IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC and JANSSEN BIOTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ZYDUS WORLDWIDE DMCC and CADILA HEALTHCARE LIMITED,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Pharmacyclics LLC ("Pharmacyclics") and Janssen Biotech, Inc. ("Janssen"), (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Zydus Worldwide DMCC ("Zydus Worldwide") and Cadila Healthcare Limited ("Cadila") (collectively, "Zydus"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Zydus's recent submission to the United States Food and Drug Administration ("FDA") of an Amendment to Abbreviated New Drug Application ("ANDA") No. 211344 (hereinafter, the "Amendment"). Through the Amendment, Zydus seeks approval to market a generic version of Plaintiffs' highly successful pharmaceutical product IMBRUVICA® (ibrutinib) capsules, 70 mg, prior to the expiration of patents listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for IMBRUVICA®. Zydus has submitted the Amendment, which seeks approval to market a generic version of IMBRUVICA® (ibrutinib) capsules, 70 mg, prior to the expiration of the U.S. Patent Nos. 7,514,444 ("the '444 Patent");

8,008,309 ("the '309 Patent"); 8,697,711 ("the '711 Patent"); 8,735,403 ("the '403 Patent"); 8,957,079 ("the '079 Patent"); 9,181,257 ("the '257 Patent"); 8,754,091 ("the '091 Patent"); 8,497,277 ("the '277 Patent"); 8,952,015 ("the '015 Patent"); 8,476,284 ("the '284 Patent"); 8,754,090 ("the '090 Patent"); 9,296,753 ("the '753 Patent"); 9,725,455 ("the '455 Patent"); 10,125,140 ("the '140 Patent"); and 10,106,548 ("the '548 Patent").

THE RELATED LITIGATION

2. This is a civil action for infringement of the '444, '309, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, '455, '140, and '548 Patents.

3. A patent infringement action relating to Zydus's ANDA No. 211344 and IMBRUVICA® is pending in this judicial district between Plaintiffs and Zydus: *Pharmacyclics LLC et al. v. Zydus Worldwide DMCC et al.*, Civil Action No. 18-275-CFC (consolidated with *Pharmacyclics LLC et al. v. Fresenius Kabi USA, LLC et al.*, Civil Action No. 18-192-CFC) (the "Related Litigation").

4. IMBRUVICA® is available in a capsule dosage form at 70 mg and 140 mg strengths. Both the 70 mg and 140 mg strength IMBRUVICA® capsule products are marketed under New Drug Application ("NDA") No. 205552.

5. The Related Litigation relates to Zydus's efforts to obtain FDA approval, through submission of ANDA No. 211344 ("Zydus's ANDA"), to market a generic version of the 140 mg strength capsule form of IMBRUVICA®. This action relates to Zydus's efforts to obtain FDA approval, through submission of the Amendment, to market a generic version of the 70 mg strength capsule form of IMBRUVICA®.

IMBRUVICA®

6. IMBRUVICA® (ibrutinib) is a ground-breaking drug which covalently binds to a protein called Bruton's tyrosine kinase ("BTK"), thereby irreversibly inhibiting BTK's activity.

7. BTK is a key signaling molecule in the pathway that leads to B-cell growth and maturation following activation of the B-cell receptor. Abnormalities in the B-cell receptor signaling pathway can lead to uncontrolled cell growth and cause cancers of the blood and bone marrow. IMBRUVICA® is the first FDA-approved BTK inhibitor.

8. Pharmacyclics invested hundreds of millions of dollars in the development of IMBRUVICA®. Pharmacyclics partnered with Janssen to bring this revolutionary drug to patients across the United States and throughout the world. Janssen, recognizing the potential of the compound, invested hundreds of millions of dollars in the clinical development and commercialization of IMBRUVICA®.

9. Initial clinical trials using IMBRUVICA® to treat mantle cell lymphoma ("MCL") showed that patients taking IMBRUVICA® had an observed response rate of 68%. These results led FDA to grant accelerated approval to IMBRUVICA® for the treatment of MCL in patients who had received at least one prior therapy through the new Breakthrough Therapy Designation pathway, a process that allows the FDA to grant priority review to drug candidates if preliminary clinical trials indicate that the therapy may offer substantial treatment advantages over existing options for patients with serious or life-threatening diseases. IMBRUVICA® was one of the first drugs ever to receive FDA approval via the Breakthrough Therapy Designation.

10. IMBRUVICA® has received three additional Breakthrough Therapy Designations for three additional indications: Waldenström's macroglobulinemia; chronic lymphocytic leukemia ("CLL") or small lymphocytic lymphoma ("SLL") with a deletion of the short arm of chromosome 17 (del 17p); and chronic graft-versus-host-disease ("cGVHD"). IMBRUVICA® is

also indicated for the treatment of marginal zone lymphoma ("MZL") in patients who require systemic therapy and have received at least one prior anti-CD20-based therapy and the treatment of CLL/SLL. For MZL and cGVHD, IMBRUVICA® represents the first FDA approved treatment specifically for patients with these disorders.

11. IMBRUVICA® has one of the most robust clinical oncology development programs for a single molecule in the industry, with more than 130 ongoing clinical trials. There are approximately 30 ongoing company-sponsored trials, 14 of which are in Phase 3, and more than 100 investigator-sponsored trials and external collaborations that are active around the world.

12. IMBRUVICA® has gained widespread acceptance in the medical community with more than 135,000 patients around the world having been treated with IMBRUVICA®. In 2015, IMBRUVICA® was awarded the prestigious Prix Galien Award for Best Pharmaceutical Agent. The Prix Galien Award is considered the biomedical industry's highest accolade.

13. The '444, '309, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, '455, '140, and '548 Patents are listed in the Orange Book for IMBRUVICA®.

THE PARTIES

14. Plaintiff Pharmacyclics LLC is a limited liability company organized and existing under the laws of the Delaware with its principal place of business at 999 East Arques Avenue, Sunnyvale, California 94085. Pharmacyclics is a wholly owned subsidiary of AbbVie Inc., a Delaware corporation with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064-6400. Pharmacyclics is the assignee and owner of the '444, '309, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, '455, '140, and '548 Patents. Pharmacyclics holds NDA No. 205552 for IMBRUVICA®.

15. Plaintiff Janssen Biotech, Inc. is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044. Janssen is a wholly owned subsidiary of Johnson & Johnson. Janssen is the exclusive licensee of the Orange Book patents for IMBRUVICA®. Janssen is engaged in the clinical development and commercialization of IMBRUVICA® and shares in the proceeds from U.S. sales of IMBRUVICA®.

16. On information and belief, Zydus Worldwide is a company organized and existing under the laws of the United Arab Emirates, with a principal place of business at Armada Tower 2, P2, Cluster P, 9 Floor, Office 908, Al Thanyah 5, Hadaeq Mohammed Bin Rashid, Dubai, United Arab Emirates.

17. On information and belief, Cadila is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India.

18. On information and belief, Zydus Worldwide acts at the direction, and for the benefit, of Cadila, and is controlled and/or dominated by Cadila.

19. On information and belief, Zydus Worldwide and Cadila collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Zydus Worldwide and Cadila 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.

20. On information and belief, Zydus caused the Amendment to be submitted to FDA and seeks FDA approval of the Amendment.

21. On information and belief, Zydus Worldwide and Cadila acted collaboratively in the preparation and submission of the Amendment and continue to act collaboratively in pursuing FDA approval of the Amendment and seeking to market the proposed generic ibrutinib capsules.

22. On information and belief, Zydus intends to commercially manufacture, market, offer for sale, and sell the proposed generic 70 mg ibrutinib capsule product ("Zydus's 70 mg ANDA Product") described in the Amendment throughout the United States, including in the State of Delaware, in the event FDA approves the Amendment. On information and belief, Zydus intends to commercially manufacture, market, and offer for sale, and sell the proposed generic 140 mg ibrutinib capsule product ("Zydus's 140 mg ANDA Product") described in its ANDA throughout the United States, including in the State of Delaware, in the event FDA approves Zydus's ANDA (collectively, Zydus's 70 mg ANDA Product and 140 mg ANDA Product referred to as "Zydus's ANDA Products").

23. On information and belief, Zydus Worldwide and Cadila 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, Zydus Worldwide and Cadila intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Zydus's 70 mg ANDA Product, in the event FDA approves the Amendment.

JURISDICTION AND VENUE

24. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271.

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

26. This Court has personal jurisdiction over Zydus because, on information and belief, Zydus, *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 its ANDA Products in the State of Delaware upon approval of its ANDA and the Amendment.

27. On information and belief, Zydus 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, throughout the United States and in this judicial district.

28. Zydus 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 Plaintiffs, which manufacture and/or market IMBRUVICA® for sale and use throughout the United States, including in this judicial district. On information and belief and as indicated by letters dated January 3, 2018 ("Zydus's First Notice Letter"), December 6, 2018 ("Zydus's Second Notice Letter"), and December 14, 2018 ("Zydus's Third Notice Letter") sent by Zydus Worldwide to, *inter alia*, Pharmacyclics and Janssen, pursuant to 21 U.S.C. § 355(j)(2)(B), Zydus prepared and filed its ANDA and the Amendment with the intention of seeking to market its ANDA Products nationwide, including within this judicial district.

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

30. On information and belief, Zydus knows and intends that its proposed ANDA Products will be distributed and sold in Delaware and will thereby displace sales of IMBRUVICA®, causing injury to Plaintiffs. Zydus intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed ANDA Products.

31. Zydus Worldwide has engaged in patent litigation concerning FDA-approved drug products in this judicial district and has not contested personal jurisdiction or venue in such litigation in this judicial district. *See UCB, Inc. v. Zydus Worldwide DMCC, et al.*, 16-1023, D.I. 15 (D. Del. Feb. 27, 2017).

32. Cadila regularly engages in patent litigation concerning FDA-approved drug products in this judicial district and has not contested personal jurisdiction or venue in such litigation in this judicial district. *See, e.g.*, *Millennium Pharmaceuticals, Inc. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 17-423, D.I. 9 (D. Del. May 24, 2017); *Pfizer Inc. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 17-214, D.I. 13 (D. Del. June 5, 2017); *Sanofi-aventis US LLC et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 17-034, D.I. 9 (D. Del. Apr. 10, 2017); *Astellas Pharma Inc. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 16-1167, D.I. 11 (D. Del. Feb. 27, 2017); *Upsher-Smith Laboratories Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 16-248, D.I. 15 (D. Del. Oct. 31, 2016).

33. Zydus Worldwide and Cadila have not contested personal jurisdiction in this judicial district in the Related Litigation. *See Pharmacyclics LLC et al. v. Zydus Worldwide DMCC et al.*, No. 18-275-CFC, D.I. 15, Answer ¶¶ 45 ("Zydus . . . avers that it does not contest this Court's personal jurisdiction over Zydus Worldwide."), 46 ("Cadila . . . avers that it does not contest this Court's personal jurisdiction over Cadila.").

34. Zydus Worldwide and Cadila have invoked the jurisdiction of this judicial district as a Counterclaimant in the Related Litigation. *See Pharmacyclics LLC et al. v. Zydus Worldwide DMCC et al.*, No. 18-275-CFC, D.I. 15, Counterclaims ¶ 5.

35. Alternatively, this Court has personal jurisdiction over Zydus Worldwide and Cadila because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Zydus Worldwide and Cadila are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Zydus Worldwide and Cadila have sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Zydus's ANDA and the Amendment to FDA, 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 Zydus Worldwide and Cadila satisfies due process.

36. Venue is proper in this district for Zydus Worldwide pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Zydus Worldwide is a corporation organized and existing under the laws of the United Arab Emirates and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

37. Venue is proper in this district for Cadila pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Cadila is a corporation organized and existing under the laws of the India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

38. Zydus Worldwide and Cadila have not contested venue in this judicial district in the Related Litigation. *See Pharmacyclics LLC et al. v. Zydus Worldwide DMCC et al.*, No. 18-275-CFC, D.I. 15, Answer ¶¶ 48 ("Zydus Worldwide does not contest venue in this District."), 49 ("Cadila does not contest venue in this District.").

THE ASSERTED PATENTS

39. The ’444 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the United States Patent and Trademark Office (“USPTO”) on April 7, 2009. A true and correct copy of the ’444 Patent is attached hereto as Exhibit A.

40. The ’309 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on August 30, 2011. A true and correct copy of the ’309 Patent is attached hereto as Exhibit B.

41. The ’711 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on April 15, 2014. A true and correct copy of the ’711 Patent is attached hereto as Exhibit C.

42. The ’403 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on May 27, 2014. A true and correct copy of the ’403 Patent is attached hereto as Exhibit D.

43. The ’079 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on February 17, 2015. A true and correct copy of the ’079 Patent is attached hereto as Exhibit E.

44. The ’257 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on November 10, 2015. A true and correct copy of the ’257 Patent is attached hereto as Exhibit F.

45. The ’091 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on June 17, 2014. A true and correct copy of the ’091 Patent is attached hereto as Exhibit G.

46. The ’277 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on July 30, 2013. A true and correct copy of the ’277 Patent is attached hereto as Exhibit H.

47. The ’015 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on February 10, 2015. A true and correct copy of the ’015 Patent is attached hereto as Exhibit I.

48. The ’284 Patent, entitled “Inhibitors of Bruton’s Tyrosine Kinase,” was duly and lawfully issued by the USPTO on July 2, 2013. A true and correct copy of the ’284 Patent is attached hereto as Exhibit J.

49. The ’090 Patent, entitled “Use of Inhibitors of Bruton’s Tyrosine Kinase (BTK),” was duly and lawfully issued by the USPTO on June 17, 2014. A true and correct copy of the ’090 Patent is attached hereto as Exhibit K.

50. The ’753 Patent, entitled “Crystalline Forms of a Bruton’s Tyrosine Kinase Inhibitor,” was duly and lawfully issued by the USPTO on March 29, 2016. A true and correct copy of the ’753 Patent is attached hereto as Exhibit L.

51. The ’455 Patent, entitled “Crystalline Forms of a Bruton’s Tyrosine Kinase Inhibitor,” was duly and lawfully issued by the USPTO on August 8, 2017. A true and correct copy of the ’455 Patent is attached hereto as Exhibit M.

52. The ’140 Patent, entitled “Crystalline Forms of a Bruton’s Tyrosine Kinase Inhibitor,” was duly and lawfully issued by the USPTO on November 13, 2018. A true and correct copy of the ’140 Patent is attached hereto as Exhibit N.

53. The ’548 Patent, entitled “Crystalline Forms of a Bruton’s Tyrosine Kinase Inhibitor,” was duly and lawfully issued by the USPTO on October 23, 2018. A true and correct copy of the ’548 Patent is attached hereto as Exhibit O.

ZYDUS’S AMENDMENT TO ANDA NO. 211344

54. On information and belief, Zydus has submitted the Amendment to FDA, or caused the Amendment to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of 70 mg ibrutinib capsules as a purported generic version of IMBRUVICA® prior to the expiration of the ’444, ’309, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’140, and ’548 Patents.

55. On information and belief, FDA has not approved the Amendment.

56. On information and belief, Zydus Worldwide sent Pharmacyclics and Janssen a First Notice Letter dated January 3, 2018. Zydus’s First Notice Letter represented that Zydus Worldwide had submitted to FDA ANDA No. 211344 seeking approval of Zydus’s 140 mg ANDA Product, and a purported Paragraph IV certification for the ’444, ’309, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, and ’455 Patents.

57. On information and belief, Zydus Worldwide sent Pharmacyclics and Janssen a Second Notice Letter dated December 6, 2018. Zydus’s Second Notice Letter represented that Zydus Worldwide had submitted to FDA ANDA No. 211344 seeking approval of Zydus’s 140 mg ANDA Product, and a purported Paragraph IV certification for the ’140 and ’548 Patents.

58. On information and belief, Zydus Worldwide sent Pharmacyclics and Janssen a Third Notice Letter dated December 14, 2018. Zydus’s Third Notice Letter represented that Zydus Worldwide had submitted to FDA the Amendment seeking approval of Zydus’s 70 mg

ANDA Product, and a purported Paragraph IV certification for the '444, '309, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, '455, '140, and '548 Patents.

59. According to applicable regulations, Notice Letters such as Zydus'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 CFR § 314.95(c)(7); *see also* 21 CFR § 314.52.

60. For at least one claim of each of the '444, '309, '711, '403, '079, '257, '091, '277, '015, '284, '090, and '548 Patents, Zydus's Third Notice Letter failed to allege that its 70 mg ANDA Product or the proposed administration of the 70 mg ANDA Product would not meet the limitations of that claim.

61. On information and belief, if FDA approves the Amendment, Zydus will manufacture, offer for sale, or sell its 70 mg ANDA Product, within the United States, including within the State of Delaware, or will import its 70 mg ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Zydus's 70 mg ANDA Product will directly infringe the '444, '309, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, '455, '140, and '548 Patents either literally or under the doctrine of equivalents, and Zydus will actively induce and/or contribute to their infringement.

62. This action is being brought within forty-five days of Plaintiffs' receipt of Zydus's Third Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). Accordingly, Plaintiffs are

entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

COUNT I
INFRINGEMENT OF THE '444 PATENT BY ZYDUS

63. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–62 as if fully set forth herein.

64. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus's 70 mg ANDA Product.

65. Plaintiffs own all rights, title, and interest in and to the '444 Patent.

66. Zydus's 70 mg ANDA Product infringes one or more claims of the '444 Patent.

67. Zydus did not contest infringement of claims 1–8 of the '444 Patent in Zydus's Third Notice Letter. If Zydus had a factual or legal basis to contest infringement of the claims of the '444 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

68. Zydus has infringed one or more claims of the '444 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '444 Patent.

69. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 70 mg ANDA Product prior to the expiration of the '444 Patent would infringe one or more claims of the '444 Patent under 35 U.S.C. § 271(a), and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the '444 Patent under 35 U.S.C. § 271 (b) and/or (c).

70. Zydus had actual and constructive notice of the '444 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the '444 Patent would constitute an act of infringement of the '444 Patent.

71. Zydus filed the Amendment without adequate justification for asserting that the '444 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus's conduct in certifying invalidity with respect to the '444 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

72. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '444 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
INFRINGEMENT OF THE '309 PATENT BY ZYDUS

73. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–72 as if fully set forth herein.

74. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus's 70 mg ANDA Product.

75. Plaintiffs own all rights, title, and interest in and to the '309 Patent.

76. Zydus's 70 mg ANDA Product infringes one or more claims of the '309 Patent.

77. Zydus did not contest infringement of at least claims 1–7, 10, and 14 of the '309 Patent in Zydus's Third Notice Letter. If Zydus had a factual or legal basis to contest infringement of the claims of the '309 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

78. Zydus has infringed one or more claims of the '309 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '309 Patent.

79. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 70 mg ANDA Product prior to the expiration of the '309 Patent would infringe one or more claims of the '309 Patent under 35 U.S.C. § 271(a), and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the '309 Patent under 35 U.S.C. § 271 (b) and/or (c).

80. Zydus had actual and constructive notice of the '309 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the '309 Patent would constitute an act of infringement of the '309 Patent.

81. Zydus filed the Amendment without adequate justification for asserting that the '309 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus's conduct in certifying invalidity with respect to the '309 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

82. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '309 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT III
INFRINGEMENT OF THE '711 PATENT BY ZYDUS

83. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–82 as if fully set forth herein.

84. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus's 70 mg ANDA Product.

85. Plaintiffs own all rights, title, and interest in and to the '711 Patent.

86. Zydus's 70 mg ANDA Product infringes one or more claims of the '711 Patent.

87. Zydus did not contest infringement of claims 1–2 of the '711 Patent in Zydus's Third Notice Letter. If Zydus had a factual or legal basis to contest infringement of the claims of the '711 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

88. Zydus has infringed one or more claims of the '711 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '711 Patent.

89. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 70 mg ANDA Product prior to the expiration of the '711 Patent would infringe one or more claims of the '711 Patent under 35 U.S.C. § 271(a), and/or Zydus would induce the

infringement of and/or contribute to the infringement of one or more claims of the ’711 Patent under 35 U.S.C. § 271 (b) and/or (c).

90. Zydus had actual and constructive notice of the ’711 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the ’711 Patent would constitute an act of infringement of the ’711 Patent.

91. Zydus filed the Amendment without adequate justification for asserting that the ’711 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus’s conduct in certifying invalidity and/or non-infringement with respect to the ’711 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

92. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’711 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV
INFRINGEMENT OF THE ’403 PATENT BY ZYDUS

93. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–92 as if fully set forth herein.

94. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus’s 70 mg ANDA Product.

95. Plaintiffs own all rights, title, and interest in and to the ’403 Patent.

96. Zydus's 70 mg ANDA Product infringes one or more claims of the '403 Patent.

97. Zydus did not contest infringement of claims 1–13 of the '403 Patent in Zydus's Third Notice Letter. If Zydus had a factual or legal basis to contest infringement of the claims of the '403 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

98. Zydus has infringed one or more claims of the '403 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '403 Patent.

99. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 70 mg ANDA Product prior to the expiration of the '403 Patent would infringe one or more claims of the '403 Patent under 35 U.S.C. § 271(a), and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the '403 Patent under 35 U.S.C. § 271 (b) and/or (c).

100. Zydus had actual and constructive notice of the '403 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the '403 Patent would constitute an act of infringement of the '403 Patent.

101. Zydus filed the Amendment without adequate justification for asserting that the '403 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus's conduct in certifying invalidity with respect to the '403 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C.

§ 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

102. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '403 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT V
INFRINGEMENT OF THE '079 PATENT BY ZYDUS

103. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–102 as if fully set forth herein.

104. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus's 70 mg ANDA Product.

105. Plaintiffs own all rights, title, and interest in and to the '079 Patent.

106. Zydus's 70 mg ANDA Product infringes one or more claims of the '079 Patent.

107. Zydus did not contest infringement of at least claims 1–7, 11, and 12 of the '079 Patent in Zydus's Third Notice Letter. If Zydus had a factual or legal basis to contest infringement of the claims of the '079 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

108. Zydus has infringed one or more claims of the '079 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '079 Patent.

109. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 70 mg ANDA Product prior to the expiration of the '079 Patent would infringe one or more claims of the '079 Patent under 35 U.S.C. § 271(a), and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the '079 Patent under 35 U.S.C. § 271 (b) and/or (c).

110. Zydus had actual and constructive notice of the '079 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the '079 Patent would constitute an act of infringement of the '079 Patent.

111. Zydus filed the Amendment without adequate justification for asserting that the '079 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus's conduct in certifying invalidity with respect to the '079 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

112. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '079 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VI
INFRINGEMENT OF THE '257 PATENT BY ZYDUS

113. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–112 as if fully set forth herein.

114. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus's 70 mg ANDA Product.

115. Plaintiffs own all rights, title, and interest in and to the '257 Patent.

116. Zydus's 70 mg ANDA Product infringes one or more claims of the '257 Patent.

117. Zydus did not contest infringement of at least claims 1–10 and 13 of the '257 Patent in Zydus's Third Notice Letter. If Zydus had a factual or legal basis to contest infringement of the claims of the '257 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

118. Zydus has infringed one or more claims of the '257 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '257 Patent.

119. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 70 mg ANDA Product prior to the expiration of the '257 Patent would infringe one or more claims of the '257 Patent under 35 U.S.C. § 271(a), and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the '257 Patent under 35 U.S.C. § 271 (b) and/or (c).

120. Zydus had actual and constructive notice of the '257 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the '257 Patent would constitute an act of infringement of the '257 Patent.

121. Zydus filed the Amendment without adequate justification for asserting that the '257 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use,

offer for sale, or sale of its 70 mg ANDA Product. Zydus's conduct in certifying invalidity with respect to the '257 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

122. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '257 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VII
INFRINGEMENT OF THE '091 PATENT BY ZYDUS

123. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–122 as if fully set forth herein.

124. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus's 70 mg ANDA Product.

125. Plaintiffs own all rights, title, and interest in and to the '091 Patent.

126. Zydus's 70 mg ANDA Product infringes one or more claims of the '091 Patent.

127. Zydus did not contest infringement of claims 1–21 of the '091 Patent in Zydus's Third Notice Letter. If Zydus had a factual or legal basis to contest infringement of the claims of the '091 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

128. Zydus has infringed one or more claims of the '091 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby

seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '091 Patent.

129. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 70 mg ANDA Product prior to the expiration of the '091 Patent would infringe one or more claims of the '091 Patent under 35 U.S.C. § 271(a), and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the '091 Patent under 35 U.S.C. § 271 (b) and/or (c).

130. Zydus had actual and constructive notice of the '091 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the '091 Patent would constitute an act of infringement of the '091 Patent.

131. Zydus filed the Amendment without adequate justification for asserting that the '091 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus's conduct in certifying invalidity with respect to the '091 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

132. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '091 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VIII
INFRINGEMENT OF THE ’277 PATENT BY ZYDUS

133. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–132 as if fully set forth herein.

134. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus’s 70 mg ANDA Product.

135. Plaintiffs own all rights, title, and interest in and to the ’277 Patent.

136. Zydus’s 70 mg ANDA Product infringes one or more claims of the ’277 Patent.

137. Zydus did not contest infringement of at least claims 1–2, 5–8, and 11–16 of the ’277 Patent in Zydus’s Third Notice Letter. If Zydus had a factual or legal basis to contest infringement of the claims of the ’277 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

138. Zydus has infringed one or more claims of the ’277 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’277 Patent.

139. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus’s 70 mg ANDA Product prior to the expiration of the ’277 Patent would infringe one or more claims of the ’277 Patent under 35 U.S.C. § 271(a), and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the ’277 Patent under 35 U.S.C. § 271 (b) and/or (c).

140. Zydus had actual and constructive notice of the ’277 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval

prior to the expiration of the ’277 Patent would constitute an act of infringement of the ’277 Patent.

141. Zydus filed the Amendment without adequate justification for asserting that the ’277 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus’s conduct in certifying invalidity and/or non-infringement with respect to the ’277 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

142. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’277 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IX
INFRINGEMENT OF THE ’015 PATENT BY ZYDUS

143. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–142 as if fully set forth herein.

144. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus’s 70 mg ANDA Product.

145. Plaintiffs own all rights, title, and interest in and to the ’015 Patent.

146. Zydus’s 70 mg ANDA Product infringes one or more claims of the ’015 Patent.

147. Zydus did not contest infringement of at least claims 1–20 of the ’015 Patent in Zydus’s Third Notice Letter. If Zydus had a factual or legal basis to contest infringement of the

claims of the ’015 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

148. Zydus has infringed one or more claims of the ’015 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’015 Patent.

149. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus’s 70 mg ANDA Product prior to the expiration of the ’015 Patent would infringe one or more claims of the ’015 Patent under 35 U.S.C. § 271(a), and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the ’015 Patent under 35 U.S.C. § 271 (b) and/or (c).

150. Zydus had actual and constructive notice of the ’015 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the ’015 Patent would constitute an act of infringement of the ’015 Patent.

151. Zydus filed the Amendment without adequate justification for asserting that the ’015 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus’s conduct in certifying invalidity and/or non-infringement with respect to the ’015 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

152. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’015 Patent. Plaintiffs do not

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

COUNT X
INFRINGEMENT OF THE '284 PATENT BY ZYDUS

153. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–152 as if fully set forth herein.

154. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus's 70 mg ANDA Product.

155. Plaintiffs own all rights, title, and interest in and to the '284 Patent.

156. Zydus's 70 mg ANDA Product infringes one or more claims of the '284 Patent.

157. Zydus did not contest infringement of at claims 1–11 of the '284 Patent in Zydus's Third Notice Letter. If Zydus had a factual or legal basis to contest infringement of the claims of the '284 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

158. Zydus has infringed one or more claims of the '284 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '284 Patent.

159. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 70 mg ANDA Product prior to the expiration of the '284 Patent would infringe one or more claims of the '284 Patent under 35 U.S.C. § 271(a), and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the '284 Patent under 35 U.S.C. § 271 (b) and/or (c).

160. Zydus had actual and constructive notice of the ’284 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the ’284 Patent would constitute an act of infringement of the ’284 Patent.

161. Zydus filed the Amendment without adequate justification for asserting that the ’284 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus’s conduct in certifying invalidity and/or non-infringement with respect to the ’284 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

162. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’284 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XI
INFRINGEMENT OF THE ’090 PATENT BY ZYDUS

163. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–162 as if fully set forth herein.

164. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus’s 70 mg ANDA Product.

165. Plaintiffs own all rights, title, and interest in and to the ’090 Patent.

166. Zydus’s 70 mg ANDA Product infringes one or more claims of the ’090 Patent.

167. Zydus did not contest infringement of claims 1–2 of the '090 Patent in Zydus's Third Notice Letter. If Zydus had a factual or legal basis to contest infringement of the claims of the '090 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

168. Zydus has infringed one or more claims of the '090 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '090 Patent.

169. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 70 mg ANDA Product prior to the expiration of the '090 Patent would infringe one or more claims of the '090 Patent under 35 U.S.C. § 271(a), and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the '090 Patent under 35 U.S.C. § 271 (b) and/or (c).

170. Zydus had actual and constructive notice of the '090 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the '090 Patent would constitute an act of infringement of the '090 Patent.

171. Zydus filed the Amendment without adequate justification for asserting that the '090 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus's conduct in certifying invalidity and/or non-infringement with respect to the '090 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

172. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’090 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XII
INFRINGEMENT OF THE ’753 PATENT BY ZYDUS

173. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–172 as if fully set forth herein.

174. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus’s 70 mg ANDA Product.

175. Plaintiffs own all rights, title, and interest in and to the ’753 Patent.

176. Zydus’s 70 mg ANDA Product infringes one or more claims of the ’753 Patent either literally or under the doctrine of equivalents.

177. Zydus has infringed one or more claims of the ’753 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’753 Patent.

178. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus’s 70 mg ANDA Product prior to the expiration of the ’753 Patent would infringe one or more claims of the ’753 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the ’753 Patent under 35 U.S.C. § 271 (b) and/or (c).

179. Zydus had actual and constructive notice of the ’753 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the ’753 Patent would constitute an act of infringement of the ’753 Patent.

180. Zydus filed the Amendment without adequate justification for asserting that the ’753 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus’s conduct in certifying invalidity and/or non-infringement with respect to the ’753 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

181. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’753 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XIII
INFRINGEMENT OF THE ’455 PATENT BY ZYDUS

182. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–181 as if fully set forth herein.

183. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus’s 70 mg ANDA Product.

184. Plaintiffs own all rights, title, and interest in and to the ’455 Patent.

185. Zydus’s 70 mg ANDA Product infringes one or more claims of the ’455 Patent either literally or under the doctrine of equivalents.

186. Zydus has infringed one or more claims of the ’455 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’455 Patent.

187. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus’s 70 mg ANDA Product prior to the expiration of the ’455 Patent would infringe one or more claims of the ’455 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the ’455 Patent under 35 U.S.C. § 271 (b) and/or (c).

188. Zydus had actual and constructive notice of the ’455 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the ’455 Patent would constitute an act of infringement of the ’455 Patent.

189. Zydus filed the Amendment without adequate justification for asserting that the ’455 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus’s conduct in certifying invalidity and/or non-infringement with respect to the ’455 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

190. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’455 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and

Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XIV
INFRINGEMENT OF THE '140 PATENT BY ZYDUS

191. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–190 as if fully set forth herein.

192. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus's 70 mg ANDA Product.

193. Plaintiffs own all rights, title, and interest in and to the '140 Patent.

194. Zydus's 70 mg ANDA Product infringes one or more claims of the '140 Patent, either literally or under the doctrine of equivalents.

195. Zydus has infringed one or more claims of the '140 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '140 Patent.

196. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 70 mg ANDA Product prior to the expiration of the '140 Patent would infringe one or more claims of the '140 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the '140 Patent under 35 U.S.C. § 271 (b) and/or (c).

197. Zydus had actual and constructive notice of the '140 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the '140 Patent would constitute an act of infringement of the '140 Patent.

198. Zydus filed the Amendment without adequate justification for asserting that the '140 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus's conduct in certifying invalidity and/or non-infringement with respect to the '140 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

199. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '140 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XV
INFRINGEMENT OF THE '548 PATENT BY ZYDUS

200. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–199 as if fully set forth herein.

201. On information and belief, Zydus submitted or caused the submission of the Amendment to FDA, and thereby seeks FDA approval of Zydus's 70 mg ANDA Product.

202. Plaintiffs own all rights, title, and interest in and to the '548 Patent.

203. Zydus's 70 mg ANDA Product infringes one or more claims of the '548 Patent, either literally or under the doctrine of equivalents.

204. Zydus did not contest infringement of claims 15–16 and 18–19 of the '548 Patent in Zydus's Third Notice Letter. If Zydus had a factual or legal basis to contest infringement of the claims of the '548 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

205. Zydus has infringed one or more claims of the '548 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Amendment and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '548 Patent.

206. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 70 mg ANDA Product prior to the expiration of the '548 Patent would infringe one or more claims of the '548 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, and/or Zydus would induce the infringement of and/or contribute to the infringement of one or more claims of the '548 Patent under 35 U.S.C. § 271 (b) and/or (c).

207. Zydus had actual and constructive notice of the '548 Patent prior to filing the Amendment, and was aware that the filing of the Amendment with the request for FDA approval prior to the expiration of the '548 Patent would constitute an act of infringement of the '548 Patent.

208. Zydus filed the Amendment without adequate justification for asserting that the '548 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its 70 mg ANDA Product. Zydus's conduct in certifying invalidity and/or non-infringement with respect to the '548 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

209. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '548 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Zydus, 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, Plaintiffs respectfully request the following relief:

(A) A judgment that Zydus has infringed the ’444, ’309, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’140, and ’548 Patents under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of the Amendment shall be no earlier than the last expiration date of any of the ’444, ’309, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’140, or ’548 Patent, or any later expiration of exclusivity for any of the ’444, ’309, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’140, or ’548 Patent, including any extensions or regulatory exclusivities;

(C) Entry of a permanent injunction enjoining Zydus, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Zydus or on its behalf from commercially manufacturing, using, offering for sale, or selling its 70 mg ANDA Product within the United States, or importing its 70 mg ANDA Product into the United States, until the day after the expiration of the ’444, ’309, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’140, and ’548 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the ’444, ’309, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’140, and ’548 Patents;

(D) A judgment declaring that making, using, selling, offering to sell, or importing Zydus’s 70 mg ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the ’444, ’309, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, ’455, ’140, and ’548 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(E) A declaration under 28 U.S.C. § 2201 that if Zydus, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with

it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Zydus's 70 mg ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(F) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Zydus engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its 70 mg ANDA Product, or any product that infringes the '444, '309, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, '455, '140, or '548 Patent, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

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

(H) Costs and expenses in this action; and

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

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