IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC., Plaintiff, v. HETERO USA, INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HOSTER LABS PRIVATE LIMITED, AUROBINDO PHARMA USA, INC., AUROBINDO PHARMA LTD., and SUN PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiff AbbVie Inc. ("AbbVie"), by its undersigned attorneys, brings this action against Defendants Hetero USA, Inc., Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hoster Labs Private Limited (collectively, "Hetero"); Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. (collectively, "Aurobindo"); and Sun Pharmaceutical Industries, Ltd. ("Sun"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271. This action arises from Hetero's, Aurobindo's, and Sun's submission of Abbreviated New Drug Applications ("ANDAs") to the United States Food and Drug Administration ("FDA") seeking approval to market generic versions of AbbVie's highly successful pharmaceutical product RINVOQ®, prior to the expiration of one or more of the following patents: United States Patent Nos. RE47,221 ("the RE'221 Patent"); 8,962,629 ("the '629 Patent"); 11,976,077 ("the '077 Patent"); 11,993,605 ("the '605 Patent"); and 11,993,606 ("the '606 Patent") (collectively, "the Asserted Patents").

2. In November 2023, Plaintiff filed related action *AbbVie Inc. v. Hetero USA, Inc. et al.*, C.A. No. 23-1332 (MN) (D. Del.) against, *inter alia*, Hetero, Aurobindo, and Sun for patent infringement arising from their respective ANDA submissions. This action arises from Plaintiff's recent receipt of notices of purported Paragraph IV certifications from Hetero, Aurobindo, and Sun for one or more of the Asserted Patents.

RINVOQ®

3. RINVOQ® (upadacitinib) is a ground-breaking, once-daily oral Janus kinase (JAK) inhibitor that has gained widespread medical acceptance. In less than five years since its first FDA approval on August 16, 2019, RINVOQ® has been approved to treat patients with several different immune-mediated diseases, including rheumatoid arthritis, psoriatic arthritis and ulcerative colitis. It has been used to treat almost 160,000 patients in the United States alone.

4. Janus kinases (JAKs), including JAK1, JAK2, JAK3 and Tyrosine kinase 2 (Tyk2), are intracellular enzymes that play a pivotal role in signaling pathways arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate signal transducers and activators of transcription (STATs) which modulate intracellular activity including gene expression. RINVOQ®'s active ingredient, upadacitinib, modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs. Upadacitinib has surprising selectivity for JAK1.

5. AbbVie invested more than three billion dollars in the development of RINVOQ® and in its extensive clinical development program, which includes more than 45 completed or ongoing company-sponsored clinical trials and has resulted in approvals for an unexpected array of onerous diseases of the immune system. AbbVie continues to invest in the clinical development of RINVOQ®.

6. AbbVie's development of RINVOQ® is part of its long legacy of research in immunology and its track record to making life better for people living with immune-mediated diseases.

7. RINVOQ® is currently approved for treatment of:

a. adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor ("TNF") blockers;

b. adults and pediatric patients 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers;

c. adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable;

d. adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers;

e. adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers;

f. adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers;

g. adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy;

h. patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.

8. RINVOQ® represents an important advance for patients with these conditions. RINVOQ® was designated as a "Breakthrough Therapy" by FDA for treatment of adult patients with moderate to severe atopic dermatitis who are candidates for systemic therapy, based on FDA's determination that RINVOQ® may offer substantial treatment advantages over existing options for patients with serious or life-threatening diseases. RINVOQ® is the first and only JAK inhibitor that is approved for both non-radiographic axial spondyloarthritis (nr-axSpA) and active ankylosing spondylitis (AS). RINVOQ® was also the first oral therapy to receive FDA approval for moderate to severe Crohn's disease.

9. As a result of the inventive work of the AbbVie scientists responsible for development and formulation, RINVOQ® is available in 15 mg, 30 mg, and 45 mg extended-release tablets, which allow for convenient once daily oral dosing.

THE PARTIES

10. Plaintiff AbbVie is a corporation organized and existing under the laws of the State of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. AbbVie's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas.

11. AbbVie is the assignee and owner of the Asserted Patents.

12. AbbVie holds NDA No. 211675 for RINVOQ®.

Hetero

13. Defendant Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

14. Defendant Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telangana, India.

15. Hetero Labs Limited is the parent company of Defendants Hetero USA, Inc. and Hetero Labs Limited Unit-V.

16. On information and belief, Hetero Labs Limited ultimately owns all of Hetero's ANDAs, including Hetero's ANDA No. 218859.

17. Defendant Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar, 509 301, Telangana, India.

18. On information and belief, Defendant Hoster Labs Private Limited is a corporation organized and existing under the laws of India, having a place of business at H. No. 8-3-166/7/1, Erragadda, Hyderabad, Telangana-500018.

19. Hoster Labs Private Limited is the holder of upadacitinib Drug Master File ("DMF") No. 038344.

20. On information and belief, Hetero Labs Limited is the parent company of Hoster Labs Private Limited.

21. On information and belief, Hoster Labs Private Limited is a corporation within the Hetero corporate family.

22. Hetero USA, Inc. is the United States regulatory agent for Defendants Hetero Labs Limited and Hetero Labs Limited Unit-V.

23. Hetero USA, Inc. filed ANDA No. 218859 with FDA on Hetero's behalf.

24. On information and belief, the specific manufacturing site for Hetero's ANDA No. 218859 is Defendant Hetero Labs Limited Unit-V.

25. On information and belief, Hetero Labs Limited and its wholly owned subsidiaries Hetero USA, Inc., Hetero Labs Limited Unit-V, and Hoster Labs Private Limited collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Hetero Labs Limited and its wholly owned subsidiaries Hetero USA, Inc., Hetero Labs Limited Unit-V, and Hoster Labs Private Limited are agents of one another and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

26. Hetero caused ANDA No. 218859 to be submitted to FDA and seeks FDA approval of ANDA No. 218859.

27. On information and belief, Hetero Labs Limited and its wholly owned subsidiaries Hetero USA, Inc., Hetero Labs Limited Unit-V, and Hoster Labs Private Limited acted collaboratively in the preparation of ANDA No. 218859 and continue to act collaboratively in pursuing FDA approval of ANDA No. 218859 and seeking to market the Hetero ANDA Products.

28. On information and belief, Hetero intends to commercially manufacture, market, offer for sale, and sell the Hetero ANDA Products throughout the United States, including in the State of Delaware, in the event FDA approves ANDA No. 218859.

29. On information and belief, Hetero Labs Limited and its wholly owned subsidiaries Hetero USA, Inc., Hetero Labs Limited Unit-V, and Hoster Labs Private Limited rely on material

assistance from one another to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of Delaware. On information and belief, Hetero Labs Limited and its wholly owned subsidiaries Hetero USA, Inc., Hetero Labs Limited Unit-V, and Hoster Labs Private Limited intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Hetero's ANDA Products, in the event FDA approves ANDA No. 218859.

Aurobindo

30. Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520. Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd.

31. Defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

32. On information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. are agents of one another and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

33. Aurobindo caused ANDA No. 218866 to be submitted to FDA and seeks FDA approval of ANDA No. 218866.

34. On information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. acted collaboratively in the preparation of ANDA No. 218866 and continue to act

collaboratively in pursuing FDA approval of ANDA No. 218866 and seeking to market the Aurobindo ANDA Products.

35. On information and belief, Aurobindo intends to commercially manufacture, market, offer for sale, and sell the Aurobindo ANDA Products throughout the United States, including in the State of Delaware, in the event FDA approves ANDA No. 218866.

36. On information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. rely on material assistance from one another to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of Delaware. On information and belief, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Aurobindo's ANDA Products, in the event FDA approves ANDA No. 218866.

Sun

37. Defendant Sun Pharmaceutical Industries, Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, CTX No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra 400 063, India.

38. Sun caused ANDA No. 217611 to be submitted to FDA and seeks FDA approval of ANDA No. 217611.

39. On information and belief, Sun intends to commercially manufacture, market, offer for sale, and sell the Sun ANDA Product throughout the United States, including in the State of Delaware, in the event FDA approves ANDA No. 217611.

JURISDICTION AND VENUE

40. This is a civil action for patent infringement arising under the patent laws of the United States, including 35 U.S.C. § 271 and 28 U.S.C. §§ 1338(a), 2201, 2202.

41. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

Hetero

42. This Court has personal jurisdiction over Hetero USA, Inc. because Hetero USA, Inc. is a corporation organized and existing under the laws of Delaware. On information and belief, Hetero USA, Inc. is registered to do business as a domestic corporation in Delaware (File Number 4837317).

43. Additionally, this Court has personal jurisdiction over Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hoster Labs Private Limited because, on information and belief, each, *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Hetero's ANDA Products in the State of Delaware upon approval of ANDA No. 218859.

44. On information and belief, Hetero is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Hetero manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

45. On information and belief, Hetero is licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

46. Hetero has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to AbbVie, which manufactures and markets RINVOQ® for sale and use throughout the United States,

including in this judicial district. On information and belief and as indicated by a letter dated October 16, 2023 sent by Hetero to AbbVie pursuant to 21 U.S.C. § 355(j)(2)(B), Hetero prepared and filed its ANDA with the intention of seeking to market Hetero's ANDA Products nationwide, including within this judicial district.

47. On information and belief, Hetero plans to sell the Hetero ANDA Products in the State of Delaware, list the Hetero ANDA Products on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the Hetero ANDA Products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

48. On information and belief, Hetero knows and intends that the Hetero ANDA Products will be distributed and sold in Delaware and will thereby displace sales of RINVOQ®, causing injury to AbbVie. Hetero intends to take advantage of its established channels of distribution in Delaware for the sale of the Hetero ANDA Products.

49. Hetero Labs Limited and Hetero Labs Limited Unit-V regularly invoke the jurisdiction of the courts of this judicial district by pleading claims and counterclaims in pharmaceutical patent infringement actions in this judicial district. *See, e.g.*, *AbbVie Inc. et al. v. Alkem Laboratories Limited et al.*, C.A. No. 22-1423-RGA, D.I. 50 (D. Del. Feb. 7, 2023); *Duchesnay, Inc. v. Hetero Labs. Ltd.*, C.A. No. 21-1130-LPS, D.I. 11 (D. Del. Oct. 18, 2021). Hetero Labs Limited and Hetero Labs Limited Unit-V have also not contested personal jurisdiction or venue in pharmaceutical patent litigation in this judicial district. *See, e.g.*, *AbbVie Inc. et al. v. Alkem Laboratories Limited et al.*, C.A. No. 22-1423-RGA, D.I. 50 (D. Del. Feb. 7, 2023); *Duchesnay, Inc. v. Hetero Labs. Ltd.*, C.A. No. 21-1130-LPS, D.I. 11 (D. Del. Oct. 18, 2021).

50. In the alternative, this Court has personal jurisdiction over Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hoster Labs Private Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) AbbVie's claims arise under federal law; (b) Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hoster Labs Private Limited are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hoster Labs Private Limited have sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Hetero's ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hoster Labs Private Limited satisfies due process.

51. Venue is proper in this district for Hetero USA, Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware.

52. Venue is proper in this district for Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hoster Labs Private Limited pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hoster Labs Private Limited are corporations organized and existing under the laws of India and may be sued in any judicial district.

53. Hetero USA, Inc., Hetero Labs Limited, and Hetero Labs Limited Unit-V did not contest personal jurisdiction or venue in this judicial district in response to the complaint Plaintiff filed in *AbbVie Inc. v. Hetero USA, Inc. et al*, C.A. No. 23-1332 (MN) (D. Del.). Hetero USA, Inc., Hetero Labs Limited, and Hetero Labs Limited Unit-V asserted counterclaims invoking this Court's jurisdiction in their answer to that complaint.

Aurobindo

54. This Court has personal jurisdiction over Aurobindo Pharma USA, Inc. because Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware. Aurobindo Pharma USA, Inc. is registered to do business as a domestic corporation in Delaware (File Number 3769913).

55. Additionally, this Court has personal jurisdiction over Aurobindo Pharma Ltd. because, on information and belief, Aurobindo Pharma Ltd., *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Aurobindo's ANDA Products in the State of Delaware upon approval of ANDA No. 218866.

56. On information and belief, Aurobindo is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Aurobindo manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

57. On information and belief, Aurobindo is licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

58. Aurobindo has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to AbbVie, which manufactures and markets RINVOQ® for sale and use throughout the United States, including in this judicial district. On information and belief and as indicated by a letter

dated October 13, 2023 sent by Aurobindo to AbbVie pursuant to 21 U.S.C. § 355(j)(2)(B), Aurobindo prepared and filed its ANDA with the intention of seeking to market Aurobindo's ANDA Products nationwide, including within this judicial district.

59. On information and belief, Aurobindo plans to sell the Aurobindo ANDA Products in the State of Delaware, list the Aurobindo ANDA Products on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the Aurobindo ANDA Products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos. On information and belief, Aurobindo knows and intends that the Aurobindo ANDA Products will be distributed and sold in Delaware and will thereby displace sales of RINVOQ®, causing injury to AbbVie. Aurobindo intends to take advantage of its established channels of distribution in Delaware for the sale of the Aurobindo ANDA Products.

60. Aurobindo Pharma Ltd. regularly invokes the jurisdiction of the courts of this judicial district by pleading claims and counterclaims in pharmaceutical patent infringement actions in this judicial district. *See, e.g.*, *Taiho Pharmaceutical Co., Ltd. et al. v. Eugia Pharma Specialities Limited et al.*, C.A. No. 23-1193-CFC, D.I. 10 (D. Del. Oct. 30, 2023); *Taiho Pharmaceutical Co., Ltd. et al. v. Eugia Pharma Specialities Limited et al.*, C.A. No. 22-1611-CFC, D.I. 9 (D. Del. Jan. 3, 2023); *Acadia Pharmaceuticals Inc. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 20-985-RGA, D.I. 215 (D. Del. June 15, 2022). Aurobindo Pharma Ltd. has also not contested personal jurisdiction or venue in pharmaceutical patent litigation in this judicial district. *See, e.g.*, *Taiho Pharmaceutical Co., Ltd. et al. v. Eugia Pharma Specialities Limited et al.*, C.A. No. 23-1193-CFC, D.I. 10 (D. Del. Oct. 30, 2023); *Taiho Pharmaceutical Co., Ltd. et al. v. Eugia Pharma Specialities Limited et al.*, C.A. No. 22-01611-CFC, D.I. 9 (D. Del. Jan. 3, 2023); *Acadia*

Pharmaceuticals Inc. v. Aurobindo Pharma Ltd. et al., C.A. No. 20-985-RGA, D.I. 215 (D. Del. June 15, 2022).

61. In the alternative, this Court has personal jurisdiction over Aurobindo Pharma Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) AbbVie's claims arise under federal law; (b) Aurobindo Pharma Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Aurobindo Pharma Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Aurobindo's ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Aurobindo Pharma Ltd. satisfies due process.

62. Venue is proper in this district for Aurobindo Pharma USA, Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware.

63. Venue is proper in this district for Aurobindo Pharma Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India and may be sued in any judicial district.

64. Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. did not contest personal jurisdiction or venue in this judicial district in response to the complaint Plaintiff filed in *AbbVie Inc. v. Hetero USA, Inc. et al*, C.A. No. 23-1332 (MN) (D. Del.). Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. asserted counterclaims invoking this Court's jurisdiction in their answer to that complaint.

Sun

65. This Court has personal jurisdiction over Sun because, on information and belief, Sun, *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly

conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Sun's ANDA Product in the State of Delaware upon approval of ANDA No. 217611.

66. On information and belief, Sun is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Sun manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

67. On information and belief, Sun is licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

68. Sun has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to AbbVie, which manufactures and markets RINVOQ® for sale and use throughout the United States, including in this judicial district. On information and belief and as indicated by a letter dated October 9, 2023 sent by Sun to AbbVie pursuant to 21 U.S.C. § 355(j)(2)(B), Sun prepared and filed its ANDA with the intention of seeking to market Sun's ANDA Product nationwide, including within this judicial district.

69. On information and belief, Sun plans to sell the Sun ANDA Product in the State of Delaware, list the Sun ANDA Product on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the Sun ANDA Product in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

70. On information and belief, Sun knows and intends that the Sun ANDA Product will be distributed and sold in Delaware and will thereby displace sales of RINVOQ®, causing injury to AbbVie. Sun intends to take advantage of its established channels of distribution in Delaware for the sale of the Sun ANDA Product.

71. Sun regularly invokes the jurisdiction of the courts of this judicial district by pleading claims and counterclaims in pharmaceutical patent infringement actions in this judicial district. *See, e.g.*, *Vertex Pharmaceuticals Incorporated v. Sun Pharmaceutical Industries Limited*, C.A. No. 23-666-RGA-CJB (D. Del. Jul. 14, 2023); *Novo Nordisk Inc. et al. v. Orbicular Pharmaceutical Technologies Pvt. Ltd., et al.*, C.A. No. 22-856-CFC (consol.), D.I. 146 (D. Del. June 23, 2023); *Novo Nordisk Inc. et al. v. Sun Pharmaceutical Industries Inc. et al.*, C.A. No. 22-897-CFC, D.I. 11 (D. Del. Sept. 13, 2023). Sun has also not contested personal jurisdiction or venue in pharmaceutical patent litigation in this judicial district. *See, e.g.*, *Vertex Pharmaceuticals Incorporated v. Sun Pharmaceutical Industries Limited*, C.A. No. 23-666-RGA-CJB (D. Del. Jul. 14, 2023); *Novo Nordisk Inc. et al. v. Rio Biopharmaceuticals Inc. et al.*, C.A. No. 22-294-CFC (consol.), D.I. 48 (D. Del. Aug. 5, 2022); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Sun Pharmaceutical Industries Limited et al.*, C.A. No. 21-1573-CFC, D.I. 13 (D. Del. Mar. 4, 2022).

72. In the alternative, this Court has personal jurisdiction over Sun because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) AbbVie's claims arise under federal law; (b) Sun is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Sun has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Sun's ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States

including in this judicial district, such that this Court's exercise of jurisdiction over Sun satisfies due process.

73. Venue is proper in this district for Sun pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun is a corporation organized and existing under the laws of India and may be sued in any judicial district.

74. Sun did not contest personal jurisdiction or venue in this judicial district in response to the complaint Plaintiff filed in *AbbVie Inc. v. Hetero USA, Inc. et al*, C.A. No. 23-1332 (MN) (D. Del.).

THE ASSERTED PATENTS

75. The RE'221 Patent, entitled "Tricyclic compounds," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on February 5, 2019. The RE'221 Patent is a reissue of U.S. Patent No. 8,426,411, which originally issued on April 23, 2013. A true and correct copy of the RE'221 Patent is attached hereto as Exhibit A. The RE'221 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

76. The '629 Patent, entitled "Tricyclic compounds," was duly and lawfully issued by the USPTO on February 24, 2015. A true and correct copy of the '629 Patent is attached hereto as Exhibit B. The '629 Patent is listed in the Orange Book for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

77. The '077 Patent, entitled "Processes for the preparation of (3S,4R)-3-ethyl-4-(3H-imidazo[1,2-α]pyrrolo[2,3-e]-pyrazin-8-yl)-n-(2,2,2-trifluoroethyl)pyrrolidine-1-carboxamide and solid state forms thereof," was duly and lawfully issued by the USPTO on May 7, 2024. A true and correct copy of the '077 Patent is attached hereto as Exhibit C. The '077 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

78. The ’605 Patent, entitled “Processes for the preparation of (3S,4R)-3-ethyl-4-(3H-imidazo[1,2-a]pyrrolo[2,3-e]-pyrazin-8-yl)-n-(2,2,2-trifluoroethyl)pyrrolidine-1-carboxamide and solid state forms thereof,” was duly and lawfully issued by the USPTO on May 28, 2024. A true and correct copy of the ’605 Patent is attached hereto as Exhibit D. The ’605 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

79. The ’606 Patent, entitled “Processes for the preparation of (3S,4R)-3-ethyl-4-(3H-imidazo[1,2-a]pyrrolo[2,3-e]-pyrazin-8-yl)-n-(2,2,2-trifluoroethyl)pyrrolidine-1-carboxamide and solid state forms thereof,” was duly and lawfully issued by the USPTO on May 28, 2024. A true and correct copy of the ’606 Patent is attached hereto as Exhibit E. The ’606 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

HETERO’S ANDA NO. 218859

80. Hetero has submitted ANDA No. 218859 (“Hetero’s ANDA”) which seeks approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of purported generic versions of RINVOQ® 15 mg, 30 mg, and 45 mg tablets (“Hetero’s ANDA Products” or “the Hetero ANDA Products”) prior to the expiration of, *inter alia*, the RE’221, ’629, ’077, ’605, and ’606 Patents.

81. On information and belief, FDA has not approved Hetero’s ANDA.

82. Hetero sent AbbVie a Notice Letter dated June 27, 2024. Hetero’s Notice Letter represented that Hetero had submitted to FDA ANDA No. 218859 and a purported Paragraph IV certification with respect to, *inter alia*, the RE’221, ’629, and ’077 Patents, which are listed in the Orange Book for RINVOQ®.

83. According to applicable regulations, Notice Letters such as Hetero’s must contain a detailed statement of the factual and legal basis for the applicant’s opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing “for

each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

84. For at least one claim of each of the RE'221, '629, and '077 Patents, Hetero's Notice Letter dated June 27, 2024 failed to allege that its ANDA Products or the proposed administration of those Products would not meet the limitations of that claim.

85. On information and belief, if FDA approves Hetero's ANDA, Hetero will manufacture, offer for sale, or sell its ANDA Products, within the United States, including within the State of Delaware, or will import its ANDA Products into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Hetero's ANDA Products will directly infringe the RE'221, '629, '077, '605, and '606 Patents, either literally or under the doctrine of equivalents, and Hetero will actively induce and/or contribute to the infringement of the patent.

86. This action is being brought within forty-five days of AbbVie's receipt of Hetero's Notice Letter dated June 27, 2024. Accordingly, AbbVie is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and 21 U.S.C. § 355(j)(5)(F)(ii) until February 16, 2027 due to RINVOQ®'s New Chemical Entity status.

AUROBINDO'S ANDA NO. 218866

87. Aurobindo has submitted ANDA No. 218866 ("Aurobindo's ANDA") which seeks approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of purported generic versions of RINVOQ® 15 mg and 30 mg tablets ("Aurobindo's ANDA Products" or "the Aurobindo ANDA Products") prior to the expiration of, *inter alia*, the '077, '605, and '606 Patents.

88. On information and belief, FDA has not approved Aurobindo's ANDA.

89. Aurobindo sent AbbVie a Notice Letter dated August 7, 2024. Aurobindo's Notice Letter dated August 7, 2024 represented that Aurobindo had submitted to FDA ANDA No. 218866 and a purported Paragraph IV certification with respect to the '077, '605, and '606 Patents, which are listed in the Orange Book for RINVOQ®. None of Aurobindo's Notice Letters (dated October 13, 2023, January 23, 2024, and August 7, 2024) represented that Aurobindo submitted a Paragraph IV certification for the RE'221 or '629 Patents, which cover the compound upadacitinib and are listed in the Orange Book for RINVOQ® 15 mg, 30 mg, and 45 mg tablets. Accordingly, on information and belief, Aurobindo submitted a Paragraph III certification for the RE'221 or '629 Patents.

90. According to applicable regulations, Notice Letters such as Aurobindo's must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

91. For at least one claim of each of the '077, '605, and '606 Patents, Aurobindo's Notice Letter dated August 7, 2024 failed to allege that its ANDA Products or the proposed administration of those Products would not meet the limitations of that claim.

92. On information and belief, if FDA approves Aurobindo's ANDA, Aurobindo will manufacture, offer for sale, or sell its ANDA Products, within the United States, including within the State of Delaware, or will import its ANDA Products into the United States, including the State

of Delaware. The manufacture, use, offer for sale, sale, or importation of Aurobindo's ANDA Products will directly infringe the '077, '605, and '606 Patents, either literally or under the doctrine of equivalents, and Aurobindo will actively induce and/or contribute to the infringement of those patents.

93. This action is being brought within forty-five days of AbbVie's receipt of Aurobindo's Notice Letter dated August 7, 2024.

SUN'S ANDA NO. 217611

94. Sun has submitted ANDA No. 217611 ("Sun's ANDA") which seeks approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of purported generic versions of RINVOQ® 15 mg tablets ("Sun's ANDA Product" or "the Sun ANDA Product") prior to the expiration of, *inter alia*, the '077 and '605 Patents.

95. On information and belief, FDA has not approved Sun's ANDA.

96. Sun sent AbbVie a Notice Letter dated June 24, 2024. Sun's Notice Letter represented that Sun had submitted to FDA ANDA No. 217611 and a purported Paragraph IV certification with respect to, *inter alia*, the '077 Patent, which is listed in the Orange Book for RINVOQ®.

97. According to applicable regulations, Notice Letters such as Sun's must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

98. For at least one claim of the ’077 Patent, Sun’s Notice Letter dated June 24, 2024 failed to allege that its ANDA Product or the proposed administration of that Product would not meet the limitations of that claim.

99. On information and belief, if FDA approves Sun’s ANDA, Sun will manufacture, offer for sale, or sell its ANDA Product, within the United States, including within the State of Delaware, or will import its ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Sun’s ANDA Product will directly infringe the ’077 and ’605 Patents, either literally or under the doctrine of equivalents, and Sun will actively induce and/or contribute to the infringement of the patent.

100. This action is being brought within forty-five days of AbbVie’s receipt of Sun’s Notice Letter dated June 24, 2024.

COUNT 1 — INFRINGEMENT OF THE RE’221 PATENT BY HETERO

101. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

102. On information and belief, Hetero has submitted or caused the submission of Hetero’s ANDA to FDA, and thereby seeks FDA approval of Hetero’s ANDA Products.

103. AbbVie owns all rights, title, and interest in and to the RE’221 Patent.

104. Hetero’s ANDA Products infringe one or more claims of the RE’221 Patent.

105. Hetero did not contest infringement of claims 13–14 of the RE’221 Patent in Hetero’s Notice Letter dated June 27, 2014. If Hetero had a factual or legal basis to contest infringement of the claims of the RE’221 Patent, it was required by applicable regulations to state such a basis in the Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

106. Hetero has infringed one or more claims of the RE’221 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Hetero’s ANDA with a Paragraph IV certification and thereby seeking

FDA approval of a purported generic version of RINVOQ® prior to the expiration of the RE'221 Patent.

107. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the RE'221 Patent would infringe one or more claims of the RE'221 Patent under 35 U.S.C. § 271(a), and/or Hetero would induce the infringement of and/or contribute to the infringement of one or more claims of the RE'221 Patent under 35 U.S.C. § 271(b) and/or (c).

108. Hetero had actual and constructive notice of the RE'221 Patent prior to submitting Hetero's ANDA, and was aware that the submission of Hetero's ANDA with the request for FDA approval prior to the expiration of the RE'221 Patent would constitute an act of infringement of the RE'221 Patent.

109. Hetero filed its ANDA without adequate justification for asserting that the RE'221 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Product. Hetero's conduct in certifying invalidity and/or non-infringement with respect to the RE'221 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles AbbVie to recovery of its attorneys' fees and such other relief as this Court deems proper.

110. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the RE'221 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Hetero, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 2 — INFRINGEMENT OF THE '629 PATENT BY HETERO

111. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

112. On information and belief, Hetero has submitted or caused the submission of Hetero's ANDA to FDA, and thereby seeks FDA approval of Hetero's ANDA Product.

113. AbbVie owns all rights, title, and interest in and to the '629 Patent.

114. Hetero's ANDA Product infringes one or more claims of the '629 Patent.

115. Hetero did not contest infringement of claims 1–53 of the '629 Patent in Hetero's Notice Letter dated June 27, 2024. If Hetero had a factual or legal basis to contest infringement of the claims of the '629 Patent, it was required by applicable regulations to state such a basis in the Notice Letter. *See* 21 C.F.R. § 314.95(c)(7); 21 C.F.R. § 314.52.

116. Hetero has infringed one or more claims of the '629 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Hetero's ANDA with a Paragraph IV certification and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '629 Patent.

117. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '629 Patent would infringe one or more claims of the '629 Patent under 35 U.S.C. § 271(a), and/or Hetero would induce the infringement of and/or contribute to the infringement of one or more claims of the '629 Patent under 35 U.S.C. § 271(b) and/or (c).

118. Hetero had actual and constructive notice of the '629 Patent prior to submitting Hetero's ANDA, and was aware that the submission of Hetero's ANDA with the request for FDA approval prior to the expiration of the '629 Patent would constitute an act of infringement of the '629 Patent.

119. Hetero filed its ANDA without adequate justification for asserting that the '629 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Product. Hetero's conduct in certifying invalidity and/or non-infringement with respect to the '629 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles AbbVie to recovery of its attorneys' fees and such other relief as this Court deems proper.

120. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '629 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Hetero, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 3 — INFRINGEMENT OF THE '077 PATENT BY HETERO

121. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

122. On information and belief, Hetero has submitted or caused the submission of Hetero's ANDA to FDA, and thereby seeks FDA approval of Hetero's ANDA Products.

123. AbbVie owns all rights, title, and interest in and to the '077 Patent.

124. Hetero's 15 mg ANDA Product infringes one or more claims of the '077 Patent.

125. Hetero has infringed one or more claims of the '077 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Hetero's ANDA with a Paragraph IV certification and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '077 Patent.

126. The importation, manufacture, sale, offer for sale, or use of Hetero's 15 mg ANDA Product prior to the expiration of the '077 Patent would infringe one or more claims of the '077

Patent under 35 U.S.C. § 271(a), and/or Hetero would induce the infringement of and/or contribute to the infringement of one or more claims of the '077 Patent under 35 U.S.C. § 271(b) and/or (c).

127. On information and belief, Hetero filed its ANDA without adequate justification for asserting that the '077 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's 15 mg ANDA Product. Hetero's conduct in certifying invalidity and/or non-infringement with respect to the '077 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles AbbVie to recovery of its attorneys' fees and such other relief as this Court deems proper.

128. On information and belief, AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '077 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Hetero, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 4 — INFRINGEMENT OF THE '605 PATENT BY HETERO

129. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

130. On information and belief, Hetero has submitted or caused the submission of Hetero's ANDA to FDA, and thereby seeks FDA approval of Hetero's ANDA Products.

131. AbbVie owns all rights, title, and interest in and to the '605 Patent.

132. Hetero's Notice Letter dated October 16, 2023 indicates that with respect to its 15 mg ANDA Product it seeks approval for, *inter alia*, the treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.

133. On information and belief, Hetero's 15 mg ANDA Product infringes one or more claims of the '605 Patent.

134. On information and belief, Hetero has infringed one or more claims of the '605 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Hetero's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '605 Patent.

135. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA 15 mg Product prior to the expiration of the '605 Patent would infringe one or more claims of the '605 Patent under 35 U.S.C. § 271(a), and/or Hetero would induce the infringement of and/or contribute to the infringement of one or more claims of the '605 Patent under 35 U.S.C. § 271(b) and/or (c).

136. On information and belief, Hetero has actual and constructive notice of the '605 Patent, and is aware that the submission of Hetero's ANDA with the request for FDA approval prior to the expiration of the '605 Patent would constitute an act of infringement of the '605 Patent.

137. On information and belief, Hetero is without adequate justification for asserting that the '605 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA 15 mg Product. Any assertion by Hetero of invalidity and/or non-infringement with respect to the '605 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles AbbVie to recovery of its attorneys' fees and such other relief as this Court deems proper.

138. On information and belief, AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '605 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Hetero, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 5 — INFRINGEMENT OF THE '606 PATENT BY HETERO

139. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

140. On information and belief, Hetero has submitted or caused the submission of Hetero's ANDA to FDA, and thereby seeks FDA approval of Hetero's ANDA Products.

141. AbbVie owns all rights, title, and interest in and to the '606 Patent.

142. Hetero's Notice Letter dated October 16, 2023 indicates that with respect to its 15 mg ANDA Product it seeks approval for, *inter alia*, the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy.

143. On information and belief, Hetero's 15 mg ANDA Product infringes one or more claims of the '606 Patent.

144. On information and belief, Hetero has infringed one or more claims of the '606 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Hetero's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '606 Patent.

145. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's 15 mg ANDA Product prior to the expiration of the '606 Patent would infringe one or more claims of the '606 Patent under 35 U.S.C. § 271(a), and/or Hetero would induce the infringement of and/or contribute to the infringement of one or more claims of the '606 Patent under 35 U.S.C. § 271(b) and/or (c).

146. On information and belief, Hetero has actual and constructive notice of the '606 Patent, and is aware that the submission of Hetero's ANDA with the request for FDA approval prior to the expiration of the '606 Patent would constitute an act of infringement of the '606 Patent.

147. On information and belief, Hetero is without adequate justification for asserting that the ’606 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero’s 15 mg ANDA Product. Any assertion by Hetero of invalidity and/or non-infringement with respect to the ’606 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles AbbVie to recovery of its attorneys’ fees and such other relief as this Court deems proper.

148. On information and belief, AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the ’606 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Hetero, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 6 — INFRINGEMENT OF THE ’077 PATENT BY AUROBINDO

149. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

150. On information and belief, Aurobindo has submitted or caused the submission of Aurobindo ’s ANDA to FDA, and thereby seeks FDA approval of Aurobindo’s ANDA Products.

151. AbbVie owns all rights, title, and interest in and to the ’077 Patent.

152. Aurobindo’s 15 mg ANDA Product infringes one or more claims of the ’077 Patent.

153. Aurobindo has infringed one or more claims of the ’077 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo’s ANDA with a Paragraph IV certification and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the ’077 Patent.

154. The importation, manufacture, sale, offer for sale, or use of Aurobindo’s 15 mg ANDA Product prior to the expiration of the ’077 Patent would infringe one or more claims of the

'077 Patent under 35 U.S.C. § 271(a), and/or Aurobindo would induce the infringement of and/or contribute to the infringement of one or more claims of the '077 Patent under 35 U.S.C. § 271(b) and/or (c).

155. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '077 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's 15 mg ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '077 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles AbbVie to recovery of its attorneys' fees and such other relief as this Court deems proper.

156. On information and belief, AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '077 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Aurobindo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 7 — INFRINGEMENT OF THE '605 PATENT BY AUROBINDO

157. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

158. On information and belief, Aurobindo has submitted or caused the submission of Aurobindo 's ANDA to FDA, and thereby seeks FDA approval of Aurobindo's ANDA Products.

159. AbbVie owns all rights, title, and interest in and to the '605 Patent.

160. Aurobindo's 15 mg ANDA Product infringes one or more claims of the '605 Patent.

161. Aurobindo has infringed one or more claims of the '605 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA with a Paragraph IV certification and thereby

seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '605 Patent.

162. The importation, manufacture, sale, offer for sale, or use of Aurobindo's 15 mg ANDA Product prior to the expiration of the '605 Patent would infringe one or more claims of the '605 Patent under 35 U.S.C. § 271(a), and/or Aurobindo would induce the infringement of and/or contribute to the infringement of one or more claims of the '605 Patent under 35 U.S.C. § 271(b) and/or (c).

163. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '605 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's 15 mg ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '605 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles AbbVie to recovery of its attorneys' fees and such other relief as this Court deems proper.

164. On information and belief, AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '605 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Aurobindo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 8 — INFRINGEMENT OF THE '606 PATENT BY AUROBINDO

165. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

166. On information and belief, Aurobindo has submitted or caused the submission of Aurobindo 's ANDA to FDA, and thereby seeks FDA approval of Aurobindo's ANDA Products.

167. AbbVie owns all rights, title, and interest in and to the '606 Patent.

168. Aurobindo's 15 mg ANDA Product infringes one or more claims of the '606 Patent.

169. Aurobindo has infringed one or more claims of the '606 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA with a Paragraph IV certification and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '606 Patent.

170. The importation, manufacture, sale, offer for sale, or use of Aurobindo's 15 mg ANDA Product prior to the expiration of the '606 Patent would infringe one or more claims of the '606 Patent under 35 U.S.C. § 271(a), and/or Aurobindo would induce the infringement of and/or contribute to the infringement of one or more claims of the '606 Patent under 35 U.S.C. § 271(b) and/or (c).

171. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '606 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's 15 mg ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '606 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles AbbVie to recovery of its attorneys' fees and such other relief as this Court deems proper.

172. On information and belief, AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '606 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Aurobindo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 9 — INFRINGEMENT OF THE '077 PATENT BY SUN

173. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

174. On information and belief, Sun has submitted or caused the submission of Sun's ANDA to FDA, and thereby seeks FDA approval of Sun's ANDA Product.

175. AbbVie owns all rights, title, and interest in and to the '077 Patent.

176. Sun's ANDA Product infringes one or more claims of the '077 Patent.

177. Sun has infringed one or more claims of the '077 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sun's ANDA with a Paragraph IV certification and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '077 Patent.

178. The importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '077 Patent would infringe one or more claims of the '077 Patent under 35 U.S.C. § 271(a), and/or Sun would induce the infringement of and/or contribute to the infringement of one or more claims of the '077 Patent under 35 U.S.C. § 271(b) and/or (c).

179. Sun filed its ANDA without adequate justification for asserting that the '077 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sun's ANDA Product. Sun's conduct in certifying invalidity and/or non-infringement with respect to the '077 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles AbbVie to recovery of its attorneys' fees and such other relief as this Court deems proper.

180. AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the '077 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sun, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 10 — INFRINGEMENT OF THE '605 PATENT BY SUN

181. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

182. On information and belief, Sun has submitted or caused the submission of Sun's ANDA to FDA, and thereby seeks FDA approval of Sun's ANDA Product.

183. AbbVie owns all rights, title, and interest in and to the '605 Patent.

184. Sun's Notice Letter dated June 24, 2024 indicates that its ANDA seeks approval for the treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers.

185. On information and belief, Sun's ANDA Product infringes one or more claims of the '605 Patent.

186. On information and belief, Sun has infringed one or more claims of the '605 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sun's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '605 Patent.

187. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '605 Patent would infringe one or more claims of the '605 Patent under 35 U.S.C. § 271(a), and/or Sun would induce the infringement of and/or contribute to the infringement of one or more claims of the '605 Patent under 35 U.S.C. § 271(b) and/or (c).

188. On information and belief, Sun has actual and constructive notice of the '605 Patent, and is aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '605 Patent would constitute an act of infringement of the '605 Patent.

189. On information and belief, Sun is without adequate justification for asserting that the '605 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture,

use, offer for sale, or sale of Sun's ANDA Product. Any assertion by Sun of invalidity and/or non-infringement with respect to the '605 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles AbbVie to recovery of its attorneys' fees and such other relief as this Court deems proper.

190. On information and belief, AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the '605 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sun, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, AbbVie respectfully requests the following relief:

(A) A judgment that Hetero has infringed the RE'221, '629, '077, '605, and '606 Patents under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment that Aurobindo has infringed the '077, '605, and '606 Patents under 35 U.S.C. § 271(e)(2)(A);

(C) A judgment that Sun has infringed the '077 and '605 Patents under 35 U.S.C. § 271(e)(2)(A);

(D) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the last expiration date of any of the RE'221, '629, '077, '605, and '606 Patents, or any later expiration of exclusivity for any of the RE'221, '629, '077, '605, and '606 Patents, including any extensions or regulatory exclusivities;

(E) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Aurobindo's ANDA shall be no earlier than the last expiration date of any

of the ’077, ’605, and ’606 Patents, or any later expiration of exclusivity for any of the ’077, ’605, and ’606 Patents, including any extensions or regulatory exclusivities;

(F) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Sun’s ANDA shall be no earlier than the last expiration date of the ’077 and ’605 Patents, or any later expiration of exclusivity for the ’077 and ’605 Patents, including any extensions or regulatory exclusivities;

(G) A judgment that making, using, selling, offering to sell, or importing Hetero’s accused ANDA Products, or inducing or contributing to such conduct, would constitute infringement of the RE’221, ’629, ’077, ’605, and ’606 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(H) A judgment that making, using, selling, offering to sell, or importing Aurobindo’s 15 mg ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the ’077, ’605, and ’606 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(I) A judgment that making, using, selling, offering to sell, or importing Sun’s ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the ’077 and ’605 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(J) Entry of a permanent injunction enjoining Hetero, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Hetero or on its behalf from commercially manufacturing, using, offering for sale, or selling its accused ANDA Products within the United States, or importing its accused ANDA Products into the United States, until the day after the expiration of the RE’221, ’629, ’077, ’605, and ’606 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the RE’221, ’629, ’077, ’605, and ’606 Patents;

(K) Entry of a permanent injunction enjoining Aurobindo, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Aurobindo or on its behalf from commercially manufacturing, using, offering for sale, or selling its accused ANDA Products within the United States, or importing its accused ANDA Products into the United States, until the day after the expiration of the '077, '605, and '606 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the '077, '605, and '606 Patents;

(L) Entry of a permanent injunction enjoining Sun, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Sun or on its behalf from commercially manufacturing, using, offering for sale, or selling its ANDA Product within the United States, or importing its ANDA Product into the United States, until the day after the expiration of the '077 and '605 Patents, including any additional exclusivity period applicable to the patent, and from otherwise infringing the claims of the '077 and '605 Patents;

(M) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Hetero engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its accused ANDA Products, or any product that infringes the RE'221, '629, '077, '605, and '606 Patents, or induces or contributes to such conduct, prior to the expiration of those patents including any additional exclusivity period applicable to those patents;

(N) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Aurobindo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its accused ANDA Products, or any product that infringes the '077, '605, and '606 Patents, or induces or contributes to such conduct, prior to the expiration of those patents including any additional exclusivity period applicable to those patents;

(O) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Sun engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product, or any product that infringes the '077 and '605 Patents, or induces or contributes to such conduct, prior to the expiration of those patents including any additional exclusivity period applicable to those patents;

(P) A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(Q) Costs and expenses in this action; and

(R) Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

Attorneys for Plaintiff AbbVie Inc.

OF COUNSEL:

Christopher N. Sipes
Erica N. Andersen
Brianne (Bharkhda) Sullivan
Nicholas L. Evoy
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

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