IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
HETERO USA, INC.,	)	
HETERO LABS LIMITED,	)	
HETERO LABS LIMITED UNIT-V,	)	
AUROBINDO PHARMA USA, INC.,	)	
AUROBINDO PHARMA LTD.,	)	
SANDOZ INC.,	)	
SANDOZ PRIVATE LIMITED,	)	
SANDOZ GMBH,	)	
INTAS PHARMACEUTICALS LTD.,	)	
ACCORD HEALTHCARE, INC., and SUN	)	
PHARMACEUTICAL INDUSTRIES, LTD.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff AbbVie Inc. ("AbbVie"), by its undersigned attorneys, brings this action against Defendants Hetero USA, Inc., Hetero Labs Limited, and Hetero Labs Limited Unit-V (collectively, "Hetero"); Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. (collectively, "Aurobindo"); Sandoz Inc., Sandoz Private Limited, and Sandoz GmbH (collectively, "Sandoz"); Intas Pharmaceuticals Ltd. and Accord Healthcare, Inc. (collectively, "Intas"); 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, Sandoz's, Intas'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 United States Patent Nos. RE47,221 ("the RE'221 Patent"); 8,962,629 ("the '629 Patent"); 9,951,080 ("the '080 Patent"); 10,981,923 ("the '923 Patent"); 11,186,584 ("the '584 Patent"); 11,661,425 ("the '425 Patent"); 11,680,069 ("the '069 Patent"); 11,718,627 ("the '627 Patent"); 11,198,697 ("the '697 Patent"); 9,963,459 ("the '459 Patent"); 10,344,036 ("the '036 Patent"); 10,202,393 ("the '393 Patent"); 10,519,164 ("the '164 Patent"); 10,730,883 ("the '883 Patent"); 10,981,924 ("the '924 Patent"); 10,597,400 ("the '400 Patent"); 11,535,624 ("the '624 Patent"); 10,995,095 ("the '095 Patent"); 10,550,126 ("the '126 Patent"); 11,535,625 ("the '625 Patent"); 11,535,626 ("the '626 Patent"); 11,365,198 ("the '198 Patent"); 11,512,092 ("the '092 Patent"); 11,524,964 ("the '964 Patent"); 11,607,411 ("the '411 Patent"); 11,564,922 ("the '922 Patent"); 11,767,326 ("the '326 Patent"); 11,773,105 ("the '105 Patent"); 11,773,106 ("the '106 Patent"); 11,780,847 ("the '847 Patent"); 11,780,848 ("the '848 Patent"); 11,787,815 ("the '815 Patent"); 11,795,175 ("the '175 Patent"); or 9,879,018 ("the '018 Patent") (collectively, "the Patents-in-Suit").

RINVOQ®

2. 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 seven 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.

3. 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.

4. 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®.

5. 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.

6. 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 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.

7. 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.

8. 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

9. 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.

10. AbbVie is the assignee and owner of the Patents-in-Suit.

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

Hetero

12. On information and belief, 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 Ave, Piscataway, NJ 08854.

13. On information and belief, 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.

14. On information and belief, Hetero Labs Limited is the parent company of Defendants Hetero USA, Inc. and Hetero Labs Limited Unit-V.

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

16. On information and belief, 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.

17. On information and belief, Hetero USA, Inc. is the United States regulatory agent for Defendants Hetero Labs Limited and Hetero Labs Limited Unit-V.

18. On information and belief, Hetero Labs Limited Unit-V filed Hetero's ANDA No. 218859 with FDA.

19. On information and belief, Hetero's practice is for ANDAs to be submitted to FDA in the name of the specific manufacturing site at Hetero for such ANDA. On information and belief, the specific manufacturing site for Hetero's ANDA No. 218859 is Defendant Hetero Labs Limited Unit-V.

20. On information and belief, Hetero USA, Inc., Hetero Labs Limited, and Hetero Labs Limited Unit-V collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Hetero USA, Inc., Hetero Labs Limited, and Hetero Labs Limited Unit-V 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.

21. On information and belief, Hetero caused ANDA No. 218859 to be submitted to FDA and seeks FDA approval of ANDA No. 218859.

22. On information and belief, Hetero USA, Inc., Hetero Labs Limited, and Hetero Labs Limited Unit-V 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.

23. 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.

24. On information and belief, Hetero USA, Inc., Hetero Labs Limited, and Hetero Labs Limited Unit-V 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 USA, Inc., Hetero Labs Limited, and Hetero Labs Limited Unit-V

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

25. On information and belief, 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. On information and belief, Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd.

26. On information and belief, 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.

27. 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.

28. On information and belief, Aurobindo caused ANDA No. 218866 to be submitted to FDA and seeks FDA approval of ANDA No. 218866.

29. 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.

30. 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.

31. 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.

Sandoz

32. On information and belief, Defendant Sandoz Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 100 College Road West, Princeton, NJ 08540.

33. On information and belief, Defendant Sandoz Private Limited is a private limited liability company organized and existing under the laws of India, having a principal place of business at Plot No. 8-A/2 and 8-B, TTC Industrial Area Kalwe Block, Village Dighe, Navi Mumbai, Maharashtra 400 708, India.

34. On information and belief, Defendant Sandoz GmbH is a corporation organized and existing under the laws of the Republic of Austria, having a principal place of business at Biochemiestrasse 10, Kundl, Tyrol A-6250, Austria.

35. On information and belief, Sandoz Inc., Sandoz Private Limited, and Sandoz GmbH collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Sandoz Inc., Sandoz Private Limited, and Sandoz GmbH 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.

36. On information and belief, Sandoz caused ANDA No. 218792 to be submitted to FDA and seeks FDA approval of ANDA No. 218792.

37. On information and belief, Sandoz Inc., Sandoz Private Limited, and Sandoz GmbH acted collaboratively in the preparation of ANDA No. 218792 and continue to act collaboratively in pursuing FDA approval of ANDA No. 218792 and seeking to market the Sandoz ANDA Products.

38. On information and belief, Sandoz intends to commercially manufacture, market, offer for sale, and sell the Sandoz ANDA Products throughout the United States, including in the State of Delaware, in the event FDA approves ANDA No. 218792.

39. On information and belief, Sandoz Inc., Sandoz Private Limited, and Sandoz GmbH 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, Sandoz Inc., Sandoz Private Limited, and Sandoz GmbH intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Sandoz's ANDA Products, in the event FDA approves ANDA No. 218792.

Intas

40. On information and belief, Defendant Intas Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Corporate House, Near Sola Bridge, S.G. Highway, Thaltej, Ahmedabad, Gujarat 380 054, India.

41. On information and belief, Defendant Accord Healthcare, Inc. is a corporation organized and existing under the laws of the State of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210-B, Durham, NC 27703.

42. On information and belief, Intas Pharmaceuticals Ltd. and Accord Healthcare, Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Intas Pharmaceuticals Ltd. and Accord Healthcare, Inc. 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.

43. On information and belief, Intas caused ANDA No. 218940 to be submitted to FDA and seeks FDA approval of ANDA No. 218940.

44. On information and belief, Intas Pharmaceuticals Ltd. and Accord Healthcare, Inc. acted collaboratively in the preparation of ANDA No. 218940 and continue to act collaboratively in pursuing FDA approval of ANDA No. 218940 and seeking to market the Intas ANDA Products.

45. On information and belief, Intas intends to commercially manufacture, market, offer for sale, and sell the Intas ANDA Products throughout the United States, including in the State of Delaware, in the event FDA approves ANDA No. 218940.

46. On information and belief, Intas Pharmaceuticals Ltd. and Accord Healthcare, Inc. 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, Intas Pharmaceuticals Ltd. and Accord Healthcare, Inc. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Intas's ANDA Products, in the event FDA approves ANDA No. 218940.

Sun

47. On information and belief, 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.

48. On information and belief, Sun caused ANDA No. 217611 to be submitted to FDA and seeks FDA approval of ANDA No. 217611.

49. 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

50. 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.

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

Hetero

52. 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).

53. Additionally, this Court has personal jurisdiction over Hetero Labs Limited and Hetero Labs Limited Unit-V 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.

54. 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.

55. 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.

56. 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.

57. 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.

58. 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.

59. 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).

60. In the alternative, this Court has personal jurisdiction over Hetero Labs Limited and Hetero Labs Limited Unit-V 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 and Hetero Labs Limited Unit-V are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Labs Limited and Hetero Labs Limited Unit-V 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 and Hetero Labs Limited Unit-V satisfies due process.

61. 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.

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

Aurobindo

63. 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. On information and belief, Aurobindo Pharma USA, Inc. is registered to do business as a domestic corporation in Delaware (File Number 3769913).

64. 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.

65. 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.

66. 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.

67. 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.

68. 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.

69. 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.

70. 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).

71. 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.

72. 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.

73. 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.

Sandoz

74. This Court has personal jurisdiction over Sandoz Inc. because it is a corporation organized and existing under the laws of Delaware. On information and belief, Sandoz Inc. is registered to do business as a domestic corporation in Delaware (File Number 7944830).

75. Additionally, this Court has personal jurisdiction over Sandoz Private Limited and Sandoz GmbH 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 Sandoz's ANDA Products in the State of Delaware upon approval of ANDA No. 218792.

76. On information and belief, Sandoz 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 Sandoz manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

77. On information and belief, Sandoz 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.

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

79. On information and belief, Sandoz plans to sell the Sandoz ANDA Products in the State of Delaware, list the Sandoz ANDA Products on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the Sandoz ANDA Products in the State

of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

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

81. Sandoz Inc. 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.*, *Astellas Pharma Inc. et al. v. Lupin Ltd. et al.*, C.A. No. 23-819-GBW-CJB, D.I. 22 (D. Del. Aug. 23, 2023); *AbbVie Inc. et al. v. Alkem Laboratories Limited et al.*, C.A. No. 22-1423-RGA, D.I. 43 (D. Del. Feb. 6, 2023); *Array BioPharma, Inc. v. Sandoz Inc.*, C.A. No. 22-1316-GBW, D.I. 12 (D. Del. Nov. 2, 2022). Sandoz Inc. has also not contested personal jurisdiction or venue in pharmaceutical patent litigation in this judicial district. *See, e.g.*, *Astellas Pharma Inc. et al. v. Lupin Ltd. et al.*, C.A. No. 23-819-GBW-CJB, D.I. 22 (D. Del. Aug. 23, 2023); *AbbVie Inc. et al. v. Alkem Laboratories Limited et al.*, C.A. No. 22-1423-RGA, D.I. 43 (D. Del. Feb. 6, 2023); *Array BioPharma, Inc. v. Sandoz Inc.*, C.A. No. 22-1316-GBW, D.I. 12 (D. Del. Nov. 2, 2022).

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

83. Venue is proper in this district for Sandoz Private Limited and Sandoz GmbH pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, each is a corporation organized and existing under foreign law and may be sued in any judicial district.

Intas

84. By email dated November 13, 2023, through their counsel, Intas Pharmaceuticals Ltd. and Accord Healthcare, Inc. consented to personal jurisdiction and venue in this judicial district for purposes of this matter.

85. Additionally, this Court has personal jurisdiction over Intas because, on information and belief, Intas, *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 Intas's ANDA Products in the State of Delaware upon approval of ANDA No. 218940.

86. On information and belief, Intas 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 Intas manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

87. On information and belief, Intas 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.

88. Intas 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 12, 2023 sent by Intas to AbbVie pursuant to 21 U.S.C. § 355(j)(2)(B), Intas prepared and filed its ANDA with the intention of seeking to market Intas's ANDA Products nationwide, including within this judicial district.

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

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

91. Intas Pharmaceuticals 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.*, *Veloxis Pharmaceuticals, Inc. v. Accord Healthcare, Inc. et al.*, C.A. No. 22-909-JDW, D.I. 25 (D. Del. Nov. 4, 2022); *Eagle Pharmaceuticals, Inc. v. Accord Healthcare Inc. et al.*, C.A. No. 22-704-CFC, D.I. 11 (D. Del. July 20, 2022); *Cephalon, Inc. v. Accord Healthcare, Inc. et al.*, C.A. No. 13-2095-GMS D.I. 12 (D. Del. Apr. 8, 2014). Intas Pharmaceuticals Ltd. has also not contested personal jurisdiction or venue in pharmaceutical patent litigation in this judicial district. *See, e.g.*, *Veloxis Pharmaceuticals, Inc. v. Accord Healthcare, Inc. et al.*, C.A. No. 22-909-JDW, D.I. 25 (D. Del. Nov. 4, 2022); *Eagle Pharmaceuticals, Inc. v. Accord Healthcare Inc. et al.*, C.A. No. 22-704-CFC, D.I. 11 (D. Del. July 20, 2022).

92. Accord Healthcare, Inc. 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.*, *Veloxis Pharmaceuticals, Inc. v. Accord Healthcare, Inc. et al.*, C.A. No. 22-909-JDW, D.I. 25 (D. Del. Nov. 4, 2022); *Novartis Pharmaceuticals Corporation et al. v. Accord Healthcare Inc. et al.*, C.A. No. 22-744-MN, D.I. 19 (D. Del.

Aug. 8, 2022); *Eagle Pharmaceuticals, Inc. v. Accord Healthcare Inc. et al.*, C.A. No. 22-704-CFC, D.I. 11 (D. Del. July 20, 2022); *Teva Pharmaceuticals International GmbH, et al. v. Accord Healthcare Inc. et al.*, C.A. No. 21-952-CFC, D.I. 24 (D. Del. Feb. 10, 2022). Accord Healthcare, Inc. has also not contested personal jurisdiction or venue in pharmaceutical patent litigation in this judicial district. *See, e.g.*, *Veloxis Pharmaceuticals, Inc. v. Accord Healthcare, Inc. et al.*, C.A. No. 22-909-JDW, D.I. 25 (D. Del. Nov. 4, 2022); *Novartis Pharmaceuticals Corporation et al. v. Accord Healthcare Inc. et al.*, C.A. No. 22-744-MN, D.I. 19 (D. Del. Aug. 8, 2022); *Eagle Pharmaceuticals, Inc. v. Accord Healthcare Inc. et al.*, C.A. No. 22-704-CFC, D.I. 11 (D. Del. July 20, 2022). Accord Healthcare, Inc. has also consented to personal jurisdiction and venue in pharmaceutical patent actions in this judicial district. *See, e.g.*, *Veloxis Pharmaceuticals, Inc. v. Accord Healthcare Inc., et al.*, C.A. No. 22-909-JDW, D.I. 25 (D. Del. Nov. 4, 2022); *Teva Pharmaceuticals International GmbH, et al. v. Accord Healthcare Inc. et al.*, C.A. No. 21-952-CFC, D.I. 24 (D. Del. Feb. 10, 2022).

93. In the alternative, this Court has personal jurisdiction over Intas Pharmaceuticals 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) Intas Pharmaceuticals Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Intas Pharmaceuticals Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Intas'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 Intas Pharmaceuticals Ltd. satisfies due process.

94. Venue is proper in this district for Accord Healthcare, Inc. because, *inter alia*, Accord Healthcare, Inc. is subject to this Court's personal jurisdiction as set forth above, and has indicated that it consents to venue in this judicial district for this matter.

95. Venue is proper in this district for Intas Pharmaceuticals Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Intas Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India and may be sued in any judicial district, and has indicated that it consents to venue in this judicial district for this matter.

Sun

96. 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.

97. 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.

98. 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.

99. 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.

100. 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.

101. 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.

102. 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).

103. 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.

104. 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.

THE ASSERTED PATENTS

105. 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.

106. 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.

107. The ’080 Patent, entitled “Processes for the preparation of (3S,4R)-3-ethyl-4-(3H-imidazo[1,2-alpha]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 April 24, 2018. A true and correct copy of the ’080 Patent is attached hereto as Exhibit C. The ’080 Patent is listed in the Orange Book for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

108. The ’923 Patent, entitled “Processes for the preparation of (3S,4R)-3-ethyl-4-(3H-imidazo[l,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 April 20, 2021. A true and correct copy of the ’923 Patent is attached hereto as Exhibit D. The ’923 Patent is listed in the Orange Book for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

109. The ’584 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 November 30, 2021. A true and correct copy of the ’584 Patent is attached hereto as Exhibit E. The ’584 Patent is listed in the Orange Book for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

110. The ’425 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 30, 2023. A true and correct copy of the ’425 Patent is attached hereto as Exhibit F. The ’425 Patent is listed in the Orange Book for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

111. The ’069 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 June 20, 2023.

A true and correct copy of the '069 Patent is attached hereto as Exhibit G. The '069 Patent is listed in the Orange Book for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

112. The '627 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 August 8, 2023. A true and correct copy of the '627 Patent is attached hereto as Exhibit H. The '627 Patent is listed in the Orange Book for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

113. The '697 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 December 14, 2021. A true and correct copy of the '697 Patent is attached hereto as Exhibit I. The '697 Patent is listed in the Orange Book for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

114. The '459 Patent, entitled "Processes for the preparation of (3S,4R)-3-ethyl-4-(3H-imidazo[1,2-alpha]pyrrolo[2,3-e]-pyrazin-8-yl)-N-(2,2,2-trifluoroethyl)pyrrol and solid state forms thereof," was duly and lawfully issued by the USPTO on May 8, 2018. A true and correct copy of the '459 Patent is attached hereto as Exhibit J. The '459 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

115. The '036 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 July 9, 2019. A true and correct copy of the '036 Patent is attached hereto as Exhibit K. The '036 Patent is listed in the Orange Book for RINVOQ® 30 mg tablets.

116. The ’393 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 February 12, 2019. A true and correct copy of the ’393 Patent is attached hereto as Exhibit L. The ’393 Patent is listed in the Orange Book for RINVOQ® 45 mg tablets.

117. The ’164 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 December 31, 2019. A true and correct copy of the ’164 Patent is attached hereto as Exhibit M. The ’629 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

118. The ’883 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 August 4, 2020. A true and correct copy of the ’883 Patent is attached hereto as Exhibit N. The ’883 Patent is listed in the Orange Book for RINVOQ® 30 mg tablets.

119. The ’924 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 April 20, 2021. A true and correct copy of the ’924 Patent is attached hereto as Exhibit O. The ’924 Patent is listed in the Orange Book for RINVOQ® 15 mg and 30 mg tablets.

120. The ’400 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 March 24, 2020.

A true and correct copy of the '400 Patent is attached hereto as Exhibit P. The '400 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

121. The '624 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 December 27, 2022. A true and correct copy of the '624 Patent is attached hereto as Exhibit Q. The '624 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

122. The '095 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 4, 2021. A true and correct copy of the '095 Patent is attached hereto as Exhibit R. The '095 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

123. The '126 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 February 4, 2020. A true and correct copy of the '126 Patent is attached hereto as Exhibit S. The '126 Patent is listed in the Orange Book for RINVOQ® 30 mg tablets.

124. The '625 Patent, entitled "Processes for the preparation of (3S,4R)-3-ethyl-4-(3H-imidazo[1,2-a]-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 December 27, 2022. A true and correct copy of the '625 Patent is attached hereto as Exhibit T. The '625 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

125. The '626 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 December 27, 2022. A true and correct copy of the '626 Patent is attached hereto as Exhibit U. The '626 Patent is listed in the Orange Book for RINVOQ® 30 mg tablets.

126. The '198 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 June 21, 2022. A true and correct copy of the '198 Patent is attached hereto as Exhibit V. The '198 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

127. The '092 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 November 29, 2022. A true and correct copy of the '092 Patent is attached hereto as Exhibit W. The '092 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

128. The '964 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 December 13, 2022. A true and correct copy of the '964 Patent is attached hereto as Exhibit X. The '964 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

129. The '411 Patent, entitled "Methods of treating Crohn's disease and ulcerative colitis," was duly and lawfully issued by the USPTO on March 21, 2023. A true and correct copy

of the ’411 Patent is attached hereto as Exhibit Y. The ’411 Patent is listed in the Orange Book for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

130. The ’922 Patent, entitled “Methods of treating Crohn’s disease and ulcerative colitis,” was duly and lawfully issued by the USPTO on January 31, 2023. A true and correct copy of the ’922 Patent is attached hereto as Exhibit Z. The ’922 Patent is listed in the Orange Book for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

131. The ’326 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 and solid state forms thereof,” was duly and lawfully issued by the USPTO on September 26, 2023. A true and correct copy of the ’326 Patent is attached hereto as Exhibit AA. The ’326 Patent is listed in the Orange Book for RINVOQ® 15 mg and 30 mg tablets.

132. The ’105 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 October 3, 2023. A true and correct copy of the ’105 Patent is attached hereto as Exhibit BB. The ’105 Patent is listed in the Orange Book for RINVOQ® 15 mg, 30 mg, and 45 mg tablets.

133. The ’106 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 October 3, 2023. A true and correct copy of the ’106 Patent is attached hereto as Exhibit CC. The ’106 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

134. The ’847 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 October 10, 2023. A true and correct copy of the '847 Patent is attached hereto as Exhibit DD. The '847 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

135. The '848 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 October 10, 2023. A true and correct copy of the '848 Patent is attached hereto as Exhibit EE. The '848 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

136. The '815 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 October 17, 2023. A true and correct copy of the '815 Patent is attached hereto as Exhibit FF. The '815 Patent is listed in the Orange Book for RINVOQ® 15 mg tablets.

137. The '175 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 October 24, 2023. A true and correct copy of the '175 Patent is attached hereto as Exhibit GG.

138. The '018 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 and solid state forms thereof," was duly and lawfully issued by the USPTO on January 30, 2018. A true and correct copy of the '018 Patent is attached hereto as Exhibit HH.

HETERO'S ANDA NO. 218859

139. 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 the '080, '923, '584, '425, '069, '627, '697, '459, '036, '393, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, '922, '326, '105, '106, '847, '848, '815, '175, and '018 Patents.

140. On information and belief, FDA has not approved Hetero's ANDA.

141. Hetero sent AbbVie a Notice Letter dated October 16, 2023. Hetero's Notice Letter represented that Hetero had submitted to FDA ANDA No. 218859 and a purported Paragraph IV certification with respect to the '080, '923, '584, '425, '069, '627, '697, '459, '036, '393, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, and '922 Patents, which are listed in the Orange Book for RINVOQ®. Hetero's Notice Letter did not represent that Hetero 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, Hetero submitted a Paragraph III certification for the RE'221 or '629 Patents.

142. 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.

143. For at least one claim of each of the '697, '459, '036, '393, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, and '922 Patents, Hetero's Notice Letter failed

to allege that its ANDA Products or the proposed administration of those Products would not meet the limitations of that claim.

144. In Hetero's Notice Letter, Hetero purported to offer confidential access to portions of ANDA No. 218859 on terms and conditions set forth in Hetero's Notice Letter ("the Hetero Offer"). Hetero requested that AbbVie accept the Hetero Offer before receiving access to ANDA No. 218859. The Hetero Offer contained unreasonable restrictions regarding access to its ANDA, well beyond those that would apply under a protective order. The Hetero Offer did not permit AbbVie's in-house counsel or scientific experts to access ANDA No. 218859. Additionally, the Hetero Offer contained provisions that unreasonably restricted the ability of outside counsel receiving access to ANDA No. 218859 to engage in any patent prosecution for AbbVie before the USPTO or in any work before or involving FDA. The restrictions the Hetero Offer placed on access to ANDA No. 218859 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, ***as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information***" (emphasis added).

145. Outside counsel for AbbVie negotiated in good faith with counsel for Hetero in an attempt to reach agreement on reasonable terms of confidential access to Hetero's ANDA. In correspondence dated October 26, 2023, counsel for AbbVie proposed edits to the Hetero Offer consistent with protective orders AbbVie and Hetero have entered into in recent litigation involving similar subject matter, and consistent with the purpose of 21 U.S.C. § 355(j)(5)(C)(i)(III). *See, e.g.*, *AbbVie Inc. et al. v. Alkem Laboratories Limited et al.*, C.A. No. 1:22-cv-01423-RGA-JLH, D.I. 101 (D. Del. May 12, 2023). In such protective orders,

Hetero allowed expert and in-house counsel access to its ANDAs and permitted outside counsel receiving access to engage in certain proceedings before the USPTO.

146. Between November 9, 2023 and November 17, 2023, counsel for AbbVie and counsel for Hetero continued to discuss the conditions of access to Hetero's ANDA. Hetero continued to insist on unreasonable terms, including with respect to the ability of outside counsel receiving access to ANDA No. 218859 to engage in post grant proceedings for AbbVie. Hetero has agreed to allow outside counsel to engage in post grant proceedings in prior Hatch-Waxman actions. *See, e.g.*, *AbbVie Inc. et al. v. Alkem Laboratories Limited et al.*, C.A. No. 1:22-cv-01423-RGA-JLH, D.I. 101 (D. Del. May 12, 2023). To date, AbbVie has not received access to Hetero's ANDA.

147. 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 '080, '923, '584, '425, '069, '627, '697, '459, '036, '393, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, '922, '326, '105, '106, '847, '848, '815, '175, and '018 Patents, either literally or under the doctrine of equivalents, and Hetero will actively induce and/or contribute to the infringement of those patents.

148. This action is being brought within forty-five days of AbbVie's receipt of Hetero's Notice Letter. 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

149. 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 the '080, '923, '584, '425, '069, '627, '697, '459, '036, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '326, '105, '106, '847, '848, '815, '175, and '018 Patents.

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

151. Aurobindo sent AbbVie a Notice Letter dated October 13, 2023. Aurobindo's Notice Letter represented that Aurobindo had submitted to FDA ANDA No. 218866 and a purported Paragraph IV certification with respect to the '080, '923, '584, '425, '069, '627, '697, '459, '036, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, and '964 Patents, which are listed in the Orange Book for RINVOQ®. Aurobindo's Notice Letter did not represent 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.

152. 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.

153. For at least one claim of each of the '923, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, and '964 Patents, Aurobindo's Notice Letter failed to allege that its ANDA Products or the proposed administration of those Products would not meet the limitations of that claim.

154. In Aurobindo's Notice Letter, Aurobindo purported to offer confidential access to portions of ANDA No. 218866 on terms and conditions set forth in Aurobindo's Notice Letter ("the Aurobindo Offer"). Aurobindo requested that AbbVie accept the Aurobindo Offer before receiving access to ANDA No. 218866. The Aurobindo Offer contained unreasonable restrictions regarding access to its ANDA, well beyond those that would apply under a protective order. The Aurobindo Offer did not permit AbbVie's in-house counsel or scientific experts to access ANDA No. 218866. Additionally, the Aurobindo Offer contained provisions that unreasonably restricted the ability of outside counsel receiving access to ANDA No. 218866 to engage in any patent prosecution before the USPTO or in any work before or involving FDA. The restrictions the Aurobindo Offer placed on access to ANDA No. 218866 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, ***as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information***" (emphasis added).

155. Outside counsel for AbbVie negotiated in good faith with counsel for Aurobindo in an attempt to reach agreement on reasonable terms of confidential access to Aurobindo's ANDA. In correspondence dated October 17, 2023, counsel for AbbVie proposed edits to the Aurobindo Offer consistent with protective orders Aurobindo has entered into in recent litigation involving similar subject matter, and consistent with the purpose of 21 U.S.C.

§ 355(j)(5)(C)(i)(III). *See, e.g.*, *Eli Lilly & Co. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 22-1114-CFC (consol.), D.I. 35 (D. Del. Feb. 23, 2023); *Amgen Inc. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 21-662-MN (consolidated), D.I. 33 (D. Del. Oct. 5, 2021). In such protective orders, Aurobindo allowed expert and in-house counsel access to its ANDAs and permitted outside counsel receiving access to engage in certain proceedings before the USPTO.

156. On October 24, 2023, counsel for Aurobindo proposed additional changes to the Aurobindo Offer, which similarly contained unreasonable restrictions on access to Aurobindo's ANDA, and continued to be inconsistent with the provisions of protective orders Aurobindo has agreed to in recent litigation involving similar subject matter. AbbVie and Aurobindo have continued to communicate and exchange edits to the Aurobindo Offer through November 17, 2023, but have been unable to reach agreement on reasonable terms of confidential access to Aurobindo's ANDA prior to the filing of this Complaint. To date, AbbVie has not received access to Aurobindo's ANDA.

157. 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 '080, '923, '584, '425, '069, '627, '697, '459, '036, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '326, '105, '106, '847, '848, '815, '175, and '018 Patents, either literally or under the doctrine of equivalents, and Aurobindo will actively induce and/or contribute to the infringement of those patents.

158. This action is being brought within forty-five days of AbbVie's receipt of Aurobindo's Notice Letter. 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.

SANDOZ'S ANDA NO. 218792

159. Sandoz has submitted ANDA No. 218792 ("Sandoz'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 ("Sandoz's ANDA Products" or "the Sandoz ANDA Products").

160. On information and belief, Sandoz seeks approval to market its 15 mg ANDA Product prior to the expiration of the RE'221, '629, '080, '923, '584, '425, '069, '627, '697, '459, '164, '924, '400, '624, '105, '847, '815, '175, and '018 Patents; and seeks approval to market its 30 mg and 45 mg ANDA Products prior to the expiration of the '425 Patent.

161. On information and belief, FDA has not approved Sandoz's ANDA.

162. Sandoz sent AbbVie a Notice Letter dated October 9, 2023. Sandoz's Notice Letter represented that Sandoz had submitted to FDA ANDA No. 218792.

163. Sandoz's Notice Letter represented that Sandoz's ANDA seeks approval to market generic versions of each dosage strength of RINVOQ®—***15 mg, 30 mg, and 45 mg ANDA Products***.

164. According to Sandoz's Notice Letter, Sandoz submitted a purported Paragraph IV certification with respect to the RE'221, '629, '080, '923, '584, '425, '069, '627, '697, '459, '164, '924, '400, and '624 Patents for its 15 mg ANDA Product.

165. The RE'221, '629, '080, '923, '584, '069, '627, and '697 Patents are listed in the Orange Book for all three dosage strengths of RINVOQ® (15 mg, 30 mg, and 45 mg). But Sandoz indicated in its Notice Letter that the Paragraph IV certifications submitted in connection with its ANDA for these patents are limited only to its 15 mg ANDA Product.

166. On information and belief, with respect to its 30 mg ANDA Product, Sandoz has submitted Paragraph III certifications for Orange Book patents that expire on October 17, 2036. Accordingly, Sandoz cannot receive final FDA approval for its 30 mg ANDA Product prior to October 17, 2036.

167. On information and belief, with respect to its 45 mg ANDA Product, Sandoz has submitted PIII certifications for Orange Book patents that expire on October 17, 2036. Accordingly, Sandoz cannot receive final FDA approval for its 45 mg ANDA Product prior to October 17, 2036.

168. According to applicable regulations, Notice Letters such as Sandoz'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.

169. For at least one claim of each of the RE'221, '629, '164, '924, '400, and '624 Patents, Sandoz's Notice Letter failed to allege that its 15 mg ANDA Product or the proposed administration of that Product would not meet the limitations of that claim.

170. On information and belief, if FDA approves Sandoz's ANDA, Sandoz 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 Sandoz's 15 mg ANDA Product will directly infringe the RE'221, '629, '080, '923, '584, '069, '627, '697, '459, '164,

'924, '400, '624, '105, '847, '815, '175, and '018 Patents, either literally or under the doctrine of equivalents, and Sandoz will actively induce and/or contribute to the infringement of those patents. The manufacture, use, offer for sale, sale, or importation of Sandoz's 15 mg, 30 mg, and 45 mg ANDA Products will directly infringe the '425 Patent, either literally or under the doctrine of equivalents, and Sandoz will actively induce and/or contribute to the infringement of that patent.

171. This action is being brought within forty-five days of AbbVie's receipt of Sandoz's Notice Letter. 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.

INTAS'S ANDA NO. 218940

172. Intas has submitted ANDA No. 218940 ("Intas'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 ("Intas's ANDA Products" or "the Intas ANDA Products") prior to the expiration of the '080, '923, '584, '425, '069, '627, '697, '459, '036, '393, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, '922, '326, '105, '106, '847, '848, '815, '175, and '018 Patents.

173. On information and belief, FDA has not approved Intas's ANDA.

174. Intas sent AbbVie a Notice Letter dated October 13, 2023. Intas's Notice Letter represented that Intas had submitted to FDA ANDA No. 218940 and a purported Paragraph IV certification with respect to the '080, '923, '584, '425, '069, '627, '697, '459, '036, '393, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, and '922 Patents, which are listed in the Orange Book for RINVOQ®. Intas's Notice Letter did not represent that Intas 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, Intas submitted a Paragraph III certification for the RE'221 or '629 Patents.

175. According to applicable regulations, Notice Letters such as Intas'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.

176. For at least one claim of each of the '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, and '922 Patents, Intas's Notice Letter failed to allege that its ANDA Products or the proposed administration of those Products would not meet the limitations of that claim.

177. In Intas's Notice Letter, Intas purported to offer confidential access to portions of ANDA No. 218940 on terms and conditions set forth in Intas's Notice Letter ("the Intas Offer"). Intas requested that AbbVie accept the Intas Offer before receiving access to ANDA No. 218940. The Intas Offer contained unreasonable restrictions regarding access to its ANDA, well beyond those that would apply under a protective order. The Intas Offer did not permit AbbVie's in-house counsel or scientific experts to access ANDA No. 218940. Additionally, the Intas Offer contained provisions that unreasonably restricted the ability of outside counsel receiving access to ANDA No. 218940 to engage in any patent prosecution before the USPTO or in any work before or involving FDA. The restrictions the Intas Offer placed on access to ANDA No. 218940 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information

accessed, ***as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information***" (emphasis added).

178. Outside counsel for AbbVie negotiated in good faith with counsel for Intas in an attempt to reach agreement on reasonable terms of confidential access to Intas's ANDA. In correspondence dated October 17, 2023, counsel for AbbVie proposed edits to the Intas Offer consistent with protective orders Intas has entered into in recent litigation involving similar subject matter, and consistent with the purpose of 21 U.S.C. § 355(j)(5)(C)(i)(III). *See, e.g.*, *Hope Medical Pharms., Inc. v. Accord Healthcare, Inc. et al.*, C.A. No. 22-978-RGA, D.I. 22 (D. Del. Nov. 15, 2022); *Celgene Corp. et al. v. Accord Healthcare Inc.*, C.A. No. 21-cv-1795-RGA, D.I. 19 (D. Del. May 9, 2022). In such protective orders, Intas allowed expert and in-house counsel access to its ANDAs and permitted outside counsel receiving access to engage in certain proceedings before the USPTO.

179. On October 24, 2023, counsel for Intas proposed additional changes to the Intas Offer, which similarly contained unreasonable restrictions on access to Intas's ANDA, and continued to be inconsistent with the provisions of protective orders Intas has agreed to in recent litigation involving similar subject matter. AbbVie and Intas have continued to communicate and exchange edits to the Intas Offer through November 17, 2023, but have been unable to reach agreement on reasonable terms of confidential access to Intas's ANDA prior to the filing of this Complaint. To date, AbbVie has not received access to Intas's ANDA.

180. On information and belief, if FDA approves Intas's ANDA, Intas 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 Intas's ANDA Products will

directly infringe the ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’393, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’411, ’922, ’326, ’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents, either literally or under the doctrine of equivalents, and Intas will actively induce and/or contribute to the infringement of those patents.

181. This action is being brought within forty-five days of AbbVie’s receipt of Intas’s Notice Letter. 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.

SUN’S ANDA NO. 217611

182. 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 the RE’221, ’629, ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’164, ’924, ’400, ’624, ’095, ’625, ’198, ’092, ’326, ’105, ’106, ’847, ’815, ’175, and ’018 Patents.

183. On information and belief, FDA has not approved Sun’s ANDA.

184. Sun sent AbbVie a Notice Letter dated October 9, 2023. Sun’s Notice Letter represented that Sun had submitted to FDA ANDA No. 217611 and a purported Paragraph IV certification with respect to the RE’221, ’629, ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’164, ’924, ’400, ’624, ’095, ’625, ’198, and ’092 Patents, which are listed in the Orange Book for RINVOQ®.

185. 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.

186. For at least one claim of each of the RE'221, '629, '164, '924, '400, '624, '095, '625, '198, and '092 Patents, Sun's Notice Letter failed to allege that its ANDA Product or the proposed administration of that Product would not meet the limitations of that claim.

187. In Sun's Notice Letter, Sun purported to offer confidential access to portions of ANDA No. 217611 on terms and conditions set forth in Sun's Notice Letter ("the Sun Offer"). Sun requested that AbbVie accept the Sun Offer before receiving access to ANDA No. 217611. The Sun Offer contained unreasonable restrictions regarding access to its ANDA, well beyond those that would apply under a protective order. The Sun Offer did not permit AbbVie's in-house counsel, scientific experts, or the staff of outside counsel to access ANDA No. 217611. Additionally, the Sun Offer contained provisions that unreasonably restricted the ability of outside counsel receiving access to ANDA No. 217611 to engage in any proceedings before the USPTO (including patent prosecution and post-grant proceedings such as *inter partes* review) or in any work before or involving FDA. The restrictions the Sun Offer placed on access to ANDA No. 217611 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, ***as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information***" (emphasis added).

188. Beginning with correspondence on October 17, 2023, outside counsel for AbbVie attempted to negotiate in good faith with counsel for Sun in order to reach agreement on reasonable terms of confidential access to Sun's ANDA. In its October 17 correspondence, counsel for AbbVie proposed edits to the Sun Offer consistent with protective orders AbbVie and Sun have entered into in recent litigation involving similar subject matter, and consistent with the purpose of 21 U.S.C. § 355(j)(5)(C)(i)(III). Specifically, Sun has allowed expert and in-house counsel access to its ANDAs and permitted outside counsel receiving access to engage in certain proceedings before the USPTO in prior Hatch-Waxman actions. *See, e.g.*, *AbbVie Inc. et al. v. Alkem Laboratories Limited et al.*, C.A. No. 1:22-cv-01423-RGA-JLH, D.I. 101 (D. Del. May 12, 2023); *Pharmacyclics LLC et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 1:18-cv-00192-CFC-CJB (consol.), D.I. 50 (D. Del. Oct. 30, 2018). Sun's counsel did not respond for more than two weeks, despite receiving follow-up correspondence from AbbVie's counsel on October 25, 2023 and November 2, 2023.

189. Sun's counsel responded on November 2, 2023, rejecting AbbVie's proposed edits outright (without further explanation) and refusing to negotiate reasonable terms of access. Instead, Sun's counsel maintained its original unreasonable Sun Offer to access to ANDA No. 217611. To date, AbbVie has not received access to Sun's ANDA.

190. 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 RE'221, '629, '080, '923, '584, '425, '069, '627, '697, '459, '164, '924, '400, '624, '095, '625, '198, '092, '326, '105, '106, '847, '815, '175, and '018 Patents, either literally or under

the doctrine of equivalents, and Sun will actively induce and/or contribute to the infringement of those patents.

191. This action is being brought within forty-five days of AbbVie's receipt of Sun's Notice Letter. 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.

COUNT 1 — INFRINGEMENT OF THE '080 PATENT BY HETERO

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

193. 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.

194. AbbVie owns all rights, title, and interest in and to the '080 Patent.

195. On information and belief, Hetero's ANDA Products infringe one or more claims of the '080 Patent, including at least claim 1.

196. On information and belief, Hetero has infringed one or more claims of the '080 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 '080 Patent.

197. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '080 Patent would infringe one or more claims of the '080 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 '080 Patent under 35 U.S.C. § 271(b) and/or (c).

198. On information and belief, Hetero had actual and constructive notice of the '080 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 '080 Patent would constitute an act of infringement of the '080 Patent.

199. On information and belief, Hetero filed its ANDA without adequate justification for asserting that the '080 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Products. Hetero's conduct in certifying invalidity and/or non-infringement with respect to the '080 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.

200. 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 '080 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 '923 PATENT BY HETERO

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

202. 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.

203. AbbVie owns all rights, title, and interest in and to the '923 Patent.

204. Hetero's ANDA Products infringe one or more claims of the '923 Patent.

205. Hetero's Notice Letter states that "the upatacitinib in Hetero's Upatacitinib Product is amorphous." Therefore, on information and belief, Hetero's ANDA Products infringe one or more claims of the '923 Patent, including at least claim 2.

206. Hetero has infringed one or more claims of the '923 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 '923 Patent.

207. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '923 Patent would infringe one or more claims of the '923 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 '923 Patent under 35 U.S.C. § 271(b) and/or (c).

208. Hetero had actual and constructive notice of the '923 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 '923 Patent would constitute an act of infringement of the '923 Patent.

209. Hetero filed its ANDA without adequate justification for asserting that the '923 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Products. Hetero's conduct in certifying invalidity and/or non-infringement with respect to the '923 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.

210. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '923 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 '584 PATENT BY HETERO

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

212. 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.

213. AbbVie owns all rights, title, and interest in and to the '584 Patent.

214. On information and belief, Hetero's ANDA Products infringe one or more claims of the '584 Patent, including at least claim 1.

215. On information and belief, Hetero has infringed one or more claims of the '584 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 '584 Patent.

216. On information and belief, On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '584 Patent would infringe one or more claims of the '584 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 '584 Patent under 35 U.S.C. § 271(b) and/or (c).

217. On information and belief, Hetero had actual and constructive notice of the '584 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 ’584 Patent would constitute an act of infringement of the ’584 Patent.

218. On information and belief, Hetero filed its ANDA without adequate justification for asserting that the ’584 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero’s ANDA Products. Hetero’s conduct in certifying invalidity and/or non-infringement with respect to the ’584 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.

219. 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 ’584 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 ’425 PATENT BY HETERO

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

221. 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.

222. AbbVie owns all rights, title, and interest in and to the ’425 Patent.

223. On information and belief, Hetero’s ANDA Products infringe one or more claims of the ’425 Patent, including at least claim 1.

224. On information and belief, Hetero has infringed one or more claims of the ’425 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 '425 Patent.

225. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '425 Patent would infringe one or more claims of the '425 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 '425 Patent under 35 U.S.C. § 271(b) and/or (c).

226. On information and belief, Hetero had actual and constructive notice of the '425 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 '425 Patent would constitute an act of infringement of the '425 Patent.

227. On information and belief, Hetero filed its ANDA without adequate justification for asserting that the '425 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Products. Hetero's conduct in certifying invalidity and/or non-infringement with respect to the '425 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.

228. 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 '425 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 '069 PATENT BY HETERO

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

230. 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.

231. AbbVie owns all rights, title, and interest in and to the '069 Patent.

232. On information and belief, Hetero's ANDA Products infringe one or more claims of the '069 Patent, including at least claim 1.

233. On information and belief, Hetero has infringed one or more claims of the '069 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 '069 Patent.

234. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '069 Patent would infringe one or more claims of the '069 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 '069 Patent under 35 U.S.C. § 271(b) and/or (c).

235. On information and belief, Hetero had actual and constructive notice of the '069 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 '069 Patent would constitute an act of infringement of the '069 Patent.

236. On information and belief, Hetero filed its ANDA without adequate justification for asserting that the '069 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Products. Hetero's conduct in certifying

invalidity and/or non-infringement with respect to the '069 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.

237. 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 '069 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 '627 PATENT BY HETERO

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

239. 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.

240. AbbVie owns all rights, title, and interest in and to the '627 Patent.

241. On information and belief, Hetero's ANDA Products infringe one or more claims of the '627 Patent, including at least claim 1.

242. On information and belief, Hetero has infringed one or more claims of the '627 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 '627 Patent.

243. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '627 Patent would infringe one or more claims of the '627 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 '627 Patent under 35 U.S.C. § 271(b) and/or (c).

244. On information and belief, Hetero had actual and constructive notice of the '627 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 '627 Patent would constitute an act of infringement of the '627 Patent.

245. On information and belief, Hetero filed its ANDA without adequate justification for asserting that the '627 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Products. Hetero's conduct in certifying invalidity and/or non-infringement with respect to the '627 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.

246. 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 '627 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 7 — INFRINGEMENT OF THE '697 PATENT BY HETERO

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

248. 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.

249. AbbVie owns all rights, title, and interest in and to the '697 Patent.

250. Hetero's ANDA Products infringe one or more claims of the '697 Patent.

251. Hetero did not contest infringement of claims 1–30 of the '697 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '697 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.

252. Hetero has infringed one or more claims of the '697 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 '697 Patent.

253. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '697 Patent would infringe one or more claims of the '697 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 '697 Patent under 35 U.S.C. § 271(b) and/or (c).

254. Hetero had actual and constructive notice of the '697 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 '697 Patent would constitute an act of infringement of the '697 Patent.

255. Hetero filed its ANDA without adequate justification for asserting that the '697 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Products. Hetero's conduct in certifying invalidity and/or non-infringement with respect to the '697 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.

256. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '697 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 8 — INFRINGEMENT OF THE '459 PATENT BY HETERO

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

258. 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.

259. AbbVie owns all rights, title, and interest in and to the '459 Patent.

260. Hetero's 15 mg ANDA Product infringes one or more claims of the '459 Patent.

261. Hetero did not contest infringement of claims 1–30 of the '459 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '459 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.

262. Hetero has infringed one or more claims of the '459 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 '459 Patent.

263. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '459 Patent would infringe one or more claims of the '459 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 '459 Patent under 35 U.S.C. § 271(b) and/or (c).

264. Hetero had actual and constructive notice of the '459 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 '459 Patent would constitute an act of infringement of the '459 Patent.

265. Hetero filed its ANDA without adequate justification for asserting that the '459 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 '459 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.

266. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '459 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 9 — INFRINGEMENT OF THE '036 PATENT BY HETERO

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

268. 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.

269. AbbVie owns all rights, title, and interest in and to the '036 Patent.

270. Hetero's 30 mg ANDA Product infringes one or more claims of the '036 Patent.

271. Hetero did not contest infringement of claims 1–30 of the '036 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the

'036 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.

272. Hetero has infringed one or more claims of the '036 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 '036 Patent.

273. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '036 Patent would infringe one or more claims of the '036 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 '036 Patent under 35 U.S.C. § 271(b) and/or (c).

274. Hetero had actual and constructive notice of the '036 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 '036 Patent would constitute an act of infringement of the '036 Patent.

275. Hetero filed its ANDA without adequate justification for asserting that the '036 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 '036 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.

276. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '036 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 10 — INFRINGEMENT OF THE '393 PATENT BY HETERO

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

278. 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.

279. AbbVie owns all rights, title, and interest in and to the '393 Patent.

280. Hetero's 45 mg ANDA Product infringes one or more claims of the '393 Patent.

281. Hetero did not contest infringement of claims 1–30 of the '393 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '393 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.

282. Hetero has infringed one or more claims of the '393 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 '393 Patent.

283. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '393 Patent would infringe one or more claims of the '393 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 '393 Patent under 35 U.S.C. § 271(b) and/or (c).

284. Hetero had actual and constructive notice of the '393 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 '393 Patent would constitute an act of infringement of the '393 Patent.

285. Hetero filed its ANDA without adequate justification for asserting that the '393 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 '393 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.

286. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '393 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 11 — INFRINGEMENT OF THE '164 PATENT BY HETERO

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

288. 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.

289. AbbVie owns all rights, title, and interest in and to the '164 Patent.

290. Hetero's 15 mg ANDA Product infringes one or more claims of the '164 Patent.

291. Hetero did not contest infringement of claims 1–10 of the '164 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '164 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.

292. Hetero has infringed one or more claims of the '164 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 '164 Patent.

293. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '164 Patent would infringe one or more claims of the '164 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 '164 Patent under 35 U.S.C. § 271(b) and/or (c).

294. Hetero had actual and constructive notice of the '164 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 '164 Patent would constitute an act of infringement of the '164 Patent.

295. Hetero filed its ANDA without adequate justification for asserting that the '164 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 '164 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.

296. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '164 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 12 — INFRINGEMENT OF THE '883 PATENT BY HETERO

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

298. 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.

299. AbbVie owns all rights, title, and interest in and to the '883 Patent.

300. Hetero's 30 mg ANDA Product infringes one or more claims of the '883 Patent.

301. Hetero did not contest infringement of claims 1–4 of the '883 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '883 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.

302. Hetero has infringed one or more claims of the '883 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 '883 Patent.

303. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '883 Patent would infringe one or more claims of the '883 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 '883 Patent under 35 U.S.C. § 271(b) and/or (c).

304. Hetero had actual and constructive notice of the '883 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 '883 Patent would constitute an act of infringement of the '883 Patent.

305. Hetero filed its ANDA without adequate justification for asserting that the '883 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 '883 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.

306. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '883 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 13 — INFRINGEMENT OF THE '924 PATENT BY HETERO

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

308. 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.

309. AbbVie owns all rights, title, and interest in and to the '924 Patent.

310. Hetero's 15 mg and 30 mg ANDA Products infringe one or more claims of the '924 Patent.

311. Hetero did not contest infringement of claims 1–25 of the '924 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '924 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.

312. Hetero has infringed one or more claims of the '924 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 '924 Patent.

313. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '924 Patent would infringe one or more claims of the '924 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 '924 Patent under 35 U.S.C. § 271(b) and/or (c).

314. Hetero had actual and constructive notice of the '924 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 '924 Patent would constitute an act of infringement of the '924 Patent.

315. Hetero filed its ANDA without adequate justification for asserting that the '924 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Products. Hetero's conduct in certifying invalidity and/or non-infringement with respect to the '924 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.

316. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '924 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 14 — INFRINGEMENT OF THE '400 PATENT BY HETERO

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

318. 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.

319. AbbVie owns all rights, title, and interest in and to the '400 Patent.

320. Hetero's 15 mg ANDA Product infringes one or more claims of the '400 Patent.

321. Hetero did not contest infringement of claims 1–5, 9–13, and 17–21 of the '400 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '400 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.

322. Hetero has infringed one or more claims of the '400 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 '400 Patent.

323. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '400 Patent would infringe one or more claims of the '400 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 '400 Patent under 35 U.S.C. § 271(b) and/or (c).

324. Hetero had actual and constructive notice of the '400 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 '400 Patent would constitute an act of infringement of the '400 Patent.

325. Hetero filed its ANDA without adequate justification for asserting that the '400 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 '400 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.

326. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '400 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 15 — INFRINGEMENT OF THE '624 PATENT BY HETERO

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

328. 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.

329. AbbVie owns all rights, title, and interest in and to the '624 Patent.

330. Hetero's 15 mg ANDA Product infringes one or more claims of the '624 Patent.

331. Hetero did not contest infringement of claims 1–5 of the '624 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '624 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.

332. Hetero has infringed one or more claims of the '624 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 '624 Patent.

333. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '624 Patent would infringe one or more claims of the '624 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 '624 Patent under 35 U.S.C. § 271(b) and/or (c).

334. Hetero had actual and constructive notice of the '624 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 '624 Patent would constitute an act of infringement of the '624 Patent.

335. Hetero filed its ANDA without adequate justification for asserting that the '624 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 '624 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.

336. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '624 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 16 — INFRINGEMENT OF THE '095 PATENT BY HETERO

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

338. 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.

339. AbbVie owns all rights, title, and interest in and to the '095 Patent.

340. Hetero's 15 mg ANDA Product infringes one or more claims of the '095 Patent.

341. Hetero did not contest infringement of claims 1–9 of the '095 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '095 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.

342. Hetero has infringed one or more claims of the '095 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 '095 Patent.

343. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '095 Patent would infringe one or more claims of the '095 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 '095 Patent under 35 U.S.C. § 271(b) and/or (c).

344. Hetero had actual and constructive notice of the '095 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 '095 Patent would constitute an act of infringement of the '095 Patent.

345. Hetero filed its ANDA without adequate justification for asserting that the '095 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 '095 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.

346. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '095 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 17 — INFRINGEMENT OF THE '126 PATENT BY HETERO

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

348. 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.

349. AbbVie owns all rights, title, and interest in and to the '126 Patent.

350. Hetero's 30 mg ANDA Product infringes one or more claims of the '126 Patent.

351. Hetero did not contest infringement of claims 1–9 of the '126 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '126 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.

352. Hetero has infringed one or more claims of the '126 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 '126 Patent.

353. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '126 Patent would infringe one or more claims of the '126 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 '126 Patent under 35 U.S.C. § 271(b) and/or (c).

354. Hetero had actual and constructive notice of the '126 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 '126 Patent would constitute an act of infringement of the '126 Patent.

355. Hetero filed its ANDA without adequate justification for asserting that the '126 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 '126 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.

356. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '126 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 18 — INFRINGEMENT OF THE '625 PATENT BY HETERO

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

358. 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.

359. AbbVie owns all rights, title, and interest in and to the '625 Patent.

360. Hetero's 15 mg ANDA Product infringes one or more claims of the '625 Patent.

361. Hetero did not contest infringement of claims 1–20 of the '625 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '625 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.

362. Hetero has infringed one or more claims of the '625 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 '625 Patent.

363. The importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '625 Patent would infringe one or more claims of the '625 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 '625 Patent under 35 U.S.C. § 271(b) and/or (c).

364. Hetero had actual and constructive notice of the '625 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 '625 Patent would constitute an act of infringement of the '625 Patent.

365. Hetero filed its ANDA without adequate justification for asserting that the '625 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 '625 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.

366. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '625 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 19 — INFRINGEMENT OF THE '626 PATENT BY HETERO

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

368. 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.

369. AbbVie owns all rights, title, and interest in and to the '626 Patent.

370. Hetero's 30 mg ANDA Product infringes one or more claims of the '626 Patent.

371. Hetero did not contest infringement of claims 1–20 of the '626 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '626 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.

372. Hetero has infringed one or more claims of the '626 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 '626 Patent.

373. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '626 Patent would infringe one or more

claims of the ’626 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 ’626 Patent under 35 U.S.C. § 271(b) and/or (c).

374. Hetero had actual and constructive notice of the ’626 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 ’626 Patent would constitute an act of infringement of the ’626 Patent.

375. Hetero filed its ANDA without adequate justification for asserting that the ’626 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 ’626 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.

376. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the ’626 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 20 — INFRINGEMENT OF THE ’198 PATENT BY HETERO

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

378. 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.

379. AbbVie owns all rights, title, and interest in and to the ’198 Patent.

380. Hetero's 15 mg ANDA Product infringes one or more claims of the '198 Patent.

381. Hetero did not contest infringement of claims 1–22 of the '198 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '198 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.

382. Hetero has infringed one or more claims of the '198 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 '198 Patent.

383. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '198 Patent would infringe one or more claims of the '198 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 '198 Patent under 35 U.S.C. § 271(b) and/or (c).

384. Hetero had actual and constructive notice of the '198 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 '198 Patent would constitute an act of infringement of the '198 Patent.

385. Hetero filed its ANDA without adequate justification for asserting that the '198 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 '198 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.

386. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '198 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 21 — INFRINGEMENT OF THE '092 PATENT BY HETERO

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

388. 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.

389. AbbVie owns all rights, title, and interest in and to the '092 Patent.

390. Hetero's 15 mg ANDA Product infringes one or more claims of the '092 Patent.

391. Hetero did not contest infringement of claims 1–22 of the '092 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '092 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.

392. Hetero has infringed one or more claims of the '092 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 '092 Patent.

393. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '092 Patent would infringe one or more

claims of the ’092 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 ’092 Patent under 35 U.S.C. § 271(b) and/or (c).

394. Hetero had actual and constructive notice of the ’092 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 ’092 Patent would constitute an act of infringement of the ’092 Patent.

395. Hetero filed its ANDA without adequate justification for asserting that the ’092 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 ’092 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.

396. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the ’092 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 22 — INFRINGEMENT OF THE ’964 PATENT BY HETERO

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

398. 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.

399. AbbVie owns all rights, title, and interest in and to the ’964 Patent.

400. Hetero's 15 mg ANDA Product infringes one or more claims of the '964 Patent.

401. Hetero did not contest infringement of claims 1–10 of the '964 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '964 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.

402. Hetero has infringed one or more claims of the '964 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 '964 Patent.

403. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '964 Patent would infringe one or more claims of the '964 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 '964 Patent under 35 U.S.C. § 271(b) and/or (c).

404. Hetero had actual and constructive notice of the '964 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 '964 Patent would constitute an act of infringement of the '964 Patent.

405. Hetero filed its ANDA without adequate justification for asserting that the '964 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 '964 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.

406. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '964 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 23 — INFRINGEMENT OF THE '411 PATENT BY HETERO

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

408. 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.

409. AbbVie owns all rights, title, and interest in and to the '411 Patent.

410. Hetero's ANDA Products infringe one or more claims of the '411 Patent.

411. Hetero did not contest infringement of claims 1–4 of the '411 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '411 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.

412. Hetero has infringed one or more claims of the '411 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 '411 Patent.

413. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '411 Patent would infringe one or more

claims of the ’411 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 ’411 Patent under 35 U.S.C. § 271(b) and/or (c).

414. Hetero had actual and constructive notice of the ’411 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 ’411 Patent would constitute an act of infringement of the ’411 Patent.

415. Hetero filed its ANDA without adequate justification for asserting that the ’411 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero’s ANDA Products. Hetero’s conduct in certifying invalidity and/or non-infringement with respect to the ’411 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.

416. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the ’411 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 24 — INFRINGEMENT OF THE ’922 PATENT BY HETERO

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

418. 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.

419. AbbVie owns all rights, title, and interest in and to the ’922 Patent.

420. Hetero's ANDA Products infringe one or more claims of the '922 Patent.

421. Hetero did not contest infringement of claims 1–4 of the '922 Patent in Hetero's Notice Letter. If Hetero had a factual or legal basis to contest infringement of the claims of the '922 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.

422. Hetero has infringed one or more claims of the '922 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 '922 Patent.

423. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '922 Patent would infringe one or more claims of the '922 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 '922 Patent under 35 U.S.C. § 271(b) and/or (c).

424. Hetero had actual and constructive notice of the '922 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 '922 Patent would constitute an act of infringement of the '922 Patent.

425. Hetero filed its ANDA without adequate justification for asserting that the '922 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Products. Hetero's conduct in certifying invalidity and/or non-infringement with respect to the '922 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.

426. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '922 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 25 — INFRINGEMENT OF THE '326 PATENT BY HETERO

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

428. 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.

429. AbbVie owns all rights, title, and interest in and to the '326 Patent.

430. Hetero's Notice Letter indicates that with respect to its 15 mg and 30 mg ANDA Products it seeks approval for the treatment of moderate to severe atopic dermatitis. Accordingly, on information and belief, Hetero's ANDA Products infringe one or more claims of the '326 Patent, including at least claim 1.

431. On information and belief, Hetero has infringed one or more claims of the '326 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 '326 Patent.

432. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '326 Patent would infringe one or more claims of the '326 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 '326 Patent under 35 U.S.C. § 271(b) and/or (c).

433. On information and belief, Hetero has actual and constructive notice of the '326 Patent, and is aware that the submission of Hetero's ANDA with the request for FDA approval prior to the expiration of the '326 Patent would constitute an act of infringement of the '326 Patent.

434. On information and belief, Hetero is without adequate justification for asserting that the '326 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Products. Any assertion by Hetero of invalidity and/or non-infringement with respect to the '326 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.

435. 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 '326 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 26 — INFRINGEMENT OF THE '105 PATENT BY HETERO

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

437. 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.

438. AbbVie owns all rights, title, and interest in and to the '105 Patent.

439. On information and belief, Hetero's ANDA Products infringe one or more claims of the '105 Patent, including at least claim 1.

440. On information and belief, Hetero has infringed one or more claims of the '105 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 '105 Patent.

441. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '105 Patent would infringe one or more claims of the '105 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 '105 Patent under 35 U.S.C. § 271(b) and/or (c).

442. On information and belief, Hetero has actual and constructive notice of the '105 Patent, and is aware that the submission of Hetero's ANDA with the request for FDA approval prior to the expiration of the '105 Patent would constitute an act of infringement of the '105 Patent.

443. On information and belief, Hetero is without adequate justification for asserting that the '105 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Products. Any assertion by Hetero of invalidity and/or non-infringement with respect to the '105 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.

444. 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 '105 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 27 — INFRINGEMENT OF THE '106 PATENT BY HETERO

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

446. 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.

447. AbbVie owns all rights, title, and interest in and to the '106 Patent.

448. Hetero's Notice Letter 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; the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers; and 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. Accordingly, on information and belief, Hetero's ANDA Product infringes one or more claims of the '106 Patent, including at least claim 1.

449. On information and belief, Hetero has infringed one or more claims of the '106 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 '106 Patent.

450. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '106 Patent would infringe one or more claims of the '106 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 '106 Patent under 35 U.S.C. § 271(b) and/or (c).

451. On information and belief, Hetero has actual and constructive notice of the '106 Patent, and is aware that the submission of Hetero's ANDA with the request for FDA approval prior to the expiration of the '106 Patent would constitute an act of infringement of the '106 Patent.

452. On information and belief, Hetero is without adequate justification for asserting that the '106 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Product. Any assertion by Hetero of invalidity and/or non-infringement with respect to the '106 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.

453. 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 '106 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 28 — INFRINGEMENT OF THE '847 PATENT BY HETERO

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

455. 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.

456. AbbVie owns all rights, title, and interest in and to the '847 Patent.

457. On information and belief, Hetero's 15 mg ANDA Product infringes one or more claims of the '847 Patent, including at least claim 1.

458. On information and belief, Hetero has infringed one or more claims of the '847 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 '847 Patent.

459. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '847 Patent would infringe one or more claims of the '847 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 '847 Patent under 35 U.S.C. § 271(b) and/or (c).

460. On information and belief, Hetero has actual and constructive notice of the '847 Patent, and is aware that the submission of Hetero's ANDA with the request for FDA approval prior to the expiration of the '847 Patent would constitute an act of infringement of the '847 Patent.

461. On information and belief, Hetero is without adequate justification for asserting that the '847 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Product. Any assertion by Hetero of invalidity and/or non-infringement with respect to the '847 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.

462. 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 '847 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 29 — INFRINGEMENT OF THE '848 PATENT BY HETERO

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

464. 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.

465. AbbVie owns all rights, title, and interest in and to the '848 Patent.

466. Hetero's Notice Letter indicates that with respect to its 15 mg ANDA Product it seeks approval for, *inter alia*, the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Accordingly, on information and belief, Hetero's ANDA Product infringes one or more claims of the '848 Patent, including at least claim 1.

467. On information and belief, Hetero has infringed one or more claims of the '848 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 '848 Patent.

468. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '848 Patent would infringe one or more claims of the '848 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 '848 Patent under 35 U.S.C. § 271(b) and/or (c).

469. On information and belief, Hetero has actual and constructive notice of the '848 Patent, and is aware that the submission of Hetero's ANDA with the request for FDA approval prior to the expiration of the '848 Patent would constitute an act of infringement of the '848 Patent.

470. On information and belief, Hetero is without adequate justification for asserting that the '848 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture,

use, offer for sale, or sale of Hetero's ANDA Product. Any assertion by Hetero of invalidity and/or non-infringement with respect to the '848 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.

471. 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 '848 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 30 — INFRINGEMENT OF THE '815 PATENT BY HETERO

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

473. 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.

474. AbbVie owns all rights, title, and interest in and to the '815 Patent.

475. On information and belief, Hetero's 15 mg ANDA Product infringes one or more claims of the '815 Patent, including at least claim 1.

476. On information and belief, Hetero has infringed one or more claims of the '815 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 '815 Patent.

477. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '815 Patent would infringe one or more claims of the '815 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 '815 Patent under 35 U.S.C. § 271(b) and/or (c).

478. On information and belief, Hetero has actual and constructive notice of the '815 Patent, and is aware that the submission of Hetero's ANDA with the request for FDA approval prior to the expiration of the '815 Patent would constitute an act of infringement of the '815 Patent.

479. On information and belief, Hetero is without adequate justification for asserting that the '815 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Product. Any assertion by Hetero of invalidity and/or non-infringement with respect to the '815 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.

480. 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 '815 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 31 — INFRINGEMENT OF THE '175 PATENT BY HETERO

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

482. 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.

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

484. Hetero's Notice Letter indicates that with respect to its 15 mg ANDA Product it seeks approval for, *inter alia*, the treatment of adults with moderately to severely active rheumatoid

arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Accordingly, on information and belief, Hetero's ANDA Product infringes one or more claims of the '175 Patent, including at least claim 1.

485. On information and belief, Hetero has infringed one or more claims of the '175 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 '175 Patent.

486. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Product prior to the expiration of the '175 Patent would infringe one or more claims of the '175 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 '175 Patent under 35 U.S.C. § 271(b) and/or (c).

487. On information and belief, Hetero has actual and constructive notice of the '175 Patent, and is aware that the submission of Hetero's ANDA with the request for FDA approval prior to the expiration of the '175 Patent would constitute an act of infringement of the '175 Patent.

488. On information and belief, Hetero is without adequate justification for asserting that the '175 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Product. Any assertion by Hetero of invalidity and/or non-infringement with respect to the '175 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.

489. 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 '175 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 32 — INFRINGEMENT OF THE '018 PATENT BY HETERO

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

491. 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.

492. AbbVie owns all rights, title, and interest in and to the '018 Patent.

493. Hetero's Notice Letter states that "the upatacitinib in Hetero's Upatacitinib Product is amorphous." Therefore, on information and belief, Hetero's ANDA Products infringe one or more claims of the '018 Patent, including at least claim 1.

494. On information and belief, Hetero has infringed one or more claims of the '018 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 '018 Patent.

495. On information and belief, the importation, manufacture, sale, offer for sale, or use of Hetero's ANDA Products prior to the expiration of the '018 Patent would infringe one or more claims of the '018 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 '018 Patent under 35 U.S.C. § 271(b) and/or (c).

496. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between AbbVie and Hetero concerning liability for the infringement of the '018 Patent for which this Court may grant relief consistent with Article III of the United States Constitution. Subject matter jurisdiction over this Count exists pursuant to 35 U.S.C. § 271(e)(2)(A) and 28 U.S.C. §§ 1338(a), 2201, 2202.

497. On information and belief, Hetero has actual and constructive notice of the '018 Patent, and is aware that the submission of Hetero's ANDA with the request for FDA approval prior to the expiration of the '018 Patent would constitute an act of infringement of the '018 Patent.

498. On information and belief, Hetero is without adequate justification for asserting that the '018 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Hetero's ANDA Products. Any assertion by Hetero of invalidity and/or non-infringement with respect to the '018 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.

499. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and from actively inducing or contributing to the infringement of the '018 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 33 — INFRINGEMENT OF THE '080 PATENT BY AUROBINDO

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

501. 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.

502. AbbVie owns all rights, title, and interest in and to the '080 Patent.

503. On information and belief, Aurobindo's ANDA Products infringe one or more claims of the '080 Patent, including at least claim 1.

504. On information and belief, Aurobindo has infringed one or more claims of the '080 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 '080 Patent.

505. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the '080 Patent would infringe one or more claims of the '080 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 '080 Patent under 35 U.S.C. § 271(b) and/or (c).

506. On information and belief, Aurobindo had actual and constructive notice of the '080 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '080 Patent would constitute an act of infringement of the '080 Patent.

507. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '080 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Products. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '080 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.

508. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '080 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 34 — INFRINGEMENT OF THE '923 PATENT BY AUROBINDO

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

510. 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.

511. AbbVie owns all rights, title, and interest in and to the '923 Patent.

512. Aurobindo's ANDA Products infringe one or more claims of the '923 Patent.

513. Aurobindo's Notice Letter states that "the ANDA product uses an amorphous form of upadacitinib[.]" Therefore, on information and belief, Aurobindo infringes one or more claims of the '923 Patent, including at least claim 2.

514. Aurobindo did not contest infringement of claims 2, 14, and 16–19 of the '923 Patent in Aurobindo's Notice Letter. If Aurobindo had a factual or legal basis to contest infringement of the claims of the '923 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.

515. Aurobindo has infringed one or more claims of the '923 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 '923 Patent.

516. The importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the '923 Patent would infringe one or more claims of the '923 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 '923 Patent under 35 U.S.C. § 271(b) and/or (c).

517. Aurobindo had actual and constructive notice of the '923 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '923 Patent would constitute an act of infringement of the '923 Patent.

518. Aurobindo filed its ANDA without adequate justification for asserting that the '923 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Products. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '923 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.

519. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '923 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 35 — INFRINGEMENT OF THE '584 PATENT BY AUROBINDO

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

521. 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.

522. AbbVie owns all rights, title, and interest in and to the '584 Patent.

523. Aurobindo's ANDA Products infringe one or more claims of the '584 Patent.

524. On information and belief, Aurobindo's ANDA Products infringe one or more claims of the '584 Patent, including at least claim 1.

525. On information and belief, Aurobindo has infringed one or more claims of the '584 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 '584 Patent.

526. On information and belief, The importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the '584 Patent would infringe one or more claims of the '584 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 '584 Patent under 35 U.S.C. § 271(b) and/or (c).

527. On information and belief, Aurobindo had actual and constructive notice of the '584 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '584 Patent would constitute an act of infringement of the '584 Patent.

528. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '584 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Products. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '584 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.

529. 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 '584 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 36 — INFRINGEMENT OF THE '425 PATENT BY AUROBINDO

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

531. 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.

532. AbbVie owns all rights, title, and interest in and to the '425 Patent.

533. On information and belief, Aurobindo's ANDA Products infringe one or more claims of the '425 Patent, including at least claim 1.

534. On information and belief, Aurobindo has infringed one or more claims of the '425 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 '425 Patent.

535. On information and belief, The importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the '425 Patent would infringe one or more claims of the '425 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 '425 Patent under 35 U.S.C. § 271(b) and/or (c).

536. On information and belief, Aurobindo had actual and constructive notice of the '425 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '425 Patent would constitute an act of infringement of the '425 Patent.

537. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '425 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Products. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '425 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.

538. 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 '425 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 37 — INFRINGEMENT OF THE '069 PATENT BY AUROBINDO

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

540. 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.

541. AbbVie owns all rights, title, and interest in and to the '069 Patent.

542. On information and belief, Aurobindo's ANDA Products infringe one or more claims of the '069 Patent, including at least claim 1.

543. On information and belief, Aurobindo has infringed one or more claims of the '069 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 '069 Patent.

544. On information and belief, The importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the '069 Patent would infringe one or more claims of the '069 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 '069 Patent under 35 U.S.C. § 271(b) and/or (c).

545. On information and belief, Aurobindo had actual and constructive notice of the '069 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '069 Patent would constitute an act of infringement of the '069 Patent.

546. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '069 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Products. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '069 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.

547. 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 '069 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 38 — INFRINGEMENT OF THE '627 PATENT BY AUROBINDO

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

549. 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.

550. AbbVie owns all rights, title, and interest in and to the '627 Patent.

551. On information and belief, Aurobindo's ANDA Products infringe one or more claims of the '627 Patent, including at least claim 1.

552. On information and belief, Aurobindo has infringed one or more claims of the '627 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 '627 Patent.

553. On information and belief, The importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the '627 Patent would infringe one or more claims of the '627 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 '627 Patent under 35 U.S.C. § 271(b) and/or (c).

554. On information and belief, Aurobindo had actual and constructive notice of the '627 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '627 Patent would constitute an act of infringement of the '627 Patent.

555. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '627 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Products. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '627 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.

556. 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 '627 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 39 — INFRINGEMENT OF THE '697 PATENT BY AUROBINDO

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

558. 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.

559. AbbVie owns all rights, title, and interest in and to the '697 Patent.

560. On information and belief, Aurobindo's ANDA Products infringe one or more claims of the '697 Patent, including at least claim 1.

561. On information and belief, Aurobindo has infringed one or more claims of the '697 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 '697 Patent.

562. On information and belief, On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the '697 Patent would infringe one or more claims of the '697 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 '697 Patent under 35 U.S.C. § 271(b) and/or (c).

563. On information and belief, Aurobindo had actual and constructive notice of the '697 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '697 Patent would constitute an act of infringement of the '697 Patent.

564. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '697 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Products. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '697 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.

565. 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 '697 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 40 — INFRINGEMENT OF THE '459 PATENT BY AUROBINDO

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

567. 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.

568. AbbVie owns all rights, title, and interest in and to the '459 Patent.

569. Aurobindo's 15 mg ANDA Product infringes one or more claims of the '459 Patent.

570. Aurobindo did not contest infringement of claims 1–20 of the '459 Patent in Aurobindo's Notice Letter. If Aurobindo had a factual or legal basis to contest infringement of the

claims of the '459 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.

571. Aurobindo has infringed one or more claims of the '459 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 '459 Patent.

572. The importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '459 Patent would infringe one or more claims of the '459 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 '459 Patent under 35 U.S.C. § 271(b) and/or (c).

573. Aurobindo had actual and constructive notice of the '459 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '459 Patent would constitute an act of infringement of the '459 Patent.

574. Aurobindo filed its ANDA without adequate justification for asserting that the '459 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '459 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.

575. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '459 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 41 — INFRINGEMENT OF THE '036 PATENT BY AUROBINDO

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

577. 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.

578. AbbVie owns all rights, title, and interest in and to the '036 Patent.

579. Aurobindo's 30 mg ANDA Product infringes one or more claims of the '036 Patent.

580. Aurobindo did not contest infringement of claims 1–20 of the '036 Patent in Aurobindo's Notice Letter. If Aurobindo had a factual or legal basis to contest infringement of the claims of the '036 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.

581. Aurobindo has infringed one or more claims of the '036 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 '036 Patent.

582. The importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '036 Patent would infringe one or more claims of the '036 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 '036 Patent under 35 U.S.C. § 271(b) and/or (c).

583. Aurobindo had actual and constructive notice of the '036 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '036 Patent would constitute an act of infringement of the '036 Patent.

584. Aurobindo filed its ANDA without adequate justification for asserting that the '036 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '036 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.

585. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '036 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 42 — INFRINGEMENT OF THE '164 PATENT BY AUROBINDO

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

587. 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.

588. AbbVie owns all rights, title, and interest in and to the '164 Patent.

589. Aurobindo's 15 mg ANDA Product infringes one or more claims of the '164 Patent.

590. Aurobindo did not contest infringement of claims 1–10 of the '164 Patent in Aurobindo's Notice Letter. If Aurobindo had a factual or legal basis to contest infringement of the

claims of the '164 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.

591. Aurobindo has infringed one or more claims of the '164 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 '164 Patent.

592. The importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '164 Patent would infringe one or more claims of the '164 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 '164 Patent under 35 U.S.C. § 271(b) and/or (c).

593. Aurobindo had actual and constructive notice of the '164 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '164 Patent would constitute an act of infringement of the '164 Patent.

594. Aurobindo filed its ANDA without adequate justification for asserting that the '164 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '164 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.

595. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '164 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 43 — INFRINGEMENT OF THE '883 PATENT BY AUROBINDO

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

597. 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.

598. AbbVie owns all rights, title, and interest in and to the '883 Patent.

599. Aurobindo's 30 mg ANDA Product infringes one or more claims of the '883 Patent.

600. Aurobindo did not contest infringement of claims 1–4 of the '883 Patent in Aurobindo's Notice Letter. If Aurobindo had a factual or legal basis to contest infringement of the claims of the '883 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.

601. Aurobindo has infringed one or more claims of the '883 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 '883 Patent.

602. The importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '883 Patent would infringe one or more claims of the '883 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 '883 Patent under 35 U.S.C. § 271(b) and/or (c).

603. Aurobindo had actual and constructive notice of the '883 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '883 Patent would constitute an act of infringement of the '883 Patent.

604. Aurobindo filed its ANDA without adequate justification for asserting that the '883 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '883 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.

605. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '883 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 44 — INFRINGEMENT OF THE '924 PATENT BY AUROBINDO

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

607. 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.

608. AbbVie owns all rights, title, and interest in and to the '924 Patent.

609. Aurobindo's ANDA Products infringe one or more claims of the '924 Patent.

610. Aurobindo did not contest infringement of claims 1–25 of the '924 Patent in Aurobindo's Notice Letter. If Aurobindo had a factual or legal basis to contest infringement of the

claims of the '924 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.

611. Aurobindo has infringed one or more claims of the '924 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 '924 Patent.

612. The importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the '924 Patent would infringe one or more claims of the '924 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 '924 Patent under 35 U.S.C. § 271(b) and/or (c).

613. Aurobindo had actual and constructive notice of the '924 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '924 Patent would constitute an act of infringement of the '924 Patent.

614. Aurobindo filed its ANDA without adequate justification for asserting that the '924 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Products. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '924 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.

615. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '924 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 45 — INFRINGEMENT OF THE '400 PATENT BY AUROBINDO

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

617. 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.

618. AbbVie owns all rights, title, and interest in and to the '400 Patent.

619. On information and belief, Aurobindo's 15 mg ANDA Product infringes one or more claims of the '400 Patent, including at least claim 1.

620. On information and belief, Aurobindo has infringed one or more claims of the '400 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 '400 Patent.

621. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '400 Patent would infringe one or more claims of the '400 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 '400 Patent under 35 U.S.C. § 271(b) and/or (c).

622. On information and belief, Aurobindo had actual and constructive notice of the '400 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '400 Patent would constitute an act of infringement of the '400 Patent.

623. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '400 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '400 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.

624. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '400 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 46 — INFRINGEMENT OF THE '624 PATENT BY AUROBINDO

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

626. 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.

627. AbbVie owns all rights, title, and interest in and to the '624 Patent.

628. On information and belief, Aurobindo's 15 mg ANDA Product infringes one or more claims of the '624 Patent, including at least claim 1.

629. On information and belief, Aurobindo has infringed one or more claims of the '624 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 '624 Patent.

630. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '624 Patent would infringe one or more claims of the '624 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 '624 Patent under 35 U.S.C. § 271(b) and/or (c).

631. On information and belief, Aurobindo had actual and constructive notice of the '624 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '624 Patent would constitute an act of infringement of the '624 Patent.

632. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '624 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '624 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.

633. 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 '624 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 47 — INFRINGEMENT OF THE '095 PATENT BY AUROBINDO

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

635. 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.

636. AbbVie owns all rights, title, and interest in and to the '095 Patent.

637. On information and belief, Aurobindo's 15 mg ANDA Product infringes one or more claims of the '095 Patent, including at least claim 1.

638. On information and belief, Aurobindo has infringed one or more claims of the '095 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 '095 Patent.

639. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '095 Patent would infringe one or more claims of the '095 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 '095 Patent under 35 U.S.C. § 271(b) and/or (c).

640. On information and belief, Aurobindo had actual and constructive notice of the '095 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '095 Patent would constitute an act of infringement of the '095 Patent.

641. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '095 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '095 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.

642. 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 '095 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 48 — INFRINGEMENT OF THE '126 PATENT BY AUROBINDO

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

644. 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.

645. AbbVie owns all rights, title, and interest in and to the '126 Patent.

646. On information and belief, Aurobindo's 30 mg ANDA Product infringes one or more claims of the '126 Patent, including at least claim 1.

647. On information and belief, Aurobindo has infringed one or more claims of the '126 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 '126 Patent.

648. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '126 Patent would infringe one or more claims of the '126 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 '126 Patent under 35 U.S.C. § 271(b) and/or (c).

649. On information and belief, Aurobindo had actual and constructive notice of the '126 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '126 Patent would constitute an act of infringement of the '126 Patent.

650. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '126 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '126 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.

651. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '126 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 49 — INFRINGEMENT OF THE '625 PATENT BY AUROBINDO

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

653. 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.

654. AbbVie owns all rights, title, and interest in and to the '625 Patent.

655. On information and belief, Aurobindo's 15 mg ANDA Product infringes one or more claims of the '625 Patent, including at least claim 1.

656. On information and belief, Aurobindo has infringed one or more claims of the '625 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 '625 Patent.

657. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '625 Patent would infringe one or more claims of the '625 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 '625 Patent under 35 U.S.C. § 271(b) and/or (c).

658. On information and belief, Aurobindo had actual and constructive notice of the '625 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '625 Patent would constitute an act of infringement of the '625 Patent.

659. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '625 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '625 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.

660. 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 '625 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 50 — INFRINGEMENT OF THE '626 PATENT BY AUROBINDO

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

662. 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.

663. AbbVie owns all rights, title, and interest in and to the '626 Patent.

664. On information and belief, Aurobindo's 30 mg ANDA Product infringes one or more claims of the '626 Patent, including at least claim 1.

665. On information and belief, Aurobindo has infringed one or more claims of the '626 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 '626 Patent.

666. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '626 Patent would infringe one or more claims of the '626 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 '626 Patent under 35 U.S.C. § 271(b) and/or (c).

667. On information and belief, Aurobindo had actual and constructive notice of the '626 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '626 Patent would constitute an act of infringement of the '626 Patent.

668. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '626 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '626 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.

669. 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 '626 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 51 — INFRINGEMENT OF THE '198 PATENT BY AUROBINDO

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

671. 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.

672. AbbVie owns all rights, title, and interest in and to the '198 Patent.

673. On information and belief, Aurobindo's 15 mg ANDA Product infringes one or more claims of the '198 Patent, including at least claim 1.

674. On information and belief, Aurobindo has infringed one or more claims of the '198 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 '198 Patent.

675. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '198 Patent would infringe one or more claims of the '198 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 '198 Patent under 35 U.S.C. § 271(b) and/or (c).

676. On information and belief, Aurobindo had actual and constructive notice of the '198 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '198 Patent would constitute an act of infringement of the '198 Patent.

677. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '198 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '198 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.

678. 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 '198 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 52 — INFRINGEMENT OF THE '092 PATENT BY AUROBINDO

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

680. 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.

681. AbbVie owns all rights, title, and interest in and to the '092 Patent.

682. On information and belief, Aurobindo's 15 mg ANDA Product infringes one or more claims of the '092 Patent, including at least claim 1.

683. On information and belief, Aurobindo has infringed one or more claims of the '092 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 '092 Patent.

684. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '092 Patent would infringe one or more claims of the '092 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 '092 Patent under 35 U.S.C. § 271(b) and/or (c).

685. On information and belief, Aurobindo had actual and constructive notice of the '092 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '092 Patent would constitute an act of infringement of the '092 Patent.

686. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '092 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '092 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.

687. 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 '092 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 53 — INFRINGEMENT OF THE '964 PATENT BY AUROBINDO

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

689. 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.

690. AbbVie owns all rights, title, and interest in and to the '964 Patent.

691. On information and belief, Aurobindo's 15 mg ANDA Product infringes one or more claims of the '964 Patent, including at least claim 1.

692. On information and belief, Aurobindo has infringed one or more claims of the '964 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 '964 Patent.

693. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '964 Patent would infringe one or more claims of the '964 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 '964 Patent under 35 U.S.C. § 271(b) and/or (c).

694. On information and belief, Aurobindo had actual and constructive notice of the '964 Patent prior to submitting Aurobindo's ANDA, and was aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '964 Patent would constitute an act of infringement of the '964 Patent.

695. On information and belief, Aurobindo filed its ANDA without adequate justification for asserting that the '964 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Aurobindo's conduct in certifying invalidity and/or non-infringement with respect to the '964 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.

696. 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 '964 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 54 — INFRINGEMENT OF THE '326 PATENT BY AUROBINDO

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

698. 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.

699. AbbVie owns all rights, title, and interest in and to the '326 Patent.

700. Aurobindo's Notice Letter indicates that with respect to its 15 mg and 30 mg ANDA Products it seeks approval for the treatment of moderate to severe atopic dermatitis.

Accordingly, on information and belief, Aurobindo's ANDA Products infringe one or more claims of the '326 Patent, including at least claim 1.

701. On information and belief, Aurobindo has infringed one or more claims of the '326 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '326 Patent.

702. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the '326 Patent would infringe one or more claims of the '326 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 '326 Patent under 35 U.S.C. § 271(b) and/or (c).

703. On information and belief, Aurobindo has actual and constructive notice of the '326 Patent, and is aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '326 Patent would constitute an act of infringement of the '326 Patent.

704. On information and belief, Aurobindo is without adequate justification for asserting that the '326 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Products. Any assertion by Aurobindo of invalidity and/or non-infringement with respect to the '326 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.

705. 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 '326 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 55 — INFRINGEMENT OF THE '105 PATENT BY AUROBINDO

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

707. 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.

708. AbbVie owns all rights, title, and interest in and to the '105 Patent.

709. On information and belief, Aurobindo's ANDA Products infringe one or more claims of the '105 Patent, including at least claim 1.

710. On information and belief, Aurobindo has infringed one or more claims of the '105 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '105 Patent.

711. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the '105 Patent would infringe one or more claims of the '105 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 '105 Patent under 35 U.S.C. § 271(b) and/or (c).

712. On information and belief, Aurobindo has actual and constructive notice of the '105 Patent, and is aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '105 Patent would constitute an act of infringement of the '105 Patent.

713. On information and belief, Aurobindo is without adequate justification for asserting that the '105 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture,

use, offer for sale, or sale of Aurobindo's ANDA Products. Any assertion by Aurobindo of invalidity and/or non-infringement with respect to the '105 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.

714. 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 '105 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 56 — INFRINGEMENT OF THE '106 PATENT BY AUROBINDO

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

716. 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.

717. AbbVie owns all rights, title, and interest in and to the '106 Patent.

718. Aurobindo's Notice Letter 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; the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers; and 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. Accordingly, on information and belief, Aurobindo's ANDA Product infringes one or more claims of the '106 Patent, including at least claim 1.

719. On information and belief, Aurobindo has infringed one or more claims of the '106 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '106 Patent.

720. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '106 Patent would infringe one or more claims of the '106 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 '106 Patent under 35 U.S.C. § 271(b) and/or (c).

721. On information and belief, Aurobindo has actual and constructive notice of the '106 Patent, and is aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '106 Patent would constitute an act of infringement of the '106 Patent.

722. On information and belief, Aurobindo is without adequate justification for asserting that the '106 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Any assertion by Aurobindo of invalidity and/or non-infringement with respect to the '106 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.

723. 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 '106 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 57 — INFRINGEMENT OF THE '847 PATENT BY AUROBINDO

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

725. 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.

726. AbbVie owns all rights, title, and interest in and to the '847 Patent.

727. On information and belief, Aurobindo's 15 mg ANDA Product infringes one or more claims of the '847 Patent, including at least claim 1.

728. On information and belief, Aurobindo has infringed one or more claims of the '847 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '847 Patent.

729. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '847 Patent would infringe one or more claims of the '847 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 '847 Patent under 35 U.S.C. § 271(b) and/or (c).

730. On information and belief, Aurobindo has actual and constructive notice of the '847 Patent, and is aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '847 Patent would constitute an act of infringement of the '847 Patent.

731. On information and belief, Aurobindo is without adequate justification for asserting that the '847 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Any assertion by Aurobindo of invalidity and/or non-infringement with respect to the '847 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.

732. 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 '847 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 58 — INFRINGEMENT OF THE '848 PATENT BY AUROBINDO

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

734. 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.

735. AbbVie owns all rights, title, and interest in and to the '848 Patent.

736. Aurobindo's Notice Letter indicates that with respect to its 15 mg ANDA Product it seeks approval for, *inter alia*, the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Accordingly, on information and belief, Aurobindo's ANDA Product infringes one or more claims of the '848 Patent, including at least claim 1.

737. On information and belief, Aurobindo has infringed one or more claims of the '848 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '848 Patent.

738. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '848 Patent would infringe one or

more claims of the ’848 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 ’848 Patent under 35 U.S.C. § 271(b) and/or (c).

739. On information and belief, Aurobindo has actual and constructive notice of the ’848 Patent, and is aware that the submission of Aurobindo’s ANDA with the request for FDA approval prior to the expiration of the ’848 Patent would constitute an act of infringement of the ’848 Patent.

740. On information and belief, Aurobindo is without adequate justification for asserting that the ’848 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo’s ANDA Product. Any assertion by Aurobindo of invalidity and/or non-infringement with respect to the ’848 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.

741. 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 ’848 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 59 — INFRINGEMENT OF THE ’815 PATENT BY AUROBINDO

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

743. 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.

744. AbbVie owns all rights, title, and interest in and to the ’815 Patent.

745. On information and belief, Aurobindo's 15 mg ANDA Product infringes one or more claims of the '815 Patent, including at least claim 1.

746. On information and belief, Aurobindo has infringed one or more claims of the '815 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '815 Patent.

747. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '815 Patent would infringe one or more claims of the '815 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 '815 Patent under 35 U.S.C. § 271(b) and/or (c).

748. On information and belief, Aurobindo has actual and constructive notice of the '815 Patent, and is aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '815 Patent would constitute an act of infringement of the '815 Patent.

749. On information and belief, Aurobindo is without adequate justification for asserting that the '815 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Any assertion by Aurobindo of invalidity and/or non-infringement with respect to the '815 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.

750. 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 '815 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 60 — INFRINGEMENT OF THE '175 PATENT BY AUROBINDO

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

752. 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.

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

754. Aurobindo's Notice Letter indicates that with respect to its 15 mg ANDA Product it seeks approval for, *inter alia*, the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Accordingly, on information and belief, Aurobindo's ANDA Product infringes one or more claims of the '175 Patent, including at least claim 1.

755. On information and belief, Aurobindo has infringed one or more claims of the '175 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '175 Patent.

756. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Product prior to the expiration of the '175 Patent would infringe one or more claims of the '175 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 '175 Patent under 35 U.S.C. § 271(b) and/or (c).

757. On information and belief, Aurobindo has actual and constructive notice of the '175 Patent, and is aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '175 Patent would constitute an act of infringement of the '175 Patent.

758. On information and belief, Aurobindo is without adequate justification for asserting that the '175 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Product. Any assertion by Aurobindo of invalidity and/or non-infringement with respect to the '175 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.

759. 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 '175 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 61 — INFRINGEMENT OF THE '018 PATENT BY AUROBINDO

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

761. 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.

762. AbbVie owns all rights, title, and interest in and to the '018 Patent.

763. Aurobindo's Notice Letter states that "the ANDA product uses an amorphous form of upadacitinib[.]" Therefore, on information and belief, Aurobindo's ANDA Products infringe one or more claims of the '018 Patent, including at least claim 1.

764. On information and belief, Aurobindo has infringed one or more claims of the '018 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Aurobindo's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '018 Patent.

765. On information and belief, the importation, manufacture, sale, offer for sale, or use of Aurobindo's ANDA Products prior to the expiration of the '018 Patent would infringe one or more claims of the '018 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 '018 Patent under 35 U.S.C. § 271(b) and/or (c).

766. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between AbbVie and Aurobindo concerning liability for the infringement of the '018 Patent for which this Court may grant relief consistent with Article III of the United States Constitution. Subject matter jurisdiction over this Count exists pursuant to 35 U.S.C. § 271(e)(2)(A) and 28 U.S.C. §§ 1338(a), 2201, 2202.

767. On information and belief, Aurobindo has actual and constructive notice of the '018 Patent, and is aware that the submission of Aurobindo's ANDA with the request for FDA approval prior to the expiration of the '018 Patent would constitute an act of infringement of the '018 Patent.

768. On information and belief, Aurobindo is without adequate justification for asserting that the '018 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Aurobindo's ANDA Products. Any assertion by Aurobindo of invalidity and/or non-infringement with respect to the '018 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.

769. AbbVie will be irreparably harmed if Aurobindo is not enjoined from infringing and from actively inducing or contributing to the infringement of the '018 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 62 — INFRINGEMENT OF THE RE'221 PATENT BY SANDOZ

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

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

772. AbbVie owns all rights, title, and interest in and to the RE'221 Patent.

773. Sandoz's 15 mg ANDA Product infringes one or more claims of the RE'221 Patent.

774. Sandoz did not contest infringement of claims 13–14 of the RE'221 Patent in Sandoz's Notice Letter. If Sandoz 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.

775. Sandoz has infringed one or more claims of the RE'221 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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.

776. The importation, manufacture, sale, offer for sale, or use of Sandoz'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 Sandoz 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).

777. Sandoz had actual and constructive notice of the RE'221 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz'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.

778. Sandoz 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 Sandoz's ANDA Product. Sandoz'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.

779. AbbVie will be irreparably harmed if Sandoz 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 Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 63 — INFRINGEMENT OF THE '629 PATENT BY SANDOZ

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

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

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

783. Sandoz's 15 mg ANDA Product infringes one or more claims of the '629 Patent.

784. Sandoz did not contest infringement of claims 1, 4, 11–16, 28, and 51–52 of the '629 Patent in Sandoz's Notice Letter. If Sandoz 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.

785. Sandoz has infringed one or more claims of the '629 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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.

786. The importation, manufacture, sale, offer for sale, or use of Sandoz'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 Sandoz 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).

787. Sandoz had actual and constructive notice of the '629 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz'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.

788. Sandoz 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 Sandoz's ANDA Product. Sandoz'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.

789. AbbVie will be irreparably harmed if Sandoz 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 Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 64 — INFRINGEMENT OF THE '080 PATENT BY SANDOZ

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

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

792. AbbVie owns all rights, title, and interest in and to the '080 Patent.

793. On information and belief, Sandoz's 15 mg ANDA Product infringes one or more claims of the '080 Patent, including at least claim 1.

794. On information and belief, Sandoz has infringed one or more claims of the '080 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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 '080 Patent.

795. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '080 Patent would infringe one or more claims of the '080 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '080 Patent under 35 U.S.C. § 271(b) and/or (c).

796. On information and belief, Sandoz had actual and constructive notice of the '080 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz's ANDA

with the request for FDA approval prior to the expiration of the '080 Patent would constitute an act of infringement of the '080 Patent.

797. On information and belief, Sandoz filed its ANDA without adequate justification for asserting that the '080 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Sandoz's conduct in certifying invalidity and/or non-infringement with respect to the '080 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.

798. On information and belief, AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '080 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 65 — INFRINGEMENT OF THE '923 PATENT BY SANDOZ

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

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

801. AbbVie owns all rights, title, and interest in and to the '923 Patent.

802. Sandoz's 15 mg ANDA Product infringes one or more claims of the '923 Patent.

803. Sandoz did not contest infringement of claims 2, 14, 17, and 19 of the '923 Patent in Sandoz's Notice Letter. If Sandoz had a factual or legal basis to contest infringement of the claims of the '923 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.

804. Sandoz has infringed one or more claims of the '923 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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 '923 Patent.

805. The importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '923 Patent would infringe one or more claims of the '923 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '923 Patent under 35 U.S.C. § 271(b) and/or (c).

806. Sandoz had actual and constructive notice of the '923 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '923 Patent would constitute an act of infringement of the '923 Patent.

807. Sandoz filed its ANDA without adequate justification for asserting that the '923 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Sandoz's conduct in certifying invalidity and/or non-infringement with respect to the '923 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.

808. AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '923 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 66 — INFRINGEMENT OF THE '584 PATENT BY SANDOZ

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

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

811. AbbVie owns all rights, title, and interest in and to the '584 Patent.

812. On information and belief, Sandoz's 15 mg ANDA Product infringes one or more claims of the '584 Patent, including at least claim 1.

813. On information and belief, Sandoz has infringed one or more claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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 '584 Patent.

814. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '584 Patent would infringe one or more claims of the '584 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '584 Patent under 35 U.S.C. § 271(b) and/or (c).

815. On information and belief, Sandoz had actual and constructive notice of the '584 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '584 Patent would constitute an act of infringement of the '584 Patent.

816. On information and belief, Sandoz filed its ANDA without adequate justification for asserting that the '584 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Sandoz's conduct in

certifying invalidity and/or non-infringement with respect to the '584 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.

817. On information and belief, AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '584 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 67 — INFRINGEMENT OF THE '425 PATENT BY SANDOZ

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

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

820. AbbVie owns all rights, title, and interest in and to the '425 Patent.

821. On information and belief, Sandoz's ANDA Products infringe one or more claims of the '425 Patent, including at least claim 1.

822. On information and belief, Sandoz has infringed one or more claims of the '425 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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 '425 Patent.

823. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Products prior to the expiration of the '425 Patent would infringe one or more claims of the '425 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement

of and/or contribute to the infringement of one or more claims of the '425 Patent under 35 U.S.C. § 271(b) and/or (c).

824. On information and belief, Sandoz had actual and constructive notice of the '425 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '425 Patent would constitute an act of infringement of the '425 Patent.

825. On information and belief, Sandoz filed its ANDA without adequate justification for asserting that the '425 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Products. Sandoz's conduct in certifying invalidity and/or non-infringement with respect to the '425 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.

826. On information and belief, AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '425 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 68 — INFRINGEMENT OF THE '069 PATENT BY SANDOZ

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

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

829. AbbVie owns all rights, title, and interest in and to the '069 Patent.

830. On information and belief, Sandoz's 15 mg ANDA Product infringes one or more claims of the '069 Patent, including at least claim 1.

831. On information and belief, Sandoz has infringed one or more claims of the '069 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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 '069 Patent.

832. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '069 Patent would infringe one or more claims of the '069 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '069 Patent under 35 U.S.C. § 271(b) and/or (c).

833. On information and belief, Sandoz had actual and constructive notice of the '069 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '069 Patent would constitute an act of infringement of the '069 Patent.

834. On information and belief, Sandoz filed its ANDA without adequate justification for asserting that the '069 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Sandoz's conduct in certifying invalidity and/or non-infringement with respect to the '069 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.

835. On information and belief, AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '069

Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 69 — INFRINGEMENT OF THE '627 PATENT BY SANDOZ

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

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

838. AbbVie owns all rights, title, and interest in and to the '627 Patent.

839. On information and belief, Sandoz's 15 mg ANDA Product infringes one or more claims of the '627 Patent, including at least claim 1.

840. On information and belief, Sandoz has infringed one or more claims of the '627 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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 '627 Patent.

841. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '627 Patent would infringe one or more claims of the '627 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '627 Patent under 35 U.S.C. § 271(b) and/or (c).

842. On information and belief, Sandoz had actual and constructive notice of the '627 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '627 Patent would constitute an act of infringement of the '627 Patent.

843. On information and belief, Sandoz filed its ANDA without adequate justification for asserting that the '627 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Sandoz's conduct in certifying invalidity and/or non-infringement with respect to the '627 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.

844. On information and belief, AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '627 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 70 — INFRINGEMENT OF THE '697 PATENT BY SANDOZ

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

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

847. AbbVie owns all rights, title, and interest in and to the '697 Patent.

848. Sandoz's 15 mg ANDA Product infringes one or more claims of the '697 Patent.

849. Sandoz did not contest infringement of claims 1–21, 23, 25, and 27 of the '697 Patent in Sandoz's Notice Letter. If Sandoz had a factual or legal basis to contest infringement of the claims of the '697 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.

850. Sandoz has infringed one or more claims of the '697 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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 '697 Patent.

851. The importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '697 Patent would infringe one or more claims of the '697 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '697 Patent under 35 U.S.C. § 271(b) and/or (c).

852. Sandoz had actual and constructive notice of the '697 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '697 Patent would constitute an act of infringement of the '697 Patent.

853. Sandoz filed its ANDA without adequate justification for asserting that the '697 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Sandoz's conduct in certifying invalidity and/or non-infringement with respect to the '697 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.

854. AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '697 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 71 — INFRINGEMENT OF THE '459 PATENT BY SANDOZ

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

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

857. AbbVie owns all rights, title, and interest in and to the '459 Patent.

858. Sandoz's 15 mg ANDA Product infringes one or more claims of the '459 Patent.

859. Sandoz did not contest infringement of claims 1–3, 5–6, 8–9, 11–13, 15–16, and 18–19 of the '459 Patent in Sandoz's Notice Letter. If Sandoz had a factual or legal basis to contest infringement of the claims of the '459 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.

860. Sandoz has infringed one or more claims of the '459 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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 '459 Patent.

861. The importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '459 Patent would infringe one or more claims of the '459 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '459 Patent under 35 U.S.C. § 271(b) and/or (c).

862. Sandoz had actual and constructive notice of the '459 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '459 Patent would constitute an act of infringement of the '459 Patent.

863. Sandoz filed its ANDA without adequate justification for asserting that the '459 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Sandoz's conduct in certifying invalidity and/or non-

infringement with respect to the '459 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.

864. AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '459 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 72 — INFRINGEMENT OF THE '164 PATENT BY SANDOZ

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

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

867. AbbVie owns all rights, title, and interest in and to the '164 Patent.

868. Sandoz's 15 mg ANDA Product infringes one or more claims of the '164 Patent.

869. Sandoz did not contest infringement of claims 1–11 of the '164 Patent. If Sandoz had a factual or legal basis to contest infringement of the claims of the '164 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.

870. Sandoz has infringed one or more claims of the '164 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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 '164 Patent.

871. The importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '164 Patent would infringe one or more claims of the '164 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '164 Patent under 35 U.S.C. § 271(b) and/or (c).

872. Sandoz had actual and constructive notice of the '164 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '164 Patent would constitute an act of infringement of the '164 Patent.

873. Sandoz filed its ANDA without adequate justification for asserting that the '164 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Sandoz's conduct in certifying invalidity and/or non-infringement with respect to the '164 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.

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

COUNT 73 — INFRINGEMENT OF THE '924 PATENT BY SANDOZ

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

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

877. AbbVie owns all rights, title, and interest in and to the '924 Patent.

878. Sandoz's 15 mg ANDA Product infringes one or more claims of the '924 Patent.

879. Sandoz did not contest infringement of claims 1–25 of the '924 Patent. If Sandoz had a factual or legal basis to contest infringement of the claims of the '924 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.

880. Sandoz has infringed one or more claims of the '924 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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 '924 Patent.

881. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '924 Patent would infringe one or more claims of the '924 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '924 Patent under 35 U.S.C. § 271(b) and/or (c).

882. Sandoz had actual and constructive notice of the '924 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '924 Patent would constitute an act of infringement of the '924 Patent.

883. Sandoz filed its ANDA without adequate justification for asserting that the '924 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Sandoz's conduct in certifying invalidity and/or non-infringement with respect to the '924 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.

884. AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '924 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 74 — INFRINGEMENT OF THE '400 PATENT BY SANDOZ

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

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

887. AbbVie owns all rights, title, and interest in and to the '400 Patent.

888. Sandoz's 15 mg ANDA Product infringes one or more claims of the '400 Patent.

889. Sandoz did not contest infringement of claims 1–3, 5–8, 10–13 and 15–24 of the '400 Patent in Sandoz's Notice Letter. If Sandoz had a factual or legal basis to contest infringement of the claims of the '400 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.

890. Sandoz has infringed one or more claims of the '400 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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 '400 Patent.

891. The importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '400 Patent would infringe one or more claims of the '400

Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '400 Patent under 35 U.S.C. § 271(b) and/or (c).

892. Sandoz had actual and constructive notice of the '400 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '400 Patent would constitute an act of infringement of the '400 Patent.

893. Sandoz filed its ANDA without adequate justification for asserting that the '400 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Sandoz's conduct in certifying invalidity and/or non-infringement with respect to the '400 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.

894. AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '400 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 75 — INFRINGEMENT OF THE '624 PATENT BY SANDOZ

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

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

897. AbbVie owns all rights, title, and interest in and to the '624 Patent.

898. Sandoz's 15 mg ANDA Product infringes one or more claims of the '624 Patent.

899. Sandoz did not contest infringement of claims 1–3 and 5 of the '624 Patent in Sandoz's Notice Letter. If Sandoz had a factual or legal basis to contest infringement of the claims of the '624 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.

900. Sandoz has infringed one or more claims of the '624 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz'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 '624 Patent.

901. The importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '624 Patent would infringe one or more claims of the '624 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '624 Patent under 35 U.S.C. § 271(b) and/or (c).

902. Sandoz had actual and constructive notice of the '624 Patent prior to submitting Sandoz's ANDA, and was aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '624 Patent would constitute an act of infringement of the '624 Patent.

903. Sandoz filed its ANDA without adequate justification for asserting that the '624 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Sandoz's conduct in certifying invalidity and/or non-infringement with respect to the '624 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.

904. AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '624 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 76 — INFRINGEMENT OF THE '105 PATENT BY SANDOZ

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

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

907. AbbVie owns all rights, title, and interest in and to the '105 Patent.

908. On information and belief, Sandoz's ANDA Products infringe one or more claims of the '105 Patent, including at least claim 1.

909. On information and belief, Sandoz has infringed one or more claims of the '105 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '105 Patent.

910. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Products prior to the expiration of the '105 Patent would infringe one or more claims of the '105 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '105 Patent under 35 U.S.C. § 271(b) and/or (c).

911. On information and belief, Sandoz has actual and constructive notice of the '105 Patent, and is aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '105 Patent would constitute an act of infringement of the '105 Patent.

912. On information and belief, Sandoz is without adequate justification for asserting that the '105 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Products. Any assertion by Sandoz of invalidity and/or non-infringement with respect to the '105 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.

913. On information and belief, AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '105 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 77 — INFRINGEMENT OF THE '847 PATENT BY SANDOZ

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

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

916. AbbVie owns all rights, title, and interest in and to the '847 Patent.

917. On information and belief, Sandoz's 15 mg ANDA Product infringes one or more claims of the '847 Patent, including at least claim 1.

918. On information and belief, Sandoz has infringed one or more claims of the '847 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '847 Patent.

919. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '847 Patent would infringe one or more

claims of the ’847 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the ’847 Patent under 35 U.S.C. § 271(b) and/or (c).

920. On information and belief, Sandoz has actual and constructive notice of the ’847 Patent, and is aware that the submission of Sandoz’s ANDA with the request for FDA approval prior to the expiration of the ’847 Patent would constitute an act of infringement of the ’847 Patent.

921. On information and belief, Sandoz is without adequate justification for asserting that the ’847 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz’s ANDA Product. Any assertion by Sandoz of invalidity and/or non-infringement with respect to the ’847 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.

922. On information and belief, AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the ’847 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 78 — INFRINGEMENT OF THE ’815 PATENT BY SANDOZ

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

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

925. AbbVie owns all rights, title, and interest in and to the ’815 Patent.

926. On information and belief, Sandoz's 15 mg ANDA Product infringes one or more claims of the '815 Patent, including at least claim 1.

927. On information and belief, Sandoz has infringed one or more claims of the '815 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '815 Patent.

928. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '815 Patent would infringe one or more claims of the '815 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '815 Patent under 35 U.S.C. § 271(b) and/or (c).

929. On information and belief, Sandoz has actual and constructive notice of the '815 Patent, and is aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '815 Patent would constitute an act of infringement of the '815 Patent.

930. On information and belief, Sandoz is without adequate justification for asserting that the '815 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Any assertion by Sandoz of invalidity and/or non-infringement with respect to the '815 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.

931. On information and belief, AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '815 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships

between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 79 — INFRINGEMENT OF THE '175 PATENT BY SANDOZ

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

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

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

935. Sandoz's Notice Letter indicates that with respect to its 15 mg ANDA Product it seeks approval for, *inter alia*, the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Accordingly, Sandoz's ANDA Product infringes one or more claims of the '175 Patent, including at least claim 1.

936. On information and belief, Sandoz has infringed one or more claims of the '175 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '175 Patent.

937. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '175 Patent would infringe one or more claims of the '175 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '175 Patent under 35 U.S.C. § 271(b) and/or (c).

938. On information and belief, Sandoz has actual and constructive notice of the '175 Patent, and is aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '175 Patent would constitute an act of infringement of the '175 Patent.

939. On information and belief, Sandoz is without adequate justification for asserting that the '175 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Product. Any assertion by Sandoz of invalidity and/or non-infringement with respect to the '175 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.

940. On information and belief, AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '175 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 80 — INFRINGEMENT OF THE '018 PATENT BY SANDOZ

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

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

943. AbbVie owns all rights, title, and interest in and to the '018 Patent.

944. Sandoz's Notice Letter does not contest infringement of claims directed to amorphous upadacitinib. Therefore, on information and belief, Sandoz's ANDA Products infringe one or more claims of the '018 Patent, including at least claim 1.

945. On information and belief, Sandoz has infringed one or more claims of the '018 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sandoz's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '018 Patent.

946. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Products prior to the expiration of the '018 Patent would infringe one or more claims of the '018 Patent under 35 U.S.C. § 271(a), and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the '018 Patent under 35 U.S.C. § 271(b) and/or (c).

947. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between AbbVie and Sandoz concerning liability for the infringement of the '018 Patent for which this Court may grant relief consistent with Article III of the United States Constitution. Subject matter jurisdiction over this Count exists pursuant to 35 U.S.C. § 271(e)(2)(A) and 28 U.S.C. §§ 1338(a), 2201, 2202.

948. On information and belief, Sandoz has actual and constructive notice of the '018 Patent, and is aware that the submission of Sandoz's ANDA with the request for FDA approval prior to the expiration of the '018 Patent would constitute an act of infringement of the '018 Patent.

949. On information and belief, Sandoz is without adequate justification for asserting that the '018 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Sandoz's ANDA Products. Any assertion by Sandoz of invalidity and/or non-infringement with respect to the '018 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.

950. AbbVie will be irreparably harmed if Sandoz is not enjoined from infringing and from actively inducing or contributing to the infringement of the '018 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and

Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 81 — INFRINGEMENT OF THE '080 PATENT BY INTAS

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

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

953. AbbVie owns all rights, title, and interest in and to the '080 Patent.

954. On information and belief, Intas's ANDA Products infringe one or more claims of the '080 Patent, including at least claim 1.

955. On information and belief, Intas has infringed one or more claims of the '080 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '080 Patent.

956. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Products prior to the expiration of the '080 Patent would infringe one or more claims of the '080 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '080 Patent under 35 U.S.C. § 271(b) and/or (c).

957. On information and belief, Intas had actual and constructive notice of the '080 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '080 Patent would constitute an act of infringement of the '080 Patent.

958. On information and belief, Intas filed its ANDA without adequate justification for asserting that the ’080 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas’s ANDA Products. Intas’s conduct in certifying invalidity and/or non-infringement with respect to the ’080 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.

959. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the ’080 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 82 — INFRINGEMENT OF THE ’923 PATENT BY INTAS

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

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

962. AbbVie owns all rights, title, and interest in and to the ’923 Patent.

963. Intas’s ANDA Products infringe one or more claims of the ’923 Patent.

964. Intas’s Notice Letter states that “the ANDA product uses an amorphous form of upadacitinib[.]” Therefore, on information and belief, Intas infringes one or more claims of the ’923 Patent, including at least claim 2.

965. Intas did not contest infringement of claims 2, 14, and 16–19 of the ’923 Patent in Intas’s Notice Letter. If Intas had a factual or legal basis to contest infringement of the claims of

the ’923 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.

966. Intas has infringed one or more claims of the ’923 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas’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 ’923 Patent.

967. The importation, manufacture, sale, offer for sale, or use of Intas’s ANDA Products prior to the expiration of the ’923 Patent would infringe one or more claims of the ’923 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the ’923 Patent under 35 U.S.C. § 271(b) and/or (c).

968. Intas had actual and constructive notice of the ’923 Patent prior to submitting Intas’s ANDA, and was aware that the submission of Intas’s ANDA with the request for FDA approval prior to the expiration of the ’923 Patent would constitute an act of infringement of the ’923 Patent.

969. Intas filed its ANDA without adequate justification for asserting that the ’923 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas’s ANDA Products. Intas’s conduct in certifying invalidity and/or non-infringement with respect to the ’923 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.

970. AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the ’923 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a

remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 83 — INFRINGEMENT OF THE '584 PATENT BY INTAS

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

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

973. AbbVie owns all rights, title, and interest in and to the '584 Patent.

974. On information and belief, Intas's ANDA Products infringe one or more claims of the '584 Patent, including at least claim 1.

975. On information and belief, Intas has infringed one or more claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '584 Patent.

976. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Products prior to the expiration of the '584 Patent would infringe one or more claims of the '584 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '584 Patent under 35 U.S.C. § 271(b) and/or (c).

977. On information and belief, Intas had actual and constructive notice of the '584 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '584 Patent would constitute an act of infringement of the '584 Patent.

978. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '584 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Products. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '584 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.

979. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '584 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 84 — INFRINGEMENT OF THE '425 PATENT BY INTAS

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

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

982. AbbVie owns all rights, title, and interest in and to the '425 Patent.

983. On information and belief, Intas's ANDA Products infringe one or more claims of the '425 Patent, including at least claim 1.

984. On information and belief, Intas has infringed one or more claims of the '425 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '425 Patent.

985. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Products prior to the expiration of the '425 Patent would infringe one or more claims of the '425 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '425 Patent under 35 U.S.C. § 271(b) and/or (c).

986. On information and belief, Intas had actual and constructive notice of the '425 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '425 Patent would constitute an act of infringement of the '425 Patent.

987. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '425 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Products. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '425 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.

988. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '425 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 85 — INFRINGEMENT OF THE '069 PATENT BY INTAS

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

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

991. AbbVie owns all rights, title, and interest in and to the '069 Patent.

992. On information and belief, Intas's ANDA Products infringe one or more claims of the '069 Patent, including at least claim 1.

993. On information and belief, Intas has infringed one or more claims of the '069 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '069 Patent.

994. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Products prior to the expiration of the '069 Patent would infringe one or more claims of the '069 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '069 Patent under 35 U.S.C. § 271(b) and/or (c).

995. On information and belief, Intas had actual and constructive notice of the '069 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '069 Patent would constitute an act of infringement of the '069 Patent.

996. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '069 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Products. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '069 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.

997. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '069 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 86 — INFRINGEMENT OF THE '627 PATENT BY INTAS

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

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

1000. AbbVie owns all rights, title, and interest in and to the '627 Patent.

1001. On information and belief, Intas's ANDA Products infringe one or more claims of the '627 Patent, including at least claim 1.

1002. On information and belief, Intas has infringed one or more claims of the '627 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '627 Patent.

1003. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Products prior to the expiration of the '627 Patent would infringe one or more claims of the '627 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '627 Patent under 35 U.S.C. § 271(b) and/or (c).

1004. On information and belief, Intas had actual and constructive notice of the '627 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '627 Patent would constitute an act of infringement of the '627 Patent.

1005. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '627 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Products. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '627 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.

1006. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '627 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 87 — INFRINGEMENT OF THE '697 PATENT BY INTAS

1007. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1008. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1009. AbbVie owns all rights, title, and interest in and to the '697 Patent.

1010. On information and belief, Intas's ANDA Products infringe one or more claims of the '697 Patent, including at least claim 1.

1011. On information and belief, Intas has infringed one or more claims of the '697 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '697 Patent.

1012. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Products prior to the expiration of the '697 Patent would infringe one or more claims of the '697 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '697 Patent under 35 U.S.C. § 271(b) and/or (c).

1013. On information and belief, Intas had actual and constructive notice of the '697 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '697 Patent would constitute an act of infringement of the '697 Patent.

1014. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '697 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Products. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '697 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.

1015. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '697 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships

between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 88 — INFRINGEMENT OF THE '459 PATENT BY INTAS

1016. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1017. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1018. AbbVie owns all rights, title, and interest in and to the '459 Patent.

1019. On information and belief, Intas's 15 mg ANDA Product infringes one or more claims of the '459 Patent, including at least claim 1.

1020. On information and belief, Intas has infringed one or more claims of the '459 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '459 Patent.

1021. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '459 Patent would infringe one or more claims of the '459 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '459 Patent under 35 U.S.C. § 271(b) and/or (c).

1022. On information and belief, Intas had actual and constructive notice of the '459 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '459 Patent would constitute an act of infringement of the '459 Patent.

1023. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '459 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '459 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.

1024. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '459 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 89 — INFRINGEMENT OF THE '036 PATENT BY INTAS

1025. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1026. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1027. AbbVie owns all rights, title, and interest in and to the '036 Patent.

1028. On information and belief, Intas's 30 mg ANDA Product infringes one or more claims of the '036 Patent, including at least claim 1.

1029. On information and belief, Intas has infringed one or more claims of the '036 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '036 Patent.

1030. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '036 Patent would infringe one or more claims of the '036 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '036 Patent under 35 U.S.C. § 271(b) and/or (c).

1031. On information and belief, Intas had actual and constructive notice of the '036 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '036 Patent would constitute an act of infringement of the '036 Patent.

1032. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '036 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '036 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.

1033. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '036 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 90 — INFRINGEMENT OF THE '393 PATENT BY INTAS

1034. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1035. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1036. AbbVie owns all rights, title, and interest in and to the '393 Patent.

1037. On information and belief, Intas's 45 mg ANDA Product infringes one or more claims of the '393 Patent, including at least claim 1.

1038. On information and belief, Intas has infringed one or more claims of the '393 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '393 Patent.

1039. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '393 Patent would infringe one or more claims of the '393 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '393 Patent under 35 U.S.C. § 271(b) and/or (c).

1040. On information and belief, Intas had actual and constructive notice of the '393 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '393 Patent would constitute an act of infringement of the '393 Patent.

1041. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '393 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '393 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.

1042. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '393 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 91 — INFRINGEMENT OF THE '164 PATENT BY INTAS

1043. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1044. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1045. AbbVie owns all rights, title, and interest in and to the '164 Patent.

1046. Intas's 15 mg ANDA Product infringes one or more claims of the '164 Patent.

1047. Intas did not contest infringement of claims 1–10 of the '164 Patent in Intas's Notice Letter. If Intas had a factual or legal basis to contest infringement of the claims of the '164 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.

1048. Intas has infringed one or more claims of the '164 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '164 Patent.

1049. The importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '164 Patent would infringe one or more claims of the '164 Patent

under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the ’164 Patent under 35 U.S.C. § 271(b) and/or (c).

1050. Intas had actual and constructive notice of the ’164 Patent prior to submitting Intas’s ANDA, and was aware that the submission of Intas’s ANDA with the request for FDA approval prior to the expiration of the ’164 Patent would constitute an act of infringement of the ’164 Patent.

1051. Intas filed its ANDA without adequate justification for asserting that the ’164 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas’s ANDA Product. Intas’s conduct in certifying invalidity and/or non-infringement with respect to the ’164 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.

1052. AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the ’164 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 92 — INFRINGEMENT OF THE ’883 PATENT BY INTAS

1053. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1054. On information and belief, Intas has submitted or caused the submission of Intas’s ANDA to FDA, and thereby seeks FDA approval of Intas’s ANDA Products.

1055. AbbVie owns all rights, title, and interest in and to the ’883 Patent.

1056. Intas’s 30 mg ANDA Product infringes one or more claims of the ’883 Patent.

1057. Intas did not contest infringement of claims 1–4 of the '883 Patent in Intas's Notice Letter. If Intas had a factual or legal basis to contest infringement of the claims of the '883 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.

1058. Intas has infringed one or more claims of the '883 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '883 Patent.

1059. The importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '883 Patent would infringe one or more claims of the '883 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '883 Patent under 35 U.S.C. § 271(b) and/or (c).

1060. Intas had actual and constructive notice of the '883 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '883 Patent would constitute an act of infringement of the '883 Patent.

1061. Intas filed its ANDA without adequate justification for asserting that the '883 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '883 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.

1062. AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '883 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 93 — INFRINGEMENT OF THE '924 PATENT BY INTAS

1063. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1064. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1065. AbbVie owns all rights, title, and interest in and to the '924 Patent.

1066. Intas's 15 mg and 30 mg ANDA Products infringe one or more claims of the '924 Patent.

1067. Intas did not contest infringement of claims 1–25 of the '924 Patent in Intas's Notice Letter. If Intas had a factual or legal basis to contest infringement of the claims of the '924 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.

1068. Intas has infringed one or more claims of the '924 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '924 Patent.

1069. The importation, manufacture, sale, offer for sale, or use of Intas's ANDA Products prior to the expiration of the '924 Patent would infringe one or more claims of the '924 Patent

under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '924 Patent under 35 U.S.C. § 271(b) and/or (c).

1070. Intas had actual and constructive notice of the '924 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '924 Patent would constitute an act of infringement of the '924 Patent.

1071. Intas filed its ANDA without adequate justification for asserting that the '924 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Products. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '924 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.

1072. AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '924 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 94 — INFRINGEMENT OF THE '400 PATENT BY INTAS

1073. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1074. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1075. AbbVie owns all rights, title, and interest in and to the '400 Patent.

1076. On information and belief, Intas's 15 mg ANDA Product infringes one or more claims of the '400 Patent, including at least claim 1.

1077. On information and belief, Intas has infringed one or more claims of the '400 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '400 Patent.

1078. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '400 Patent would infringe one or more claims of the '400 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '400 Patent under 35 U.S.C. § 271(b) and/or (c).

1079. On information and belief, Intas had actual and constructive notice of the '400 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '400 Patent would constitute an act of infringement of the '400 Patent.

1080. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '400 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '400 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.

1081. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '400

Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 95 — INFRINGEMENT OF THE '624 PATENT BY INTAS

1082. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1083. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1084. AbbVie owns all rights, title, and interest in and to the '624 Patent.

1085. On information and belief, Intas's 15 mg ANDA Product infringes one or more claims of the '624 Patent, including at least claim 1.

1086. On information and belief, Intas has infringed one or more claims of the '624 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '624 Patent.

1087. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '624 Patent would infringe one or more claims of the '624 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '624 Patent under 35 U.S.C. § 271(b) and/or (c).

1088. On information and belief, Intas had actual and constructive notice of the '624 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '624 Patent would constitute an act of infringement of the '624 Patent.

1089. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '624 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '624 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.

1090. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '624 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 96 — INFRINGEMENT OF THE '095 PATENT BY INTAS

1091. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1092. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1093. AbbVie owns all rights, title, and interest in and to the '095 Patent.

1094. On information and belief, Intas's 15 mg ANDA Product infringes one or more claims of the '095 Patent, including at least claim 1.

1095. On information and belief, Intas has infringed one or more claims of the '095 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '095 Patent.

1096. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '095 Patent would infringe one or more claims of the '095 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '095 Patent under 35 U.S.C. § 271(b) and/or (c).

1097. On information and belief, Intas had actual and constructive notice of the '095 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '095 Patent would constitute an act of infringement of the '095 Patent.

1098. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '095 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '095 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.

1099. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '095 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 97 — INFRINGEMENT OF THE '126 PATENT BY INTAS

1100. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1101. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1102. AbbVie owns all rights, title, and interest in and to the '126 Patent.

1103. On information and belief, Intas's 30 mg ANDA Product infringes one or more claims of the '126 Patent, including at least claim 1.

1104. On information and belief, Intas has infringed one or more claims of the '126 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '126 Patent.

1105. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '126 Patent would infringe one or more claims of the '126 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '126 Patent under 35 U.S.C. § 271(b) and/or (c).

1106. On information and belief, Intas had actual and constructive notice of the '126 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '126 Patent would constitute an act of infringement of the '126 Patent.

1107. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '126 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '126 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.

1108. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '126 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 98 — INFRINGEMENT OF THE '625 PATENT BY INTAS

1109. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1110. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1111. AbbVie owns all rights, title, and interest in and to the '625 Patent.

1112. On information and belief, Intas's 15 mg ANDA Product infringes one or more claims of the '625 Patent, including at least claim 1.

1113. On information and belief, Intas has infringed one or more claims of the '625 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '625 Patent.

1114. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '625 Patent would infringe one or more claims of the '625 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '625 Patent under 35 U.S.C. § 271(b) and/or (c).

1115. On information and belief, Intas had actual and constructive notice of the '625 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '625 Patent would constitute an act of infringement of the '625 Patent.

1116. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '625 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '625 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.

1117. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '625 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 99 — INFRINGEMENT OF THE '626 PATENT BY INTAS

1118. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1119. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1120. AbbVie owns all rights, title, and interest in and to the '626 Patent.

1121. On information and belief, Intas's 30 mg ANDA Product infringes one or more claims of the '626 Patent, including at least claim 1.

1122. On information and belief, Intas has infringed one or more claims of the '626 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '626 Patent.

1123. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '626 Patent would infringe one or more claims of the '626 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '626 Patent under 35 U.S.C. § 271(b) and/or (c).

1124. On information and belief, Intas had actual and constructive notice of the '626 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '626 Patent would constitute an act of infringement of the '626 Patent.

1125. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '626 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '626 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.

1126. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '626 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships

between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 100 — INFRINGEMENT OF THE '198 PATENT BY INTAS

1127. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1128. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1129. AbbVie owns all rights, title, and interest in and to the '198 Patent.

1130. On information and belief, Intas's 15 mg ANDA Product infringes one or more claims of the '198 Patent, including at least claim 1.

1131. On information and belief, Intas has infringed one or more claims of the '198 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '198 Patent.

1132. On information and belief, On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '198 Patent would infringe one or more claims of the '198 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '198 Patent under 35 U.S.C. § 271(b) and/or (c).

1133. On information and belief, Intas had actual and constructive notice of the '198 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '198 Patent would constitute an act of infringement of the '198 Patent.

1134. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '198 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '198 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.

1135. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '198 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 101 — INFRINGEMENT OF THE '092 PATENT BY INTAS

1136. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1137. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1138. AbbVie owns all rights, title, and interest in and to the '092 Patent.

1139. On information and belief, Intas's 15 mg ANDA Product infringes one or more claims of the '092 Patent, including at least claim 1.

1140. On information and belief, Intas has infringed one or more claims of the '092 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '092 Patent.

1141. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '092 Patent would infringe one or more claims of the '092 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '092 Patent under 35 U.S.C. § 271(b) and/or (c).

1142. On information and belief, Intas had actual and constructive notice of the '092 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '092 Patent would constitute an act of infringement of the '092 Patent.

1143. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '092 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '092 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.

1144. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '092 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 102 — INFRINGEMENT OF THE '964 PATENT BY INTAS

1145. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1146. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1147. AbbVie owns all rights, title, and interest in and to the '964 Patent.

1148. On information and belief, Intas's 15 mg ANDA Product infringes one or more claims of the '964 Patent, including at least claim 1.

1149. On information and belief, Intas has infringed one or more claims of the '964 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '964 Patent.

1150. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '964 Patent would infringe one or more claims of the '964 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '964 Patent under 35 U.S.C. § 271(b) and/or (c).

1151. On information and belief, Intas had actual and constructive notice of the '964 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '964 Patent would constitute an act of infringement of the '964 Patent.

1152. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '964 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '964 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.

1153. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '964 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 103 — INFRINGEMENT OF THE '411 PATENT BY INTAS

1154. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1155. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1156. AbbVie owns all rights, title, and interest in and to the '411 Patent.

1157. On information and belief, Intas's ANDA Products infringe one or more claims of the '411 Patent, including at least claim 1.

1158. On information and belief, Intas has infringed one or more claims of the '411 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '411 Patent.

1159. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Products prior to the expiration of the '411 Patent would infringe one or more claims of the '411 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '411 Patent under 35 U.S.C. § 271(b) and/or (c).

1160. On information and belief, Intas had actual and constructive notice of the '411 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '411 Patent would constitute an act of infringement of the '411 Patent.

1161. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '411 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Products. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '411 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.

1162. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '411 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 104 — INFRINGEMENT OF THE '922 PATENT BY INTAS

1163. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1164. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1165. AbbVie owns all rights, title, and interest in and to the '922 Patent.

1166. On information and belief, Intas's ANDA Products infringe one or more claims of the '922 Patent, including at least claim 1.

1167. On information and belief, Intas has infringed one or more claims of the '922 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas'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 '922 Patent.

1168. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Products prior to the expiration of the '922 Patent would infringe one or more claims of the '922 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '922 Patent under 35 U.S.C. § 271(b) and/or (c).

1169. On information and belief, Intas had actual and constructive notice of the '922 Patent prior to submitting Intas's ANDA, and was aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '922 Patent would constitute an act of infringement of the '922 Patent.

1170. On information and belief, Intas filed its ANDA without adequate justification for asserting that the '922 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Products. Intas's conduct in certifying invalidity and/or non-infringement with respect to the '922 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.

1171. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '922 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships

between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 105 — INFRINGEMENT OF THE '326 PATENT BY INTAS

1172. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1173. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1174. AbbVie owns all rights, title, and interest in and to the '326 Patent.

1175. Intas's Notice Letter indicates that with respect to its 15 mg and 30 mg ANDA Products it seeks approval for the treatment of moderate to severe atopic dermatitis. Accordingly, on information and belief, Intas's ANDA Products infringe one or more claims of the '326 Patent, including at least claim 1.

1176. On information and belief, Intas has infringed one or more claims of the '326 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '326 Patent.

1177. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Products prior to the expiration of the '326 Patent would infringe one or more claims of the '326 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '326 Patent under 35 U.S.C. § 271(b) and/or (c).

1178. On information and belief, Intas has actual and constructive notice of the '326 Patent, and is aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '326 Patent would constitute an act of infringement of the '326 Patent.

1179. On information and belief, Intas is without adequate justification for asserting that the '326 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Products. Any assertion by Intas of invalidity and/or non-infringement with respect to the '326 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.

1180. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '326 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 106 — INFRINGEMENT OF THE '105 PATENT BY INTAS

1181. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1182. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1183. AbbVie owns all rights, title, and interest in and to the '105 Patent.

1184. On information and belief, Intas's ANDA Products infringe one or more claims of the '105 Patent, including at least claim 1.

1185. On information and belief, Intas has infringed one or more claims of the '105 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '105 Patent.

1186. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Products prior to the expiration of the '105 Patent would infringe one or more

claims of the ’105 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the ’105 Patent under 35 U.S.C. § 271(b) and/or (c).

1187. On information and belief, Intas has actual and constructive notice of the ’105 Patent, and is aware that the submission of Intas’s ANDA with the request for FDA approval prior to the expiration of the ’105 Patent would constitute an act of infringement of the ’105 Patent.

1188. On information and belief, Intas is without adequate justification for asserting that the ’105 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas’s ANDA Products. Any assertion by Intas of invalidity and/or non-infringement with respect to the ’105 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.

1189. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the ’105 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 107 — INFRINGEMENT OF THE ’106 PATENT BY INTAS

1190. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1191. On information and belief, Intas has submitted or caused the submission of Intas’s ANDA to FDA, and thereby seeks FDA approval of Intas’s ANDA Products.

1192. AbbVie owns all rights, title, and interest in and to the ’106 Patent.

1193. Intas's Notice Letter 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; the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers; and 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. Accordingly, on information and belief, Intas's ANDA Product infringes one or more claims of the '106 Patent, including at least claim 1.

1194. On information and belief, Intas has infringed one or more claims of the '106 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '106 Patent.

1195. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '106 Patent would infringe one or more claims of the '106 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '106 Patent under 35 U.S.C. § 271(b) and/or (c).

1196. On information and belief, Intas has actual and constructive notice of the '106 Patent, and is aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '106 Patent would constitute an act of infringement of the '106 Patent.

1197. On information and belief, Intas is without adequate justification for asserting that the '106 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Any assertion by Intas of invalidity and/or non-infringement with respect to the '106 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.

1198. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '106 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 108 — INFRINGEMENT OF THE '847 PATENT BY INTAS

1199. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1200. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1201. AbbVie owns all rights, title, and interest in and to the '847 Patent.

1202. On information and belief, Intas's 15 mg ANDA Product infringes one or more claims of the '847 Patent, including at least claim 1.

1203. On information and belief, Intas has infringed one or more claims of the '847 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '847 Patent.

1204. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '847 Patent would infringe one or more claims of the '847 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '847 Patent under 35 U.S.C. § 271(b) and/or (c).

1205. On information and belief, Intas has actual and constructive notice of the '847 Patent, and is aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '847 Patent would constitute an act of infringement of the '847 Patent.

1206. On information and belief, Intas is without adequate justification for asserting that the '847 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Any assertion by Intas of invalidity and/or non-infringement with respect to the '847 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.

1207. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '847 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 108 — INFRINGEMENT OF THE '848 PATENT BY INTAS

1208. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1209. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1210. AbbVie owns all rights, title, and interest in and to the '848 Patent.

1211. Intas's Notice Letter indicates that with respect to its 15 mg ANDA Product it seeks approval for, *inter alia*, the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Accordingly, on information

and belief, Intas's ANDA Product infringes one or more claims of the '848 Patent, including at least claim 1.

1212. On information and belief, Intas has infringed one or more claims of the '848 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '848 Patent.

1213. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '848 Patent would infringe one or more claims of the '848 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '848 Patent under 35 U.S.C. § 271(b) and/or (c).

1214. On information and belief, Intas has actual and constructive notice of the '848 Patent, and is aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '848 Patent would constitute an act of infringement of the '848 Patent.

1215. On information and belief, Intas is without adequate justification for asserting that the '848 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Any assertion by Intas of invalidity and/or non-infringement with respect to the '848 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.

1216. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '848 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships

between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 109 — INFRINGEMENT OF THE '815 PATENT BY INTAS

1217. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1218. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1219. AbbVie owns all rights, title, and interest in and to the '815 Patent.

1220. On information and belief, Intas's 15 mg ANDA Product infringes one or more claims of the '815 Patent, including at least claim 1.

1221. On information and belief, Intas has infringed one or more claims of the '815 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '815 Patent.

1222. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '815 Patent would infringe one or more claims of the '815 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '815 Patent under 35 U.S.C. § 271(b) and/or (c).

1223. On information and belief, Intas has actual and constructive notice of the '815 Patent, and is aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '815 Patent would constitute an act of infringement of the '815 Patent.

1224. On information and belief, Intas is without adequate justification for asserting that the '815 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Product. Any assertion by Intas of invalidity and/or

non-infringement with respect to the '815 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.

1225. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '815 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 110 — INFRINGEMENT OF THE '175 PATENT BY INTAS

1226. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1227. On information and belief, Intas has submitted or caused the submission of Intas's ANDA to FDA, and thereby seeks FDA approval of Intas's ANDA Products.

1228. AbbVie owns all rights, title, and interest in and to the '175 Patent.

1229. Intas's Notice Letter indicates that with respect to its 15 mg ANDA Product it seeks approval for, *inter alia*, the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Accordingly, on information and belief, Intas's ANDA Product infringes one or more claims of the '175 Patent, including at least claim 1.

1230. On information and belief, Intas has infringed one or more claims of the '175 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '175 Patent.

1231. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Product prior to the expiration of the '175 Patent would infringe one or more

claims of the ’175 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the ’175 Patent under 35 U.S.C. § 271(b) and/or (c).

1232. On information and belief, Intas has actual and constructive notice of the ’175 Patent, and is aware that the submission of Intas’s ANDA with the request for FDA approval prior to the expiration of the ’175 Patent would constitute an act of infringement of the ’175 Patent.

1233. On information and belief, Intas is without adequate justification for asserting that the ’175 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas’s ANDA Product. Any assertion by Intas of invalidity and/or non-infringement with respect to the ’175 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.

1234. On information and belief, AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the ’175 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 111 — INFRINGEMENT OF THE ’018 PATENT BY INTAS

1235. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1236. On information and belief, Intas has submitted or caused the submission of Intas’s ANDA to FDA, and thereby seeks FDA approval of Intas’s ANDA Products.

1237. AbbVie owns all rights, title, and interest in and to the ’018 Patent.

1238. Intas's Notice Letter states that Intas's "ANDA product uses an amorphous form of upadacitinib[.]" Therefore, on information and belief, Intas's ANDA Products infringe one or more claims of the '018 Patent, including at least claim 1.

1239. On information and belief, Intas has infringed one or more claims of the '018 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Intas's ANDA and thereby seeking FDA approval of a purported generic version of RINVOQ® prior to the expiration of the '018 Patent.

1240. On information and belief, the importation, manufacture, sale, offer for sale, or use of Intas's ANDA Products prior to the expiration of the '018 Patent would infringe one or more claims of the '018 Patent under 35 U.S.C. § 271(a), and/or Intas would induce the infringement of and/or contribute to the infringement of one or more claims of the '018 Patent under 35 U.S.C. § 271(b) and/or (c).

1241. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between AbbVie and Intas concerning liability for the infringement of the '018 Patent for which this Court may grant relief consistent with Article III of the United States Constitution. Subject matter jurisdiction over this Count exists pursuant to 35 U.S.C. § 271(e)(2)(A) and 28 U.S.C. §§ 1338(a), 2201, 2202.

1242. On information and belief, Intas has actual and constructive notice of the '018 Patent, and is aware that the submission of Intas's ANDA with the request for FDA approval prior to the expiration of the '018 Patent would constitute an act of infringement of the '018 Patent.

1243. On information and belief, Intas is without adequate justification for asserting that the '018 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Intas's ANDA Products. Any assertion by Intas of invalidity and/or non-infringement with respect to the '018 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.

1244. AbbVie will be irreparably harmed if Intas is not enjoined from infringing and from actively inducing or contributing to the infringement of the '018 Patent. AbbVie does not have an adequate remedy at law, and considering the balance of hardships between AbbVie and Intas, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 112 — INFRINGEMENT OF THE RE'221 PATENT BY SUN

1245. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1246. 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.

1247. AbbVie owns all rights, title, and interest in and to the RE'221 Patent.

1248. Sun's ANDA Product infringes one or more claims of the RE'221 Patent.

1249. Sun did not contest infringement of claims 13–14 of the RE'221 Patent in Sun's Notice Letter. If Sun 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.

1250. Sun has infringed one or more claims of the RE'221 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 RE'221 Patent.

1251. The importation, manufacture, sale, offer for sale, or use of Sun'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 Sun 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).

1252. Sun had actual and constructive notice of the RE'221 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun'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.

1253. Sun 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 Sun's ANDA Product. Sun'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.

1254. AbbVie will be irreparably harmed if Sun 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 Sun, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 113 — INFRINGEMENT OF THE '629 PATENT BY SUN

1255. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1256. 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.

1257. AbbVie owns all rights, title, and interest in and to the '629 Patent.

1258. Sun's ANDA Product infringes one or more claims of the '629 Patent.

1259. Sun did not contest infringement of claims 1–53 of the '629 Patent in Sun's Notice Letter. If Sun 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.

1260. Sun has infringed one or more claims of the '629 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 '629 Patent.

1261. The importation, manufacture, sale, offer for sale, or use of Sun'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 Sun 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).

1262. Sun had actual and constructive notice of the '629 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun'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.

1263. Sun 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 Sun's ANDA Product. Sun'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.

1264. AbbVie will be irreparably harmed if Sun 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 Sun, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT 114 — INFRINGEMENT OF THE '080 PATENT BY SUN

1265. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1266. 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.

1267. AbbVie owns all rights, title, and interest in and to the '080 Patent.

1268. On information and belief, Sun's ANDA Product infringes one or more claims of the '080 Patent, including at least claim 1.

1269. On information and belief, Sun has infringed one or more claims of the '080 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 '080 Patent.

1270. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '080 Patent would infringe one or more claims of the '080 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 '080 Patent under 35 U.S.C. § 271(b) and/or (c).

1271. On information and belief, Sun had actual and constructive notice of the '080 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the

request for FDA approval prior to the expiration of the '080 Patent would constitute an act of infringement of the '080 Patent.

1272. On information and belief, Sun filed its ANDA without adequate justification for asserting that the '080 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 '080 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.

1273. 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 '080 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 115 — INFRINGEMENT OF THE '923 PATENT BY SUN

1274. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1275. 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.

1276. AbbVie owns all rights, title, and interest in and to the '923 Patent.

1277. Sun's ANDA Product infringes one or more claims of the '923 Patent.

1278. Sun did not contest infringement of claims 2, and 14–19 of the '923 Patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest infringement of the claims of the '923 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.

1279. Sun has infringed one or more claims of the '923 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 '923 Patent.

1280. The importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '923 Patent would infringe one or more claims of the '923 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 '923 Patent under 35 U.S.C. § 271(b) and/or (c).

1281. Sun had actual and constructive notice of the '923 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '923 Patent would constitute an act of infringement of the '923 Patent.

1282. Sun filed its ANDA without adequate justification for asserting that the '923 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 '923 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.

1283. AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the '923 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 116 — INFRINGEMENT OF THE '584 PATENT BY SUN

1284. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1285. 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.

1286. AbbVie owns all rights, title, and interest in and to the '584 Patent.

1287. On information and belief, Sun's ANDA Product infringes one or more claims of the '584 Patent, including at least claim 1.

1288. On information and belief, Sun has infringed one or more claims of the '584 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 '584 Patent.

1289. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '584 Patent would infringe one or more claims of the '584 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 '584 Patent under 35 U.S.C. § 271(b) and/or (c).

1290. On information and belief, Sun had actual and constructive notice of the '584 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '584 Patent would constitute an act of infringement of the '584 Patent.

1291. On information and belief, Sun filed its ANDA without adequate justification for asserting that the '584 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 '584 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.

1292. 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 '584 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 117 — INFRINGEMENT OF THE '425 PATENT BY SUN

1293. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1294. 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.

1295. AbbVie owns all rights, title, and interest in and to the '425 Patent.

1296. On information and belief, Sun's ANDA Product infringes one or more claims of the '425 Patent, including at least claim 1.

1297. On information and belief, Sun has infringed one or more claims of the '425 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 '425 Patent.

1298. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '425 Patent would infringe one or more claims of the '425 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 '425 Patent under 35 U.S.C. § 271(b) and/or (c).

1299. On information and belief, Sun had actual and constructive notice of the '425 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '425 Patent would constitute an act of infringement of the '425 Patent.

1300. On information and belief, Sun filed its ANDA without adequate justification for asserting that the '425 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 '425 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.

1301. 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 '425 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 118 — INFRINGEMENT OF THE '069 PATENT BY SUN

1302. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1303. 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.

1304. AbbVie owns all rights, title, and interest in and to the '069 Patent.

1305. On information and belief, Sun's ANDA Product infringes one or more claims of the '069 Patent, including at least claim 1.

1306. On information and belief, Sun has infringed one or more claims of the '069 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 '069 Patent.

1307. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '069 Patent would infringe one or more claims of the '069 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 '069 Patent under 35 U.S.C. § 271(b) and/or (c).

1308. On information and belief, Sun had actual and constructive notice of the '069 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '069 Patent would constitute an act of infringement of the '069 Patent.

1309. On information and belief, Sun filed its ANDA without adequate justification for asserting that the '069 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 '069 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.

1310. 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 '069 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 119 — INFRINGEMENT OF THE '627 PATENT BY SUN

1311. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1312. 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.

1313. AbbVie owns all rights, title, and interest in and to the '627 Patent.

1314. On information and belief, Sun's ANDA Product infringes one or more claims of the '627 Patent, including at least claim 1.

1315. On information and belief, Sun has infringed one or more claims of the '627 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 '627 Patent.

1316. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '627 Patent would infringe one or more claims of the '627 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 '627 Patent under 35 U.S.C. § 271(b) and/or (c).

1317. On information and belief, Sun had actual and constructive notice of the '627 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '627 Patent would constitute an act of infringement of the '627 Patent.

1318. On information and belief, Sun filed its ANDA without adequate justification for asserting that the '627 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 '627 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.

1319. 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 '627 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 120 — INFRINGEMENT OF THE '697 PATENT BY SUN

1320. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1321. 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.

1322. AbbVie owns all rights, title, and interest in and to the '697 Patent.

1323. Sun's ANDA Product infringes one or more claims of the '697 Patent.

1324. Sun did not contest infringement of claims 1–5, 7–18, and 20–30 of the '697 Patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest infringement of the claims of the '697 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.

1325. Sun has infringed one or more claims of the '697 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 '697 Patent.

1326. The importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '697 Patent would infringe one or more claims of the '697 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 '697 Patent under 35 U.S.C. § 271(b) and/or (c).

1327. Sun had actual and constructive notice of the '697 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '697 Patent would constitute an act of infringement of the '697 Patent.

1328. Sun filed its ANDA without adequate justification for asserting that the '697 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 '697 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.

1329. AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the '697 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 121 — INFRINGEMENT OF THE '459 PATENT BY SUN

1330. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1331. 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.

1332. AbbVie owns all rights, title, and interest in and to the '459 Patent.

1333. Sun's ANDA Product infringes one or more claims of the '459 Patent.

1334. Sun did not contest infringement of claims 1–20 of the '459 Patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest infringement of the claims of the '459 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.

1335. Sun has infringed one or more claims of the '459 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 '459 Patent.

1336. The importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '459 Patent would infringe one or more claims of the '459 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 '459 Patent under 35 U.S.C. § 271(b) and/or (c).

1337. Sun had actual and constructive notice of the '459 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '459 Patent would constitute an act of infringement of the '459 Patent.

1338. Sun filed its ANDA without adequate justification for asserting that the '459 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 '459 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.

1339. AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the '459 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 122 — INFRINGEMENT OF THE '164 PATENT BY SUN

1340. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1341. 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.

1342. AbbVie owns all rights, title, and interest in and to the '164 Patent.

1343. Sun's ANDA Product infringes one or more claims of the '164 Patent.

1344. Sun did not contest infringement of claims 1–10 of the '164 Patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest infringement of the claims of the '164 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.

1345. Sun has infringed one or more claims of the '164 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 '164 Patent.

1346. The importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '164 Patent would infringe one or more claims of the '164 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 '164 Patent under 35 U.S.C. § 271(b) and/or (c).

1347. Sun had actual and constructive notice of the '164 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '164 Patent would constitute an act of infringement of the '164 Patent.

1348. Sun filed its ANDA without adequate justification for asserting that the '164 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 '164 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.

1349. AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the '164 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 123 — INFRINGEMENT OF THE '924 PATENT BY SUN

1350. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1351. 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.

1352. AbbVie owns all rights, title, and interest in and to the '924 Patent.

1353. Sun's ANDA Product infringes one or more claims of the '924 Patent.

1354. Sun did not contest infringement of claims 1–3, 7–9, and 13–19 of the '924 Patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest infringement of the claims of the '924 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.

1355. Sun has infringed one or more claims of the '924 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 '924 Patent.

1356. The importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '924 Patent would infringe one or more claims of the '924 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 '924 Patent under 35 U.S.C. § 271(b) and/or (c).

1357. Sun had actual and constructive notice of the '924 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '924 Patent would constitute an act of infringement of the '924 Patent.

1358. Sun filed its ANDA without adequate justification for asserting that the '924 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 '924 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.

1359. AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the '924 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 124 — INFRINGEMENT OF THE '400 PATENT BY SUN

1360. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1361. 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.

1362. AbbVie owns all rights, title, and interest in and to the '400 Patent.

1363. Sun's ANDA Product infringes one or more claims of the '400 Patent.

1364. Sun did not contest infringement of claims 1–24 of the '400 Patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest infringement of the claims of the '400 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.

1365. Sun has infringed one or more claims of the '400 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 '400 Patent.

1366. The importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '400 Patent would infringe one or more claims of the '400 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 '400 Patent under 35 U.S.C. § 271(b) and/or (c).

1367. Sun had actual and constructive notice of the ’400 Patent prior to submitting Sun’s ANDA, and was aware that the submission of Sun’s ANDA with the request for FDA approval prior to the expiration of the ’400 Patent would constitute an act of infringement of the ’400 Patent.

1368. Sun filed its ANDA without adequate justification for asserting that the ’400 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 ’400 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.

1369. AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the ’400 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 125 — INFRINGEMENT OF THE ’624 PATENT BY SUN

1370. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1371. 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.

1372. AbbVie owns all rights, title, and interest in and to the ’624 Patent.

1373. Sun’s ANDA Product infringes one or more claims of the ’624 Patent.

1374. Sun did not contest infringement of claims 1–5 of the ’624 Patent in Sun’s Notice Letter. If Sun had a factual or legal basis to contest infringement of the claims of the ’624 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.

1375. Sun has infringed one or more claims of the '624 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 '624 Patent.

1376. The importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '624 Patent would infringe one or more claims of the '624 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 '624 Patent under 35 U.S.C. § 271(b) and/or (c).

1377. Sun had actual and constructive notice of the '624 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '624 Patent would constitute an act of infringement of the '624 Patent.

1378. Sun filed its ANDA without adequate justification for asserting that the '624 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 '624 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.

1379. AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the '624 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 126 — INFRINGEMENT OF THE '095 PATENT BY SUN

1380. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1381. 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.

1382. AbbVie owns all rights, title, and interest in and to the '095 Patent.

1383. Sun's ANDA Product infringes one or more claims of the '095 Patent.

1384. Sun did not contest infringement of claims 1–9 of the '095 Patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest infringement of the claims of the '095 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.

1385. Sun has infringed one or more claims of the '095 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 '095 Patent.

1386. The importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '095 Patent would infringe one or more claims of the '095 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 '095 Patent under 35 U.S.C. § 271(b) and/or (c).

1387. Sun had actual and constructive notice of the '095 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '095 Patent would constitute an act of infringement of the '095 Patent.

1388. Sun filed its ANDA without adequate justification for asserting that the '095 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 '095 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.

1389. AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the '095 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 127 — INFRINGEMENT OF THE '625 PATENT BY SUN

1390. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1391. 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.

1392. AbbVie owns all rights, title, and interest in and to the '625 Patent.

1393. Sun's ANDA Product infringes one or more claims of the '625 Patent.

1394. Sun did not contest infringement of claims 1–20 of the '625 Patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest infringement of the claims of the '625 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.

1395. Sun has infringed one or more claims of the '625 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 '625 Patent.

1396. The importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '625 Patent would infringe one or more claims of the '625 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 '625 Patent under 35 U.S.C. § 271(b) and/or (c).

1397. Sun had actual and constructive notice of the '625 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '625 Patent would constitute an act of infringement of the '625 Patent.

1398. Sun filed its ANDA without adequate justification for asserting that the '625 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 '625 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.

1399. AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the '625 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 128 — INFRINGEMENT OF THE '198 PATENT BY SUN

1400. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1401. 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.

1402. AbbVie owns all rights, title, and interest in and to the '198 Patent.

1403. Sun's ANDA Product infringes one or more claims of the '198 Patent.

1404. Sun did not contest infringement of claims 1–22 of the '198 Patent in Sun's Notice Letter. If Sun had a factual or legal basis to contest infringement of the claims of the '198 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.

1405. Sun has infringed one or more claims of the '198 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 '198 Patent.

1406. The importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '198 Patent would infringe one or more claims of the '198 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 '198 Patent under 35 U.S.C. § 271(b) and/or (c).

1407. Sun had actual and constructive notice of the '198 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '198 Patent would constitute an act of infringement of the '198 Patent.

1408. Sun filed its ANDA without adequate justification for asserting that the '198 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 '198 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.

1409. AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the '198 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 129 — INFRINGEMENT OF THE '092 PATENT BY SUN

1410. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1411. 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.

1412. AbbVie owns all rights, title, and interest in and to the '092 Patent.

1413. On information and belief, Sun's ANDA Product infringes one or more claims of the '092 Patent, including at least claim 1.

1414. On information and belief, Sun has infringed one or more claims of the '092 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 '092 Patent.

1415. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '092 Patent would infringe one or more claims of the '092 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 '092 Patent under 35 U.S.C. § 271(b) and/or (c).

1416. On information and belief, Sun had actual and constructive notice of the '092 Patent prior to submitting Sun's ANDA, and was aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '092 Patent would constitute an act of infringement of the '092 Patent.

1417. On information and belief, Sun filed its ANDA without adequate justification for asserting that the '092 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 '092 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.

1418. 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 '092 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 130 — INFRINGEMENT OF THE '326 PATENT BY SUN

1419. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1420. 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.

1421. AbbVie owns all rights, title, and interest in and to the '326 Patent.

1422. Sun's Notice Letter indicates that with respect to its ANDA Product it seeks approval for the treatment of moderate to severe atopic dermatitis. Accordingly, on information

and belief, Sun's ANDA Product infringes one or more claims of the '326 Patent, including at least claim 1.

1423. On information and belief, Sun has infringed one or more claims of the '326 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 '326 Patent.

1424. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '326 Patent would infringe one or more claims of the '326 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 '326 Patent under 35 U.S.C. § 271(b) and/or (c).

1425. On information and belief, Sun has actual and constructive notice of the '326 Patent, and is aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '326 Patent would constitute an act of infringement of the '326 Patent.

1426. On information and belief, Sun is without adequate justification for asserting that the '326 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 '326 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.

1427. 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 '326 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 131 — INFRINGEMENT OF THE '105 PATENT BY SUN

1428. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1429. 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.

1430. AbbVie owns all rights, title, and interest in and to the '105 Patent.

1431. On information and belief, Sun's ANDA Product infringes one or more claims of the '105 Patent, including at least claim 1.

1432. On information and belief, Sun has infringed one or more claims of the '105 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 '105 Patent.

1433. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '105 Patent would infringe one or more claims of the '105 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 '105 Patent under 35 U.S.C. § 271(b) and/or (c).

1434. On information and belief, Sun has actual and constructive notice of the '105 Patent, and is aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '105 Patent would constitute an act of infringement of the '105 Patent.

1435. On information and belief, Sun is without adequate justification for asserting that the '105 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 '105 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.

1436. 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 '105 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 132 — INFRINGEMENT OF THE '106 PATENT BY SUN

1437. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1438. 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.

1439. AbbVie owns all rights, title, and interest in and to the '106 Patent.

1440. Sun's Notice Letter indicates that with respect to its 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. Accordingly, on information and belief, Sun's ANDA Product infringes one or more claims of the '106 Patent, including at least claim 1.

1441. On information and belief, Sun has infringed one or more claims of the '106 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 '106 Patent.

1442. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '106 Patent would infringe one or more

claims of the ’106 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 ’106 Patent under 35 U.S.C. § 271(b) and/or (c).

1443. On information and belief, Sun has actual and constructive notice of the ’106 Patent, and is aware that the submission of Sun’s ANDA with the request for FDA approval prior to the expiration of the ’106 Patent would constitute an act of infringement of the ’106 Patent.

1444. On information and belief, Sun is without adequate justification for asserting that the ’106 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 ’106 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.

1445. 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 ’106 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 133 — INFRINGEMENT OF THE ’847 PATENT BY SUN

1446. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1447. 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.

1448. AbbVie owns all rights, title, and interest in and to the ’847 Patent.

1449. On information and belief, Sun'sANDA Product infringes one or more claims of the '847 Patent, including at least claim 1.

1450. On information and belief, Sun has infringed one or more claims of the '847 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 '847 Patent.

1451. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '847 Patent would infringe one or more claims of the '847 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 '847 Patent under 35 U.S.C. § 271(b) and/or (c).

1452. On information and belief, Sun has actual and constructive notice of the '847 Patent, and is aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '847 Patent would constitute an act of infringement of the '847 Patent.

1453. On information and belief, Sun is without adequate justification for asserting that the '847 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 '847 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.

1454. 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 '847 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 134 — INFRINGEMENT OF THE '815 PATENT BY SUN

1455. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1456. 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.

1457. AbbVie owns all rights, title, and interest in and to the '815 Patent.

1458. On information and belief, Sun's 15 mg ANDA Product infringes one or more claims of the '815 Patent, including at least claim 1.

1459. On information and belief, Sun has infringed one or more claims of the '815 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 '815 Patent.

1460. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '815 Patent would infringe one or more claims of the '815 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 '815 Patent under 35 U.S.C. § 271(b) and/or (c).

1461. On information and belief, Sun has actual and constructive notice of the '815 Patent, and is aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '815 Patent would constitute an act of infringement of the '815Patent.

1462. On information and belief, Sun is without adequate justification for asserting that the '815 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 '815 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.

1463. 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 '815 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 135 — INFRINGEMENT OF THE '175 PATENT BY SUN

1464. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1465. 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.

1466. AbbVie owns all rights, title, and interest in and to the '175 Patent.

1467. Sun's Notice Letter indicates that with respect to its 15 mg ANDA Product it seeks approval for, *inter alia*, the treatment of adults with moderatively to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Accordingly, on information and belief, Sun's ANDA Product infringes one or more claims of the '175Patent, including at least claim 1.

1468. On information and belief, Sun has infringed one or more claims of the '175 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 '175 Patent.

1469. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '175 Patent would infringe one or more

claims of the ’175 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 ’175 Patent under 35 U.S.C. § 271(b) and/or (c).

1470. On information and belief, Sun has actual and constructive notice of the ’175 Patent, and is aware that the submission of Sun’s ANDA with the request for FDA approval prior to the expiration of the ’175 Patent would constitute an act of infringement of the ’175 Patent.

1471. On information and belief, Sun is without adequate justification for asserting that the ’175 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 ’175 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.

1472. 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 ’175 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 136 — INFRINGEMENT OF THE ’018 PATENT BY SUN

1473. AbbVie restates, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

1474. 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.

1475. AbbVie owns all rights, title, and interest in and to the ’018 Patent.

1476. Sun's Notice Letter does not contest infringement of claims directed to amorphous upadacitinib. Therefore, on information and belief, Sun's ANDA Product infringes one or more claims of the '018 Patent, including at least claim 1.

1477. On information and belief, Sun has infringed one or more claims of the '018 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 '018 Patent.

1478. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '018 Patent would infringe one or more claims of the '018 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 '018 Patent under 35 U.S.C. § 271(b) and/or (c).

1479. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between AbbVie and Sun concerning liability for the infringement of the '018 Patent for which this Court may grant relief consistent with Article III of the United States Constitution. Subject matter jurisdiction over this Count exists pursuant to 35 U.S.C. § 271(e)(2)(A) and 28 U.S.C. §§ 1338(a), 2201, 2202.

1480. On information and belief, Sun has actual and constructive notice of the '018 Patent, and is aware that the submission of Sun's ANDA with the request for FDA approval prior to the expiration of the '018 Patent would constitute an act of infringement of the '018 Patent.

1481. On information and belief, Sun is without adequate justification for asserting that the '018 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 '018 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.

1482. AbbVie will be irreparably harmed if Sun is not enjoined from infringing and from actively inducing or contributing to the infringement of the '018 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 '080, '923, '584, '425, '069, '627, '697, '459, '036, '393, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, '922, '326, '105, '106, '847, '848, '815, '175, and '018 Patents under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment that Aurobindo has infringed the '080, '923, '584, '425, '069, '627, '697, '459, '036, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '326, '105, '106, '847, '848, '815, '175, and '018 Patents under 35 U.S.C. § 271(e)(2)(A);

(C) A judgment that Sandoz has infringed the RE'221, '629, '080, '923, '584, '425, '069, '627, '697, '459, '164, '924, '400, '624, '105, '847, '815, '175, and '018 Patents under 35 U.S.C. § 271(e)(2)(A);

(D) A judgment that Intas has infringed the '080, '923, '584, '425, '069, '627, '697, '459, '036, '393, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, '922, '326, '105, '106, '847, '848, '815, '175, and '018 Patents under 35 U.S.C. § 271(e)(2)(A);

(E) A judgment that Sun has infringed the RE'221, '629, '080, '923, '584, '425, '069, '627, '697, '459, '164, '924, '400, '624, '095, '625, '198, '092, '326, '105, '106, '847, '815, '175, and '018 Patents under 35 U.S.C. § 271(e)(2)(A);

(F) 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 '080, '923, '584, '425, '069, '627, '697, '459, '036, '393, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, '922, '326, '105, '106, '847, '848, '815, '175, and '018 Patents, or any later expiration of exclusivity for any of the '080, '923, '584, '425, '069, '627, '697, '459, '036, '393, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, '922, '326, '105, '106, '847, '848, '815, '175, and '018 Patents, including any extensions or regulatory exclusivities;

(G) 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 '080, '923, '584, '425, '069, '627, '697, '459, '036, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '326, '105, '106, '847, '848, '815, '175, and '018 Patents, or any later expiration of exclusivity for any of the '080, '923, '584, '425, '069, '627, '697, '459, '036, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '326, '105, '106, '847, '848, '815, '175, and '018 Patents, including any extensions or regulatory exclusivities;

(H) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Sandoz's ANDA shall be no earlier than the last expiration date of any of the RE'221, '629, '080, '923, '584, '425, '069, '627, '697, '459, '164, '924, '400, '624, '105, '847, '815, '175, and '018 Patents, or any later expiration of exclusivity for any of the RE'221, '629, '080, '923, '584, '425, '069, '627, '697, '459, '164, '924, '400, '624, '105, '847, '815, '175, and '018 Patents, including any extensions or regulatory exclusivities;

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

the ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’393, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’411, ’922, ’326, ’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents, or any later expiration of exclusivity for any of the ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’393, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’411, ’922, ’326, ’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents, including any extensions or regulatory exclusivities;

(J) 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 any of the RE’221, ’629, ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’164, ’924, ’400, ’624, ’095, ’625, ’198, ’092, ’326, ’105, ’106, ’847, ’815, ’175, and ’018 Patents, or any later expiration of exclusivity for any of the RE’221, ’629, ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’164, ’924, ’400, ’624, ’095, ’625, ’198, ’092, ’326, ’105, ’106, ’847, ’815, ’175, and ’018 Patents, including any extensions or regulatory exclusivities;

(K) 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 ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’393, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’411, ’922, ’326, ’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(L) A judgment that making, using, selling, offering to sell, or importing Aurobindo’s accused ANDA Products, or inducing or contributing to such conduct, would constitute infringement of the ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’326, ’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(M) A judgment that making, using, selling, offering to sell, or importing Sandoz's 15 mg ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the RE'221, '629, '080, '923, '584, '425, '069, '627, '697, '459, '164, '924, '400, '624, '105, '847, '815, '175, and '018 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c), and that making, using, selling, offering to sell, or importing Sandoz's 30 mg and 45 mg ANDA Products, or inducing or contributing to such conduct, would constitute infringement of the'425, '105, and '018 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(N) A judgment that making, using, selling, offering to sell, or importing Intas's accused ANDA Products, or inducing or contributing to such conduct, would constitute infringement of the '080, '923, '584, '425, '069, '627, '697, '459, '036, '393, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, '922, '326, '105, '106, '847, '848, '815, '175, and '018 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(O) 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 RE'221, '629, '080, '923, '584, '425, '069, '627, '697, '459, '164, '924, '400, '624, '095, '625, '198, '092, '326, '105, '106, '847, '815, '175, and '018 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(P) 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 '080, '923, '584, '425, '069, '627, '697, '459, '036, '393, '164, '883, '924, '400, '624, '095, '126, '625, '626, '198, '092, '964, '411, '922, '326, '105, '106,

’847, ’848, ’815, ’175, and ’018 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’393, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’411, ’922, ’326, ’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents;

(Q) 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 ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’326, ’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’326, ’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents;

(R) Entry of a permanent injunction enjoining Sandoz, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Sandoz 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, ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’164, ’924, ’400, ’624, ’105, ’847, ’815, ’175, and ’018 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the RE’221, ’629, ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’164, ’924, ’400, ’624, ’105, ’847, ’815, ’175, and ’018 Patents;

(S) Entry of a permanent injunction enjoining Intas, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Intas 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 ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’393, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’411, ’922, ’326, ’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’393, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’411, ’922, ’326, ’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents;

(T) 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 RE’221, ’629, ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’164, ’924, ’400, ’624, ’095, ’625, ’198, ’092, ’326, ’105, ’106, ’847, ’815, ’175, and ’018 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the RE’221, ’629, ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’164, ’924, ’400, ’624, ’095, ’625, ’198, ’092, ’326, ’105, ’106, ’847, ’815, ’175, and ’018 Patents;

(U) 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’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’393, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’411, ’922, ’326,

’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

(V) 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 ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’326, ’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

(W) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Sandoz 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, ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’164, ’924, ’400, ’624, ’105, ’847, ’815, ’175, and ’018 Patents, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

(X) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Intas engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its accused ANDA Products, or any product that infringes the ’080, ’923, ’584, ’425, ’069, ’627, ’697, ’459, ’036, ’393, ’164, ’883, ’924, ’400, ’624, ’095, ’126, ’625, ’626, ’198, ’092, ’964, ’411, ’922, ’326, ’105, ’106, ’847, ’848, ’815, ’175, and ’018 Patents, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

(Y) 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 RE'221, '629, '080, '923, '584, '425, '069, '627, '697, '459, '164, '924, '400, '624, '095, '625, '198, '092, '326, '105, '106, '847, '815, '175, and '018 Patents, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

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

(AA) Costs and expenses in this action; and

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

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