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, CADILA HEALTHCARE LIMITED, TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., SANDOZ INC., and LEK PHARMACEUTICALS D.D.,	)	
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"); Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva"); and Sandoz Inc. and Lek Pharmaceuticals d.d. ("Lek") (collectively, "Sandoz"), 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, Teva's, and Sandoz's recent submissions to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Applications ("ANDAs") seeking approval to market generic versions of Plaintiffs' highly successful pharmaceutical product IMBRUVICA®, 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 ANDA No. 211344 ("Zydus's ANDA") which seeks approval to market a generic version of IMBRUVICA®, prior to the expiration of the U.S. Patent Nos. 8,008,309 ("the '309 Patent"); 7,514,444 ("the '444 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"); and 9,725,455 ("the '455 Patent"). Teva has submitted ANDA No. 211350 ("Teva's ANDA") which seeks approval to market a generic version of IMBRUVICA®, prior to the expiration of the '753, '455, and '090 Patents, and U.S. Patent Nos. 8,999,999 ("the '999 Patent"); 9,125,889 ("the '889 Patent"); 9,801,881 ("the '881 Patent"); 9,801,883 ("the '883 Patent"); 9,814,721 ("the '721 Patent"); and 9,795,604 ("the '604 Patent"). Sandoz has submitted ANDA No. 211267 ("Sandoz's ANDA") which seeks approval to market a generic version of IMBRUVICA®, prior to the expiration of the '753, '455, and '604 Patents; and U.S. Patent No. 9,713,617 ("the '617 Patent").

IMBRUVICA®

2. 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.

3. 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.

4. 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®.

5. 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.

6. 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.

7. IMBRUVICA® has one of the most robust clinical oncology development programs for a single molecule in the industry, with approximately 130 ongoing clinical trials. There are approximately 30 ongoing company-sponsored trials, 14 of which are in Phase 3, and

approximately 100 investigator-sponsored trials and external collaborations that are active around the world.

8. IMBRUVICA® has gained widespread acceptance in the medical community with more than 70,000 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.

9. The '309, '444, '711, '403, '079, '257, '091, '277, '015, '284, '090, '999, '889, '881, '883, '721, '753, '455, '617, and '604 Patents are listed in the Orange Book for IMBRUVICA®.

THE PARTIES

10. 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 '309, '444, '711, '403, '079, '257, '091, '277, '015, '284, '090, '999, '889, '881, '883, '721, '753, '455, '617, and '604 Patents. Pharmacyclics holds New Drug Application ("NDA") No. 205552 for IMBRUVICA®.

11. 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®.

12. 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.

13. On information and belief, Defendant 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.

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

15. 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.

16. On information and belief, Zydus caused ANDA No. 211344 to be submitted to FDA and seeks FDA approval of ANDA No. 211344.

17. On information and belief, Zydus Worldwide and Cadila acted collaboratively in the preparation and submission of ANDA No. 211344 and continue to act collaboratively in pursuing FDA approval of ANDA No. 211344 and seeking to market the proposed generic ibrutinib capsules.

18. On information and belief, Zydus intends to commercially manufacture, market, offer for sale, and sell the proposed generic ibrutinib capsules described in Zydus's ANDA

("Zydus's ANDA Product") throughout the United States, including in the State of Delaware, in the event FDA approves Zydus's ANDA.

19. 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 ANDA Product, in the event FDA approves Zydus's ANDA.

20. On information and belief, Defendant Teva Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of Israel, with a principal place of business at 5 Basel Street, Petach Tikva, 4951033, Israel.

21. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1090 Horsham Road, North Wales, PA 19454.

22. On information and belief, Teva Pharmaceuticals USA, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

23. On information and belief, Teva Pharmaceuticals USA, Inc. acts at the direction, and for the benefit, of Teva Pharmaceutical Industries Ltd., and is controlled and/or dominated by Teva Pharmaceutical Industries Ltd.

24. On information and belief, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries 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.

25. On information and belief, Teva caused ANDA No. 211350 to be submitted to FDA and seeks FDA approval of ANDA No. 211350.

26. On information and belief, Teva Pharmaceutical Industries Ltd. holds Drug Master File ("DMF") No. 031631 for ibrutinib.

27. On information and belief, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. acted collaboratively in the preparation and submission of ANDA No. 211350 and DMF No. 031631 and continue to act collaboratively in pursuing FDA approval of ANDA No. 211350 and seeking to market the proposed generic ibrutinib capsules.

28. On information and belief, Teva Pharmaceuticals USA, Inc. acts as the U.S. agent for Teva Pharmaceutical Industries Ltd. for purposes of regulatory submissions to FDA in seeking approval for generic drugs.

29. On information and belief, Teva intends to commercially manufacture, market, offer for sale, and sell the proposed generic ibrutinib capsules described in Teva's ANDA ("Teva's ANDA Product") throughout the United States, including in the State of Delaware, in the event FDA approves Teva's ANDA.

30. On information and belief, Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, 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, Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Teva's ANDA Product, in the event FDA approves Teva's ANDA.

31. On information and belief, Defendant Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, with a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

32. On information and belief, Defendant Lek Pharmaceuticals d.d. is a corporation existing under the laws of Slovenia, having its principal place of business at Verovškova 57, 1526 Ljubljana, Slovenia.

33. On further information and belief, Sandoz Inc., and Lek collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of drug substances and pharmaceutical products. On further information and belief, Sandoz Inc., and Lek 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.

34. On information and belief, Sandoz caused ANDA No. 211267 to be submitted to FDA and seeks FDA approval of ANDA No. 211267.

35. On information and belief, Sandoz Inc. and Lek acted collaboratively in the preparation and submission of ANDA No. 211267 and continue to act collaboratively in pursuing FDA approval of ANDA No. 211267 and seeking to market the proposed generic ibrutinib capsules.

36. On information and belief, Sandoz intends to commercially manufacture, market, offer for sale, and sell the proposed generic ibrutinib capsules described in Sandoz's ANDA ("Sandoz's ANDA Product") throughout the United States, including in the State of Delaware, in the event FDA approves Sandoz's ANDA.

37. On information and belief, Sandoz Inc. and Lek 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. and Lek intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Sandoz's ANDA Product, in the event FDA approves Sandoz's ANDA.

JURISDICTION AND VENUE

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

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

40. 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 Product in the State of Delaware upon approval of ANDA No. 211344.

41. 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.

42. 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 a letter dated January 3, 2018 sent by Zydus Worldwide to, *inter alia*, Pharmacyclics and Janssen,

pursuant to 21 U.S.C. § 355(j)(2)(B) ("Zydus's Notice Letter"), Zydus prepared and filed its ANDA with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

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

44. On information and belief, Zydus knows and intends that its proposed ANDA Product 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 Product.

45. 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).

46. 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.*, 17-cv-00423, D.I. 9 (D. Del. May 24, 2017); *Pfizer Inc. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, 17-cv-00214, D.I. 13 (D. Del. June 5, 2017); *Sanofi-aventis US LLC et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, 17-cv-00034, D.I. 9 (D. Del. Apr. 10, 2017); *Astellas Pharma Inc. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, 16-cv-

01167, D.I. 11 (D. Del. Feb. 27, 2017); *Upsher-Smith Laboratories Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, 16-cv-00248, D.I. 15 (D. Del. Oct. 31, 2016).

47. 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 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.

48. 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).

49. 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).

50. This Court has personal jurisdiction over Teva Pharmaceuticals USA, Inc. because Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of Delaware. On information and belief, Teva Pharmaceuticals USA, Inc. is registered to do business as a domestic corporation in Delaware (File Number 2053734).

51. Additionally, this Court has personal jurisdiction over Teva because, on information and belief, Teva, *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 Teva's ANDA Product in the State of Delaware upon approval of ANDA No. 211350.

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

53. On information and belief, Teva 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.

54. Teva 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 a letter dated January 4, 2018 sent by Teva Pharmaceuticals USA, Inc. to Pharmacyclics pursuant to 21 U.S.C. § 355(j)(2)(B) ("Teva's Notice Letter"), Teva prepared and filed its ANDA with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

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

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

57. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. regularly invoke the jurisdiction of the courts of this judicial district by filing patent infringement actions concerning FDA-approved drug products in this judicial district. *See, e.g., Teva Pharmaceuticals USA, Inc. et al. v. Biocon Ltd. et al.*, 16-cv-00278, D.I. 1 (D. Del. Apr. 19, 2016); *Teva Pharmaceuticals USA, Inc. et al. v. Doctor Reddy's Laboratories, Ltd. et al.*, 15-cv-00306, D.I. 1 (D. Del. Apr. 10, 2015); *Teva Pharmaceuticals USA, Inc. et al. v. Amneal Pharmaceuticals LLC, et al.*, 15-cv-00124, D.I. 1 (D. Del. Feb. 3, 2015); *Teva Pharmaceuticals USA, Inc. v. AstraZeneca Pharmaceuticals LP, et al.*, 15-cv-00050, D.I. 1 (D. Del. Jan 19, 2015); *Teva Pharmaceuticals USA, Inc. et al. v. Synthon Pharmaceuticals Inc., et al.*, 14-cv-01419, D.I. 1 (D. Del. Nov. 18, 2014); *Teva Pharmaceuticals USA, Inc. et al. v. Forest Laboratories, Inc.*, 13-cv-02002, D.I. 1 (D. Del. Dec. 5, 2013). Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. regularly engage in patent litigation concerning FDA-approved drug products in this judicial district and have not contested personal jurisdiction or venue in such litigation in this judicial district. *See, e.g., Neos Therapeutics, Inc. et al. v. Teva Pharmaceuticals USA, Inc.*, 17-cv-01793, D.I. 8 (D. Del. Jan. 31, 2018); *Insys Therapeutics,*

Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al., 17-cv-01303, D.I. 10 (D. Del. Jan 15, 2018); *Galderma Labs. L.P., et al. v. Teva Pharmaceuticals USA, Inc.*, 17-cv-01783, D.I. 70 (D. Del. Jan. 5, 2018); *Forest Laboratories, LLC, et al. v. Teva Pharmaceuticals USA, Inc.*, 17-cv-01481, D.I. 7 (D. Del. Nov. 15, 2017); *BioDelivery Sciences International, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, 17-cv-00282, D.I. 10 (D. Del. May 4, 2017).

58. Alternatively, this Court has personal jurisdiction over Teva Pharmaceutical Industries Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Teva Pharmaceutical Industries Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Teva Pharmaceutical Industries Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Teva's ANDA, preparing and submitting DMF No. 031631 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 Teva Pharmaceutical Industries Ltd. satisfies due process.

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

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

61. This Court has personal jurisdiction over Sandoz because, on information and belief, Sandoz, *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 Product in the State of Delaware upon approval of ANDA No. 211267.

62. 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.

63. 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.

64. 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 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 a letter dated January 3, 2018 sent by Sandoz Inc. to, *inter alia*, Pharmacyclics pursuant to 21 U.S.C. § 355(j)(2)(B) ("Sandoz's Notice Letter"), Sandoz prepared and filed its ANDA with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

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

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

67. Sandoz Inc. regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction or venue in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., ViiV Healthcare Company et al. v. Sandoz Inc. et al.*, 17-cv-01784, D.I. 12 (D. Del. Jan. 24, 2018); *Biogen International GMBH et al. v. Sandoz Inc.*, 17-00874, D.I. 9 (D. Del. Oct. 16, 2017); *Bristol-Myers Squibb Company et al. v. Sandoz Inc.*, 17-cv-00407, D.I. 9 (D. Del. June 12, 2017); *Omeros Corporation v. Sandoz Inc.*, 17-cv-00799, D.I. 11 (D. Del. Sept. 13, 2017).

68. Alternatively, this Court has personal jurisdiction over Lek because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Lek is not subject to general personal jurisdiction in the courts of any state; and (c) Lek has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Sandoz's ANDA, and/or developing, manufacturing, and/or selling drug substances and pharmaceutical products

distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Lek satisfies due process.

69. Venue is proper in this district for Sandoz Inc. pursuant to 28 U.S.C. § 1400(b).

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

THE ASSERTED PATENTS

71. The '309 Patent, entitled "Inhibitors of Bruton's Tyrosine Kinase," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on August 30, 2011. A true and correct copy of the '309 Patent is attached hereto as Exhibit A.

72. The '444 Patent, entitled "Inhibitors of Bruton's Tyrosine Kinase," was duly and lawfully issued by the USPTO on April 7, 2009. A true and correct copy of the '444 Patent is attached hereto as Exhibit B.

73. 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.

74. 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.

75. 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.

76. 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.

77. 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.

78. 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.

79. 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.

80. 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.

81. The ’721 Patent, entitled “Use of Inhibitors of Bruton’s Tyrosine Kinase (BTK),” was duly and lawfully issued by the USPTO on November 14, 2017. A true and correct copy of the ’721 Patent is attached hereto as Exhibit K.

82. 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 L.

83. The ’889 Patent, entitled “Use of Inhibitors of Bruton’s Tyrosine Kinase (BTK),” was duly and lawfully issued by the USPTO on September 8, 2015. A true and correct copy of the ’889 Patent is attached hereto as Exhibit M.

84. The ’999 Patent, entitled “Use of Inhibitors of Bruton’s Tyrosine Kinase (BTK),” was duly and lawfully issued by the USPTO on April 7, 2015. A true and correct copy of the ’999 Patent is attached hereto as Exhibit N.

85. The ’881 Patent, entitled “Use of Inhibitors of Bruton’s Tyrosine Kinase (BTK),” was duly and lawfully issued by the USPTO on October 31, 2017. A true and correct copy of the ’881 Patent is attached hereto as Exhibit O.

86. The ’883 Patent, entitled “Use of Inhibitors of Bruton’s Tyrosine Kinase (BTK),” was duly and lawfully issued by the USPTO on October 31, 2017. A true and correct copy of the ’883 Patent is attached hereto as Exhibit P.

87. 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 Q.

88. 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 R.

89. The ’617 Patent, entitled “Crystalline Forms of a Bruton’s Tyrosine Kinase Inhibitor,” was duly and lawfully issued by the USPTO on July 25, 2017. A true and correct copy of the ’617 Patent is attached hereto as Exhibit S.

90. The ’604 Patent, entitled “Methods of Treating and Preventing Graft Versus Host Disease,” was duly and lawfully issued by the USPTO on October 24, 2017. A true and correct copy of the ’604 Patent is attached hereto as Exhibit T.

ZYDUS’S ANDA NO. 211344

91. On information and belief, Zydus has submitted ANDA No. 211344 to FDA, or caused ANDA No. 211344 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 ibrutinib capsules as a purported generic version of IMBRUVICA® prior to the expiration of the ’309, ’444, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, and ’455 Patents.

92. On information and belief, FDA has not approved Zydus’s ANDA.

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

94. On January 16, 2018, in connection with the parties’ negotiation over Zydus’s Offer of Confidential Access, Plaintiffs requested the Drug Master File for the ibrutinib used in Zydus’s ANDA Product. On January 26, 2018, Zydus stated it could not provide the requested Drug Master File. On February 7, 2018, Plaintiffs received Zydus’s ANDA. On February 13, 2018, Plaintiffs requested additional information and renewed their request for the Drug Master File in order to fully evaluate Zydus’s claims of non-infringement of the ’455 and ’753 Patents. On February 15, 2018, Zydus informed Plaintiffs it would not be producing the Drug Master File. To date, Zydus has not produced the requested information.

95. 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.

96. For at least one claim of each of the '309, '444, '711, '403, '079, '257, '091, and '277 Patents, Zydus'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.

97. On information and belief, if FDA approves Zydus's ANDA, Zydus 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 Zydus's ANDA Product will directly infringe the '309, '444, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, and '455 Patents either literally or under the doctrine of equivalents, and Zydus will actively induce and/or contribute to their infringement.

98. This action is being brought within forty-five days of Plaintiffs' receipt of Zydus's Notice Letter. 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).

TEVA'S ANDA NO. 211350

99. On information and belief, Teva has submitted ANDA No. 211350 to FDA, or caused ANDA No. 211350 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 ibrutinib capsules as a purported generic version of IMBRUVICA® prior to the expiration of the '753, '455, '090, '999, '889, '881, '883, '721, and '604 Patents.

100. On information and belief, FDA has not approved Teva's ANDA.

101. On information and belief, Teva sent Pharmacyclics a Notice Letter dated January 4, 2018. Teva's Notice Letter represented that Teva had submitted to FDA ANDA No. 211350 and a purported Paragraph IV certification for the '753, '455,'090, '999, '889, '881, '883, '721, and '604 Patents.

102. On February 9, 2018, Plaintiffs received Teva's ANDA. On February 13, 2018, Plaintiffs requested additional information from Teva, including the Drug Master File for the ibrutinib used in Teva's ANDA Product, in order to fully evaluate Teva's claims of non-infringement for the '753 and '455 Patents. On February 15, 2018, Teva informed Plaintiffs it likely would not be able to supply the information before Plaintiffs' deadline to file suit under the Hatch-Waxman Act. To date, Teva has not produced the requested information.

103. According to applicable regulations, Notice Letters such as Teva'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.

104. For at least one claim of each of the '999, '090, '883, '721, '604, and '889 Patents, Teva'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. Teva's Notice Letter failed to allege that one or more of the claims of each of the '753, '455, and '604 Patents is invalid or unenforceable.

105. On information and belief, if FDA approves Teva's ANDA, Teva 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 Teva's ANDA Product will directly infringe the '753, '455, '090, '999, '889, '881, '883, '721, and '604 Patents either literally or under the doctrine of equivalents, and Teva will actively induce and/or contribute to their infringement.

106. This action is being brought within forty-five days of Plaintiffs' receipt of Teva's Notice Letter. 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).

SANDOZ'S ANDA NO. 211267

107. On information and belief, Sandoz has submitted ANDA No. 211267 to FDA, or caused ANDA No. 211267 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 ibrutinib capsules as a purported generic version of IMBRUVICA® prior to the expiration of the '753, '455, '617, and '604 Patents.

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

109. On information and belief, Sandoz sent Pharmacyclics a Notice Letter dated January 3, 2018. Sandoz's Notice Letter represented that Sandoz had submitted to FDA ANDA No. 211267 and a purported Paragraph IV certification for the '753, '455, '617, and '604 Patents.

110. In Sandoz's Notice Letter, Sandoz purported to offer confidential access to portions of its ANDA No. 211267 on terms and conditions set forth in Sandoz's Notice Letter ("the Sandoz Offer"). Sandoz requested that Pharmacyclics accept the Sandoz Offer before receiving access to ANDA No. 211267. The Sandoz Offer contained unreasonable restrictions on

who could view the ANDA, well beyond those that would apply under a protective order. The Sandoz Offer did not permit any of Pharmacyclics' in-house attorneys to access ANDA No. 211267. Nor did it permit any scientific experts to access ANDA No. 211267. Nor did it permit outside counsel, in-house attorneys, or scientific experts for Plaintiff Janssen to access Sandoz's ANDA. Additionally, the Sandoz Offer contained provisions that unreasonably restricted the ability of counsel receiving access to ANDA No. 211267 to engage in any patent prosecution or work before or involving the FDA. The restrictions the Sandoz Offer placed on access to ANDA No. 211267 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).

111. Beginning with correspondence on January 16, 2018, outside counsel for Plaintiffs negotiated in good faith with counsel for Sandoz in an attempt to reach agreement on reasonable terms of confidential access to the ANDA. Sandoz continued to insist on unreasonable restrictions on access to the ANDA, which are inconsistent with the provisions of Protective Orders Sandoz has agree to in recent litigation involving similar subject matter. Sandoz refused to provide confidential access to its ANDA to Plaintiff Janssen. Plaintiffs explained that Janssen is the exclusive licensee of the asserted patents, and, as such, Janssen would be a plaintiff in any Hatch-Waxman litigation involving the asserted patents and would be included on any protective order/discovery confidentiality order entered in such a litigation. Nonetheless, until February 11, 2018, Sandoz categorically refused to allow Janssen any access to its ANDA and therefore to information that would be necessary to evaluate Sandoz's ANDA

and the representations in its Notice Letter. Additionally, even though Sandoz regularly agrees to permit at least two in-house attorneys from opposing parties in Hatch-Waxman to access its confidential information, Sandoz refused to do so here. *See, e.g., Forest Labs., LLC et al. v. Teva Pharmaceuticals USA, Inc. et al.*, 16-cv-1114, D.I. 83 (D. Del. Aug. 9, 2017); *Teva Pharmaceuticals USA, Inc. et al. v. Sandoz Inc.*, 17-cv-597, D.I. 49 (D. Del. Feb. 1, 2017); *AMAG Pharmaceuticals, Inc. v. Sandoz Inc.*, 16-cv-1508, D.I. 31 (D. Del. Jul. 29, 2016). Outside counsel for Janssen and Pharmacyclics, and one in-house representative for Pharmacyclics, received access to portions of Sandoz's ANDA on February 12, 2018.

112. On February 14, 2018, Plaintiffs informed Sandoz that information Sandoz purportedly relied on in its Notice Letter to support non-infringement assertions for the '753 and '455 Patents was not contained in Sandoz's ANDA. Plaintiffs requested that Sandoz produce the relied-upon information in order to fully evaluate Sandoz's claim of non-infringement. Sandoz refused to produce the requested information.

113. 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 CFR § 314.95(c)(7); *see also* 21 CFR § 314.52.

114. Sandoz's Notice Letter failed to allege that the claims of the '604 Patent are not infringed.

115. On information and belief, if FDA approves Sandoz's ANDA, Sandoz 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 Sandoz's ANDA Product will directly infringe the '753, '455, '617, and '604 Patents either literally or under the doctrine of equivalents, and Sandoz will actively induce and/or contribute to their infringement.

116. This action is being brought within forty-five days of Plaintiffs' receipt of Sandoz's Notice Letter. 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 '309 PATENT BY ZYDUS

117. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–116 as if fully set forth herein.

118. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus's ANDA Product.

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

120. Zydus's ANDA Product infringes one or more claims of the '309 Patent.

121. Zydus did not contest infringement of at least claims 1–7, 10, and 14 of the '309 Patent in Zydus Worldwide's 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.

122. Zydus has infringed one or more claims of the '309 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby

seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '309 Patent.

123. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 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).

124. Zydus had actual and constructive notice of the '309 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA approval prior to the expiration of the '309 Patent would constitute an act of infringement of the '309 Patent.

125. Zydus filed its ANDA 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 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.

126. 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 II
INFRINGEMENT OF THE ’444 PATENT BY ZYDUS

127. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–126 as if fully set forth herein.

128. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus’s ANDA Product.

129. Plaintiffs own all rights, title, and interest in and to the ’444 Patent.

130. Zydus’s ANDA Product infringes one or more claims of the ’444 Patent.

131. Zydus did not contest infringement of claims 1–8 of the ’444 Patent in Zydus Worldwide’s 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.

132. Zydus has infringed one or more claims of the ’444 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’444 Patent.

133. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus’s 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).

134. Zydus had actual and constructive notice of the ’444 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA

approval prior to the expiration of the ’444 Patent would constitute an act of infringement of the ’444 Patent.

135. Zydus filed its ANDA 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 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.

136. 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 III
INFRINGEMENT OF THE ’711 PATENT BY ZYDUS

137. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–136 as if fully set forth herein.

138. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus’s ANDA Product.

139. Plaintiffs own all rights, title, and interest in and to the ’711 Patent.

140. Zydus’s ANDA Product infringes one or more claims of the ’711 Patent.

141. Zydus did not contest infringement of claims 1–2 of the ’711 Patent in Zydus Worldwide’s 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.

142. Zydus has infringed one or more claims of the ’711 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’711 Patent.

143. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus’s 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).

144. Zydus had actual and constructive notice of the ’711 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA approval prior to the expiration of the ’711 Patent would constitute an act of infringement of the ’711 Patent.

145. Zydus filed its ANDA 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 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.

146. 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

147. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–146 as if fully set forth herein.

148. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus's ANDA Product.

149. Plaintiffs own all rights, title, and interest in and to the '403 Patent.

150. Zydus's ANDA Product infringes one or more claims of the '403 Patent.

151. Zydus did not contest infringement of claims 1–13 of the '403 Patent in Zydus Worldwide's 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.

152. Zydus has infringed one or more claims of the '403 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '403 Patent.

153. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 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).

154. Zydus had actual and constructive notice of the ’403 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA approval prior to the expiration of the ’403 Patent would constitute an act of infringement of the ’403 Patent.

155. Zydus filed its ANDA 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 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.

156. 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

157. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–156 as if fully set forth herein.

158. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus’s ANDA Product.

159. Plaintiffs own all rights, title, and interest in and to the ’079 Patent.

160. Zydus’s ANDA Product infringes one or more claims of the ’079 Patent.

161. Zydus did not contest infringement of at least claims 1–7, 11, and 12 of the ’079 Patent in Zydus Worldwide’s 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.

162. Zydus has infringed one or more claims of the ’079 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’079 Patent.

163. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus’s 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).

164. Zydus had actual and constructive notice of the ’079 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA approval prior to the expiration of the ’079 Patent would constitute an act of infringement of the ’079 Patent.

165. Zydus filed its ANDA 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 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.

166. 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

167. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–166 as if fully set forth herein.

168. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus’s ANDA Product.

169. Plaintiffs own all rights, title, and interest in and to the ’257 Patent.

170. Zydus’s ANDA Product infringes one or more claims of the ’257 Patent.

171. Zydus did not contest infringement of at least claims 1–10 and 13 of the ’257 Patent in Zydus Worldwide’s 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.

172. Zydus has infringed one or more claims of the ’257 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’257 Patent.

173. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus’s 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).

174. Zydus had actual and constructive notice of the ’257 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA approval prior to the expiration of the ’257 Patent would constitute an act of infringement of the ’257 Patent.

175. Zydus filed its ANDA 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 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.

176. 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

177. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–176 as if fully set forth herein.

178. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus’s ANDA Product.

179. Plaintiffs own all rights, title, and interest in and to the ’091 Patent.

180. Zydus's ANDA Product infringes one or more claims of the '091 Patent.

181. Zydus did not contest infringement of claims 1–21 of the '091 Patent in Zydus Worldwide's 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.

182. Zydus has infringed one or more claims of the '091 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '091 Patent.

183. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 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).

184. Zydus had actual and constructive notice of the '091 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA approval prior to the expiration of the '091 Patent would constitute an act of infringement of the '091 Patent.

185. Zydus filed its ANDA 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 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.

186. 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

187. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–186 as if fully set forth herein.

188. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus's ANDA Product.

189. Plaintiffs own all rights, title, and interest in and to the '277 Patent.

190. Zydus's ANDA Product infringes one or more claims of the '277 Patent.

191. Zydus did not contest infringement of at least claims 1–2, 5–8, and 11–16 of the '277 Patent in Zydus Worldwide's 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.

192. Zydus has infringed one or more claims of the '277 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '277 Patent.

193. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 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).

194. Zydus had actual and constructive notice of the '277 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA approval prior to the expiration of the '277 Patent would constitute an act of infringement of the '277 Patent.

195. Zydus filed its ANDA 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 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.

196. 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

197. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–196 as if fully set forth herein.

198. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus's ANDA Product.

199. Plaintiffs own all rights, title, and interest in and to the '015 Patent.

200. Zydus's ANDA Product infringes one or more claims of the '015 Patent.

201. Zydus has infringed one or more claims of the '015 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '015 Patent.

202. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 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).

203. Zydus had actual and constructive notice of the '015 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA approval prior to the expiration of the '015 Patent would constitute an act of infringement of the '015 Patent.

204. Zydus filed ANDA 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 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.

205. 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

206. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–205 as if fully set forth herein.

207. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus’s ANDA Product.

208. Plaintiffs own all rights, title, and interest in and to the ’284 Patent.

209. Zydus’s ANDA Product infringes one or more claims of the ’284 Patent.

210. Zydus has infringed one or more claims of the ’284 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’284 Patent.

211. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus’s 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).

212. Zydus had actual and constructive notice of the ’284 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA

approval prior to the expiration of the ’284 Patent would constitute an act of infringement of the ’284 Patent.

213. Zydus filed its ANDA 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 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.

214. 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

215. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–214 as if fully set forth herein.

216. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus’s ANDA Product.

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

218. Zydus’s ANDA Product infringes one or more claims of the ’090 Patent.

219. Zydus has infringed one or more claims of the ’090 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby

seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '090 Patent.

220. On information and belief, the importation, manufacture, sale, offer for sale, or use of Zydus's 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).

221. Zydus had actual and constructive notice of the '090 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA approval prior to the expiration of the '090 Patent would constitute an act of infringement of the '090 Patent.

222. Zydus filed its ANDA 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 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.

223. 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

224. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–223 as if fully set forth herein.

225. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus's ANDA Product.

226. Plaintiffs own all rights, title, and interest in and to the '753 Patent.

227. On February 7, 2018, Plaintiffs received Zydus's ANDA. On February 13, 2018, Plaintiffs requested additional information and renewed their request for the Drug Master File for the ibrutinib used in Zydus's ANDA Product in order to fully evaluate Zydus's claims of non-infringement of the '753 Patent. On February 15, 2018, Zydus informed Plaintiffs it would not be producing the Drug Master File. To date, Zydus has not produced the requested information.

228. Zydus's ANDA Product infringes one or more claims of the '753 Patent either literally or under the doctrine of equivalents.

229. Zydus has infringed one or more claims of the '753 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '753 Patent.

230. On information and belief, including Zydus's failure to produce requested information, the importation, manufacture, sale, offer for sale, or use of Zydus's 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).

231. Zydus had actual and constructive notice of the ’753 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA approval prior to the expiration of the ’753 Patent would constitute an act of infringement of the ’753 Patent.

232. Zydus filed its ANDA 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 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.

233. 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

234. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–233 as if fully set forth herein.

235. On information and belief, Zydus submitted or caused the submission of ANDA No. 211344 to FDA, and thereby seeks FDA approval of Zydus’s ANDA Product.

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

237. On February 7, 2018, Plaintiffs received Zydus’s ANDA. On February 13, 2018, Plaintiffs requested additional information and renewed their request for the Drug Master File for

the ibrutinib used in Zydus's ANDA Product in order to fully evaluate Zydus's claims of non-infringement of the '455 Patent. On February 15, 2018, Zydus informed Plaintiffs it would not be producing the Drug Master File. To date, Zydus has not produced the requested information.

238. Zydus's ANDA Product infringes one or more claims of the '455 Patent either literally or under the doctrine of equivalents.

239. Zydus has infringed one or more claims of the '455 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211344 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '455 Patent.

240. On information and belief, including Zydus's failure to produce requested information, the importation, manufacture, sale, offer for sale, or use of Zydus's 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).

241. Zydus had actual and constructive notice of the '455 Patent prior to filing ANDA No. 211344, and was aware that the filing of ANDA No. 211344 with the request for FDA approval prior to the expiration of the '455 Patent would constitute an act of infringement of the '455 Patent.

242. Zydus filed its ANDA 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 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.

243. 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 '090 PATENT BY TEVA

244. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–243 as if fully set forth herein.

245. On information and belief, Teva submitted or caused the submission of ANDA No. 211350 to FDA, and thereby seeks FDA approval of Teva's ANDA Product.

246. Plaintiffs own all rights, title, and interest in and to the '090 Patent.

247. Teva's ANDA Product infringes one or more claims of the '090 Patent.

248. Teva did not contest infringement of claims 1–2 of the '090 Patent in Teva's Notice Letter. If Teva 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.

249. Teva has infringed one or more claims of the '090 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211350 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '090 Patent.

250. On information and belief, the importation, manufacture, sale, offer for sale, or use of Teva's 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 Teva 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).

251. Teva had actual and constructive notice of the '090 Patent prior to filing ANDA No. 211350, and was aware that the filing of ANDA No. 211350 with the request for FDA approval prior to the expiration of the '090 Patent would constitute an act of infringement of the '090 Patent.

252. Teva filed its ANDA 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 ANDA Product. Teva's conduct in certifying invalidity 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.

253. Plaintiffs will be irreparably harmed if Teva 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 Teva, 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 '999 PATENT BY TEVA

254. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–253 as if fully set forth herein.

255. On information and belief, Teva submitted or caused the submission of ANDA No. 211350 to FDA, and thereby seeks FDA approval of Teva's ANDA Product.

256. Plaintiffs own all rights, title, and interest in and to the '999 Patent.

257. Teva's ANDA Product infringes one or more claims of the '999 Patent.

258. Teva did not contest infringement of claims 1–18 of the '999 Patent in Teva's Notice Letter. If Teva had a factual or legal basis to contest infringement of the claims of the '999 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.

259. Teva has infringed one or more claims of the '999 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211350 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '999 Patent.

260. On information and belief, the importation, manufacture, sale, offer for sale, or use of Teva's ANDA Product prior to the expiration of the '999 Patent would infringe one or more claims of the '999 Patent under 35 U.S.C. § 271(a), and/or Teva would induce the infringement of and/or contribute to the infringement of one or more claims of the '999 Patent under 35 U.S.C. § 271 (b) and/or (c).

261. Teva had actual and constructive notice of the '999 Patent prior to filing ANDA No. 211350, and was aware that the filing of ANDA No. 211350 with the request for FDA approval prior to the expiration of the '999 Patent would constitute an act of infringement of the '999 Patent.

262. Teva filed its ANDA without adequate justification for asserting that the '999 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer

for sale, or sale of its ANDA Product. Teva's conduct in certifying invalidity with respect to the '999 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.

263. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '999 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Teva, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XVI
INFRINGEMENT OF THE '889 PATENT BY TEVA

264. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–263 as if fully set forth herein.

265. On information and belief, Teva submitted or caused the submission of ANDA No. 211350 to FDA, and thereby seeks FDA approval of Teva's ANDA Product.

266. Plaintiffs own all rights, title, and interest in and to the '889 Patent.

267. Teva's ANDA Product infringes one or more claims of the '889 Patent.

268. Teva did not contest infringement of claims 1–2 of the '889 Patent in Teva's Notice Letter. If Teva had a factual or legal basis to contest infringement of the claims of the '889 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.

269. Teva has infringed one or more claims of the '889 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211350 with a Paragraph IV certification and thereby

seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '889 Patent.

270. On information and belief, the importation, manufacture, sale, offer for sale, or use of Teva's ANDA Product prior to the expiration of the '889 Patent would infringe one or more claims of the '889 Patent under 35 U.S.C. § 271(a), and/or Teva would induce the infringement of and/or contribute to the infringement of one or more claims of the '889 Patent under 35 U.S.C. § 271 (b) and/or (c).

271. Teva had actual and constructive notice of the '889 Patent prior to filing ANDA No. 211350, and was aware that the filing of ANDA No. 211350 with the request for FDA approval prior to the expiration of the '889 Patent would constitute an act of infringement of the '889 Patent.

272. Teva filed its ANDA without adequate justification for asserting that the '889 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Teva's conduct in certifying invalidity with respect to the '889 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.

273. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '889 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Teva, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XVII
INFRINGEMENT OF THE ’881 PATENT BY TEVA

274. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–273 as if fully set forth herein.

275. On information and belief, Teva submitted or caused the submission of ANDA No. 211350 to FDA, and thereby seeks FDA approval of Teva’s ANDA Product.

276. Plaintiffs own all rights, title, and interest in and to the ’881 Patent.

277. On information and belief, Teva’s ANDA Product will be marketed for the same indications and will contain the same prescribing information as IMBRUVICA®.

278. Teva’s ANDA Product infringes one or more claims of the ’881 Patent.

279. Teva has infringed one or more claims of the ’881 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211350 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’881 Patent.

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

281. Teva had actual and constructive notice of the ’881 Patent prior to filing ANDA No. 211350, and was aware that the filing of ANDA No. 211350 with the request for FDA approval prior to the expiration of the ’881 Patent would constitute an act of infringement of the ’881 Patent.

282. Teva filed its ANDA without adequate justification for asserting that the ’881 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Teva’s conduct in certifying invalidity and/or non-infringement with respect to the ’881 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.

283. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’881 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Teva, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XVIII
INFRINGEMENT OF THE ’883 PATENT BY TEVA

284. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–283 as if fully set forth herein.

285. On information and belief, Teva submitted or caused the submission of ANDA No. 211350 to FDA, and thereby seeks FDA approval of Teva’s ANDA Product.

286. Plaintiffs own all rights, title, and interest in and to the ’883 Patent.

287. Teva’s ANDA Product infringes one or more claims of the ’883 Patent.

288. Teva did not contest infringement of at least claims 1, 3–4, 9–13, 16–17, and 19–31 of the ’883 Patent in Teva’s Notice Letter. If Teva had a factual or legal basis to contest infringement of the claims of the ’889 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.

289. Teva has infringed one or more claims of the ’883 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211350 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’883 Patent.

290. On information and belief, the importation, manufacture, sale, offer for sale, or use of Teva’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 Teva 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).

291. Teva had actual and constructive notice of the ’883 Patent prior to filing ANDA No. 211350, and was aware that the filing of ANDA No. 211350 with the request for FDA approval prior to the expiration of the ’883 Patent would constitute an act of infringement of the ’883 Patent.

292. Teva 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 its ANDA Product. Teva’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 Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

293. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’883 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and

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

COUNT XIX
INFRINGEMENT OF THE '721 PATENT BY TEVA

294. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–293 as if fully set forth herein.

295. On information and belief, Teva submitted or caused the submission of ANDA No. 211350 to FDA, and thereby seeks FDA approval of Teva's ANDA Product.

296. Plaintiffs own all rights, title, and interest in and to the '721 Patent.

297. Teva's ANDA Product infringes one or more claims of the '721 Patent.

298. Teva did not contest infringement of at least claims 1 and 7–11 of the '721 Patent in Teva's Notice Letter. If Teva had a factual or legal basis to contest infringement of the claims of the '889 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.

299. Teva has infringed one or more claims of the '721 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211350 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '721 Patent.

300. On information and belief, the importation, manufacture, sale, offer for sale, or use of Teva's ANDA Product prior to the expiration of the '721 Patent would infringe one or more claims of the '721 Patent under 35 U.S.C. § 271(a), and/or Teva would induce the infringement of and/or contribute to the infringement of one or more claims of the '721 Patent under 35 U.S.C. § 271 (b) and/or (c).

301. Teva had actual and constructive notice of the ’721 Patent prior to filing ANDA No. 211350, and was aware that the filing of ANDA No. 211350 with the request for FDA approval prior to the expiration of the ’721 Patent would constitute an act of infringement of the ’721 Patent.

302. Teva filed its ANDA without adequate justification for asserting that the ’721 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Teva’s conduct in certifying invalidity and/or non-infringement with respect to the ’721 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.

303. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’721 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Teva, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XX
INFRINGEMENT OF THE ’604 PATENT BY TEVA

304. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–303 as if fully set forth herein.

305. On information and belief, Teva submitted or caused the submission of ANDA No. 211350 to FDA, and thereby seeks FDA approval of Teva’s ANDA Product.

306. Plaintiffs own all rights, title, and interest in and to the ’604 Patent.

307. Teva’s ANDA Product infringes one or more claims of the ’604 Patent.

308. Teva did not contest infringement of claims 1, 5–8, 20–24, 32–39, and 54–55 of the ’604 Patent in Teva’s Notice Letter. Additionally, Teva did not contend that claims 2–4, 9–19, 29–31, and 40–53 of the ’604 Patent are invalid or unenforceable in Teva’s Notice Letter. If Teva had a factual or legal basis to contest infringement of the claims of the ’604 Patent, or if Teva had a factual or legal basis to contend that the claims of the ’604 Patent are invalid or unenforceable, 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.

309. Teva has infringed one or more claims of the ’604 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211350 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’604 Patent.

310. On information and belief, the importation, manufacture, sale, offer for sale, or use of Teva’s ANDA Product prior to the expiration of the ’604 Patent would infringe one or more claims of the ’604 Patent under 35 U.S.C. § 271(a), and/or Teva would induce the infringement of and/or contribute to the infringement of one or more claims of the ’604 Patent under 35 U.S.C. § 271 (b) and/or (c).

311. Teva had actual and constructive notice of the ’604 Patent prior to filing ANDA No. 211350, and was aware that the filing of ANDA No. 211350 with the request for FDA approval prior to the expiration of the ’604 Patent would constitute an act of infringement of the ’604 Patent.

312. Teva filed its ANDA without adequate justification for asserting that the ’604 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Teva’s conduct in certifying invalidity and/or non-

infringement with respect to the ’604 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.

313. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’604 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Teva, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XXI
INFRINGEMENT OF THE ’753 PATENT BY TEVA

314. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–313 as if fully set forth herein.

315. On information and belief, Teva submitted or caused the submission of ANDA No. 211350 to FDA, and thereby seeks FDA approval of Teva’s ANDA Product.

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

317. Teva’s ANDA Product infringes one or more claims of the ’753 Patent either literally or under the doctrine of equivalents.

318. Teva did not contend that claims 1–18 of ’753 Patent are invalid or unenforceable in Teva’s Notice Letter. If Teva had a factual or legal basis to contend that the claims of the ’753 Patent are invalid or unenforceable, 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.

319. On February 9, 2018, Plaintiffs received Teva’s ANDA. On February 13, 2018, Plaintiffs requested additional information from Teva, including the Drug Master File for the ibrutinib used in Teva’s ANDA Product, in order to fully evaluate Teva’s claims of non-

infringement for the ’753 Patent. On February 15, 2018, Teva informed Plaintiffs it likely would not be able to supply the information before Plaintiffs’ deadline to file suit under the Hatch-Waxman Act. To date, Teva has not produced the requested information.

320. Teva has infringed one or more claims of the ’753 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211350 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’753 Patent.

321. On information and belief, the importation, manufacture, sale, offer for sale, or use of Teva’s 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 Teva 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).

322. Teva had actual and constructive notice of the ’753 Patent prior to filing ANDA No. 211350, and was aware that the filing of ANDA No. 211350 with the request for FDA approval prior to the expiration of the ’753 Patent would constitute an act of infringement of the ’753 Patent.

323. Teva filed its ANDA 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 ANDA Product. Teva’s conduct in certifying 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.

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

COUNT XXII
INFRINGEMENT OF THE ’455 PATENT BY TEVA

325. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–324 as if fully set forth herein.

326. On information and belief, Teva submitted or caused the submission of ANDA No. 211350 to FDA, and thereby seeks FDA approval of Teva’s ANDA Product.

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

328. Teva’s ANDA Product infringes one or more claims of the ’455 Patent either literally or under the doctrine of equivalents.

329. Teva did not contend that claims 1–13 of ’455 Patent are invalid or unenforceable in Teva’s Notice Letter. If Teva had a factual or legal basis to contend that the claims of the ’455 Patent are invalid or unenforceable, 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.

330. On February 9, 2018, Plaintiffs received Teva’s ANDA. On February 13, 2018, Plaintiffs requested additional information from Teva, including the Drug Master File for the ibrutinib used in Teva’s ANDA Product, in order to fully evaluate Teva’s claims of non-infringement for the ’455 Patent. On February 15, 2018, Teva informed Plaintiffs it likely would not be able to supply the information before Plaintiffs’ deadline to file suit under the Hatch-Waxman Act. To date, Teva has not produced the requested information.

331. Teva has infringed one or more claims of the ’455 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211350 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’455 Patent.

332. On information and belief, including Teva’s failure to produce requested information, the importation, manufacture, sale, offer for sale, or use of Teva’s 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 Teva 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).

333. Teva had actual and constructive notice of the ’455 Patent prior to filing ANDA No. 211350, and was aware that the filing of ANDA No. 211350 with the request for FDA approval prior to the expiration of the ’455 Patent would constitute an act of infringement of the ’455 Patent.

334. Teva filed its ANDA 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 ANDA Product. Teva’s conduct in certifying 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.

335. Plaintiffs will be irreparably harmed if Teva 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

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

COUNT XXIII
INFRINGEMENT OF THE '604 PATENT BY SANDOZ

336. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–335 as if fully set forth herein.

337. On information and belief, Sandoz submitted or caused the submission of ANDA No. 211267 to FDA, and thereby seeks FDA approval of Sandoz's ANDA Product.

338. Plaintiffs own all rights, title, and interest in and to the '604 Patent.

339. Sandoz's ANDA Product infringes one or more claims of the '604 Patent.

340. Sandoz did not contest infringement of claims 1–55 of the '604 Patent in Sandoz's Notice Letter. If Sandoz had a factual or legal basis to contest infringement of the claims of the '604 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.

341. Sandoz has infringed one or more claims of the '604 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211267 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '604 Patent.

342. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz's ANDA Product prior to the expiration of the '604 Patent would infringe one or more claims of the '604 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 '604 Patent under 35 U.S.C. § 271 (b) and/or (c).

343. Sandoz had actual and constructive notice of the ’604 Patent prior to filing ANDA No. 211267, and was aware that the filing of ANDA No. 211267 with the request for FDA approval prior to the expiration of the ’604 Patent would constitute an act of infringement of the ’604 Patent.

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

345. Plaintiffs will be irreparably harmed if Sandoz is not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’604 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Sandoz, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XXIV
INFRINGEMENT OF THE ’753 PATENT BY SANDOZ

346. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–345 as if fully set forth herein.

347. On information and belief, Sandoz submitted or caused the submission of ANDA No. 211267 to FDA, and thereby seeks FDA approval of Sandoz’s ANDA Product.

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

349. Sandoz’s ANDA Product infringes one or more claims of the ’753 Patent either literally or under the doctrine of equivalents.

350. Information that Sandoz purportedly relied on in its Notice Letter to support its non-infringement claims for the ’753 Patent was not contained in Sandoz’s ANDA. Plaintiffs requested that Sandoz produce the relied-upon information in order to fully evaluate Sandoz’s claim of non-infringement. Sandoz refused to produce the requested information.

351. Sandoz has infringed one or more claims of the ’753 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211267 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’753 Patent.

352. On information and belief, including Sandoz’s failure to produce requested information, the importation, manufacture, sale, offer for sale, or use of Sandoz’s 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 Sandoz 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).

353. Sandoz had actual and constructive notice of the ’753 Patent prior to filing ANDA No. 211267, and was aware that the filing of ANDA No. 211267 with the request for FDA approval prior to the expiration of the ’753 Patent would constitute an act of infringement of the ’753 Patent.

354. Sandoz filed its ANDA 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 ANDA Product. Sandoz’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.

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

COUNT XXV
INFRINGEMENT OF THE '455 PATENT BY SANDOZ

356. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–355 as if fully set forth herein.

357. On information and belief, Sandoz submitted or caused the submission of ANDA No. 211267 to FDA, and thereby seeks FDA approval of Sandoz's ANDA Product.

358. Plaintiffs own all rights, title, and interest in and to the '455 Patent.

359. Sandoz's ANDA Product infringes one or more claims of the '455 Patent either literally or under the doctrine of equivalents.

360. Information that Sandoz purportedly relied on in its Notice Letter to support its non-infringement claims for the '455 Patent was not contained in Sandoz's ANDA. Plaintiffs requested the Sandoz produce the relied-upon information in order to fully evaluate Sandoz's claim of non-infringement. Sandoz refused to produce the requested information.

361. Sandoz has infringed one or more claims of the '455 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211267 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '455 Patent.

362. On information and belief, including based on Sandoz's failure to produce requested information, the importation, manufacture, sale, offer for sale, or use of Sandoz's 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 Sandoz 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).

363. Sandoz had actual and constructive notice of the '455 Patent prior to filing ANDA No. 211267, and was aware that the filing of ANDA No. 211267 with the request for FDA approval prior to the expiration of the '455 Patent would constitute an act of infringement of the '455 Patent.

364. Sandoz filed its ANDA 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 ANDA Product. Sandoz'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.

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

COUNT XXVI
INFRINGEMENT OF THE ’617 PATENT BY SANDOZ

366. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–365 as if fully set forth herein.

367. On information and belief, Sandoz submitted or caused the submission of ANDA No. 211267 to FDA, and thereby seeks FDA approval of Sandoz’s ANDA Product.

368. Plaintiffs own all rights, title, and interest in and to the ’617 Patent.

369. Sandoz’s ANDA Product infringes one or more claims of the ’617 Patent literally or under the doctrine of equivalents.

370. Sandoz has infringed one or more claims of the ’617 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211267 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’617 Patent.

371. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sandoz’s ANDA Product prior to the expiration of the ’617 Patent would infringe one or more claims of the ’617 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, and/or Sandoz would induce the infringement of and/or contribute to the infringement of one or more claims of the ’617 Patent under 35 U.S.C. § 271 (b) and/or (c).

372. Sandoz had actual and constructive notice of the ’617 Patent prior to filing ANDA No. 211267, and was aware that the filing of ANDA No. 211267 with the request for FDA approval prior to the expiration of the ’617 Patent would constitute an act of infringement of the ’617 Patent.

373. Sandoz filed its ANDA without adequate justification for asserting that the ’617 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer

for sale, or sale of its ANDA Product. Sandoz's conduct in certifying invalidity and/or non-infringement with respect to the '617 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.

374. Plaintiffs will be irreparably harmed if Sandoz is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '617 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Sandoz, 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 '309, '444, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, and '455 Patents under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment that Teva has infringed the '753, '455, '090, '999, '889, '881, '883, '721, and '604 Patents under 35 U.S.C. § 271(e)(2)(A);

(C) A judgment that Sandoz has infringed the '753, '455, '617, and '604 Patents under 35 U.S.C. § 271(e)(2)(A);

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

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

any of the ’753, ’455, ’090, ’999, ’889, ’881, ’883, ’721, or ’604 Patent, or any later expiration of exclusivity for any of the ’753, ’455, ’090, ’999, ’889, ’881, ’883, ’721, or ’604 Patent, including any extensions or regulatory exclusivities;

(F) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Sandoz’s ANDA shall be no earlier than the last expiration date of any of the ’753, ’455, ’617, or ’604 Patent, or any later expiration of exclusivity for any of the ’753, ’455, ’617, or ’604 Patent, including any extensions or regulatory exclusivities;

(G) 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 ANDA Product within the United States, or importing its ANDA Product into the United States, until the day after the expiration of the ’309, ’444, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, and ’455 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the ’309, ’444, ’711, ’403, ’079, ’257, ’091, ’277, ’015, ’284, ’090, ’753, and ’455 Patents;

(H) Entry of a permanent injunction enjoining Teva, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Teva 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 ’753, ’455,’090, ’999, ’889, ’881, ’883, ’721, and ’604 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the ’753, ’455, ’090, ’999, ’889, ’881, ’883, ’721, and ’604 Patents;

(I) 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 ANDA Product within the United States, or importing its ANDA Product into the United States, until the day after the expiration of the ’753, ’455, ’617, and ’604 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the ’753, ’455, ’617, and ’604 Patents;

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

(K) A judgment declaring that making, using, selling, offering to sell, or importing Teva’s ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the ’753, ’455, ’090, ’999, ’889, ’881, ’883, ’721, and ’604 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(L) A judgment declaring that making, using, selling, offering to sell, or importing Sandoz’s ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the ’753, ’455, ’617, and ’604 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(M) 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 ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(N) A declaration under 28 U.S.C. § 2201 that if Teva, 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 Teva's ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(O) A declaration under 28 U.S.C. § 2201 that if Sandoz, 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 Sandoz's ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(P) 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 ANDA Product, or any product that infringes the '309, '444, '711, '403, '079, '257, '091, '277, '015, '284, '090, '753, or '455 Patent, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

(Q) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Teva engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product, or any product that infringes the '753, '455, '090, '999, '889, '881, '883, '721, or '604 Patent, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

(R) 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 ANDA Product, or any product that infringes the '753, '455, '617, or '604 Patent, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

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

(T) Costs and expenses in this action; and

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

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February 16, 2018

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