
> 3. … wherein the antibody comprises a heavy chain of the amino acid sequence of SEQ ID NO:10 and a light chain of the amino acid sequence of SEQ ID NO:11.

78. As a biosimilar to STELARA®, the active ingredient in ABP 654 is an anti-IL-12/IL-23p40 antibody. The heavy chain of SEQ ID NO:10 is the heavy chain sequence of ustekinumab. The light chain of SEQ ID NO:11 is the light chain sequence of ustekinumab. As a biosimilar to STELARA®, and on information and belief, the active ingredient in ABP 654 has the same heavy chain sequence as ustekinumab and SEQ ID NO:10 and the same light chain sequence as ustekinumab and SEQ ID NO:11.

79. As a biosimilar to STELARA®, and on information and belief, ABP 654 will be prescribed, recommended, or suggested in its label for administration to subjects with moderately

to severely active ulcerative colitis as a pharmaceutical composition comprising a clinically proven safe and clinically proven effective amount of a biosimilar to ustekinumab.

80. As a biosimilar to STELARA®, and on information and belief, ABP 654 will be prescribed, recommended, or suggested in its label that UC patients receiving ABP 654 will be responders achieving the same or highly similar clinical responses as those for STELARA®.

81. The STELARA® label indicates that UC patients receiving STELARA® include patients that achieved clinical remission defined as a Mayo stool frequency subscore of 0 or 1, Mayo rectal bleeding subscore of 0, and Mayo endoscopy subscore of 0 or 1 (modified so that 1 does not include friability; endoscopic improvement defined as a Mayo endoscopy subscore of 0 or 1 (modified so that 1 does not include friability); clinical response defined as a decrease from baseline in the modified Mayo score by >30% and > 2 points, with either a decrease from bassline in the rectal bleeding subscore >1 or a rectal bleeding subscore of 0 or 1; and/or mucosal improvement defined as a combined endoscopic improvement (Mayo endoscopy subscore of 0 or 1) and histologic improvement of the colon tissue (neutrophil infiltration of <5% of crypts, no crypt destruction, and no erosions, ulcerations, or granulations of tissue). Accordingly, UC patients receiving STELARA® include responders that at least demonstrate "(i) clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤2 points with no individual subscore >1 and the US definition of clinical remission with absolute stool number ≤3, rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1," "(ii) endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) clinical response based on the Mayo endoscopy subscore," "(v) mucosal healing," or "(vi) decrease from baseline in Mayo score."

82. Thus, on information and belief, Amgen's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, sale, offer to sell, and/or importation of

ABP 654 prior to the expiration of the ’307 patent is an act of infringement of one or more of the claims of the ’307 patent under 35 U.S.C. § 271(e)(2)(C)(ii), either literally or under the doctrine of equivalents.

83. On information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that the prescription, recommendation, or suggestion of ABP 654 to subjects with moderately to severely active ulcerative colitis directly infringes at least one claim of the ’307 patent, either literally or under the doctrine of equivalents.

84. On information and belief, Amgen will knowingly or with willful blindness induce or contribute to another’s direct infringement of at least one claim of the ’307 patent, either literally or under the doctrine of equivalents.

85. Amgen has knowledge of and is aware of the ’307 patent, including due to both Janssen’s counsel’s November 11, 2022 email, *see* E. K, and the filing of this Complaint, and on information and belief, has been aware of the ’307 patent for months, if not years, before then.

86. Janssen will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the ’307 patent.

87. Janssen seeks an injunction preventing Amgen from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of ABP 654.

COUNT IV
Declaratory Judgment of Infringement of the ’307 Patent

88. Janssen incorporates by reference the allegations set forth in paragraphs 1 through 38 as though fully set forth herein.

89. This declaratory judgment action is authorized by, *inter alia*, the BPCIA due to Amgen’s provision of a notice of commercial marketing, and by the Declaratory Judgment Act.

See 42 U.S.C. §§ 262(*l*)(8)(A-B), 262(*l*)(9)(C); 35 U.S.C. § 271(e); 28 U.S.C. §§ 2201, 2202. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

90. On information and belief, on or before November 3, 2022, Amgen submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of ABP 654, its biosimilar version of STELARA® (ustekinumab). Ex. J at 42. The reference products for ustekinumab are BLA Nos. 125261 and 761044. Janssen is the holder of BLA Nos. 125261 and 761044.

91. On November 7, 2022, Amgen provided Janssen a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Ex. A.

92. On information and belief, Amgen has made substantial preparations and intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of ABP 654 after 180 days, i.e., on May 6, 2023 (or as soon thereafter as it receives FDA approval to do so). Ex. A (Amgen "intends to be ready to commence commercial marketing upon receiving FDA approval"). Amgen informed Janssen it intends to market ABP 654 for all indications and patient groups for which STELARA® is approved. Ex. A ("Amgen intends to commercially market its ABP 654 drug products with a full label that includes all the FDA approved indications for the Stelara® drug products."). Amgen's stated intention to launch its ABP 654 biosimilar product as soon as possible presents a controversy of sufficient immediacy to support declaratory judgment of patent infringement under 35 U.S.C. § 271(b)-(c) and (e).

93. Amgen's submission of its aBLA, combined with its stated intention in its Notice of Commercial Marketing to begin commercial manufacture, use, sale, offers for sale, and/or importation of ABP 654 prior to the expiration of the '307 patent (i.e., on May 6, 2023 or immediately upon FDA approval thereafter), creates an actual, immediate, and real controversy

within the Declaratory Judgment Act that Amgen will infringe one or more of the claims of the '307 patent, literally or under the doctrine of equivalents.

94. Amgen has not provided Janssen a copy of its aBLA. But to be marketed as biosimilar to STELARA® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), ABP 654 must be highly similar to STELARA® with only minor differences in clinically inactive components, and with no clinically meaningful difference between ABP 654 and STELARA® in terms of safety, purity, and potency. Ustekinumab is the active ingredient in STELARA®. Accordingly, ABP 654 must contain either ustekinumab or a human monoclonal antibody identical or highly similar in amino acid sequence to ustekinumab, and also highly similar in other characteristics (*e.g.*, post-translational modifications, carbohydrate profile, etc.).

95. Moreover, pursuant to 42 U.S.C. § 262(k)(2)(A)(i), the active ingredient in ABP 654 and ustekinumab must utilize the same mechanism or mechanisms of action for the condition or conditions of use. Amgen has publicly stated that its Phase 3 study "evaluating the efficacy and safety of ABP 654 compared to STELARA® … demonstrat[ed] no clinically meaningful differences between ABP 654 and STELARA." *See* Ex. B at 1.

96. Furthermore, ABP 654 must be prescribed, recommended, or suggested for the condition or conditions previously approved for STELARA® with the same route of administration, dosage form, and strength as STELARA®. STELARA® is approved for treatment of, among other things, moderately to severely active ulcerative colitis, with recommended dosing comprising: (1) a single intravenous infusion using weight-based dosing of 260 mg for patients up to 55 kg, 390 mg for patients greater than 55 kg to 85 kg, and 520 mg for patients greater than 85 kg, followed by (2) a subcutaneous 90 mg dose 8 weeks after the initial intravenous dose, and every 8 weeks thereafter. Accordingly, on information and belief, ABP 654 will be prescribed,

recommended, or suggested in its labeling for treatment of moderately to severely active ulcerative colitis, with recommended dosing the same as STELARA®.

97. Use of ABP 654 as directed on its label for the treatment of moderately to severely active ulcerative colitis meets each limitation of representative Claim 3 of the '307 patent, which depends from Claim 1 and recites:

> 1. A method of treating moderately to severely active ulcerative colitis (UC) in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising a clinically proven safe and clinically proven effective amount of an anti-IL-12/IL-23p40 antibody, wherein the antibody comprises a heavy chain variable region and a light chain variable region, the heavy chain variable region comprising: a complementarity determining region heavy chain 1 (CDRH1) amino acid sequence of SEQ ID NO:1; a CDRH2 amino acid sequence of SEQ ID NO:2; and a CDRH3 amino acid sequence of SEQ ID NO:3; and the light chain variable region comprising: a complementarity determining region light chain 1 (CDRL1) amino acid sequence of SEQ ID NO:4; a CDRL2 amino acid sequence of SEQ ID NO:5; and a CDRL3 amino acid sequence of SEQ ID NO:6, wherein after treating with the antibody, the subject is a responder to treatment by at least one measure of response to treatment selected from the group consisting of: (i) clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤2 points with no individual subscore >1 and the US definition of clinical remission with absolute stool number ≤3, rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1, (ii) endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) clinical response based on the Mayo endoscopy subscore, (iv) improvements from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) score, (v) mucosal healing, (vi) decrease from baseline in Mayo score, and (vii) clinical response as determined by a decrease from baseline in the Mayo score by ≥30% and ≥3 points and a decrease from baseline in the rectal bleeding subscore ≥1 points or a rectal bleeding subscore of 0 or 1.
>
> 3. … wherein the antibody comprises a heavy chain of the amino acid sequence of SEQ ID NO:10 and a light chain of the amino acid sequence of SEQ ID NO:11.

98. As a biosimilar to STELARA®, the active ingredient in ABP 654 is an anti-IL-12/IL-23p40 antibody. The heavy chain of SEQ ID NO:10 is the heavy chain sequence of ustekinumab. The light chain of SEQ ID NO:11 is the light chain sequence of ustekinumab. As a

biosimilar to STELARA®, and on information and belief, the active ingredient in ABP 654 has the same heavy chain sequence as ustekinumab and SEQ ID NO:10 and the same light chain sequence as ustekinumab and SEQ ID NO:11.

99. As a biosimilar to STELARA®, and on information and belief, ABP 654 will be prescribed, recommended, or suggested in its label for administration to subjects with moderately to severely active ulcerative colitis as a pharmaceutical composition comprising a clinically proven safe and clinically proven effective amount of a biosimilar to ustekinumab.

100. As a biosimilar to STELARA®, and on information and belief, ABP 654 will be prescribed, recommended, or suggested in its label that UC patients receiving ABP 654 will be responders achieving the same or highly similar clinical responses as those for STELARA®.

101. The STELARA® label indicates that UC patients receiving STELARA® include patients that achieved clinical remission defined as a Mayo stool frequency subscore of 0 or 1, Mayo rectal bleeding subscore of 0, and Mayo endoscopy subscore of 0 or 1 (modified so that 1 does not include friability; endoscopic improvement defined as a Mayo endoscopy subscore of 0 or 1 (modified so that 1 does not include friability); clinical response defined as a decrease from baseline in the modified Mayo score by >30% and > 2 points, with either a decrease from bassline in the rectal bleeding subscore >1 or a rectal bleeding subscore of 0 or 1; and/or mucosal improvement defined as a combined endoscopic improvement (Mayo endoscopy subscore of 0 or 1) and histologic improvement of the colon tissue (neutrophil infiltration of <5% of crypts, no crypt destruction, and no erosions, ulcerations, or granulations of tissue). Accordingly, UC patients receiving STELARA® include responders that at least demonstrate "(i) clinical remission based on at least one of the global definition of clinical remission with Mayo score ≤2 points with no individual subscore >1 and the US definition of clinical remission with absolute stool number ≤3,

rectal bleeding subscore of 0 and Mayo endoscopy subscore of 0 or 1," "(ii) endoscopic healing with a Mayo endoscopy subscore of 0 or 1, (iii) clinical response based on the Mayo endoscopy subscore," "(v) mucosal healing," or "(vi) decrease from baseline in Mayo score."

102. On information and belief, Amgen has an affirmative intent to actively induce or contribute to infringement by others of at least one claim of the '307 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b)-(c).

103. On information and belief, through submitting its aBLA to FDA, Amgen has infringed or will infringe at least one claim of the '307 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(e).

104. On information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that the prescription, recommendation, or suggestion of ABP 654 to subjects with moderately to severely active ulcerative colitis directly infringes at least one claim of the '307 patent, either literally or under the doctrine of equivalents.

105. On information and belief, Amgen will knowingly or with willful blindness induce or contribute to another's direct infringement of at least one claim of the '307 patent, either literally or under the doctrine of equivalents.

106. Amgen has knowledge of and is aware of the '307 patent, including due to both Janssen's counsel's November 11, 2022 email, *see* Ex. K, and the filing of this Complaint, and on information and belief, has been aware of the '307 patent for months, if not years, before then.

107. Janssen will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '307 patent.

108. Janssen seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of ABP 654 will infringe the '307 patent.

109. Janssen seeks an injunction preventing Amgen from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of ABP 654.

PRAYER FOR RELIEF

WHEREFORE, Janssen respectfully requests that this Court enter judgment in its favor against Amgen and grant the following relief:

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

B. preliminary and permanent equitable relief, including but not limited to a preliminary and permanent injunction that enjoins Amgen, 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 Asserted Patents, or contributing to or inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, or distribution within the United States, or importation into the United States, of any current or future versions of the Amgen aBLA Product, the use or manufacturing of which infringes the Asserted Patents;

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

D. any available damages pursuant to 35 U.S.C. § 284; and

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

November 29, 2022

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