IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC, and JANSSEN BIOTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
CIPLA LIMITED and CIPLA USA INC.,	)	
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 Cipla Limited and Cipla USA Inc. (collectively, "Cipla"), 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 Cipla's recent submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") 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®. Cipla has submitted ANDA No. 211249 ("Cipla's ANDA") which seeks approval to market a generic version of IMBRUVICA®, prior to the expiration of U.S. Patent Nos. 9,296,753 ("the '753 Patent"); 9,725,455 ("the '455 Patent"); 9,540,382 ("the '382 Patent"); 9,713,617 ("the '617 Patent"); 8,754,090 ("the '090 Patent"); and 9,125,889 ("the '889 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 '753, '455, '382, '617, '090, and '889, 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 '753, '455, '382, '617, '090, and '889 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, Defendant Cipla Limited is a corporation organized and existing under the laws of India, with a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

13. On information and belief, Defendant Cipla USA Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, Florida 33323.

14. On information and belief, Cipla USA Inc. is a wholly owned subsidiary of Cipla Limited.

15. On information and belief, Cipla USA Inc. acts at the direction, and for the benefit, of Cipla Limited, and is controlled and/or dominated by Cipla Limited.

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

17. On information and belief, Cipla caused ANDA No. 211249 to be submitted to FDA and seeks FDA approval of ANDA No. 211249.

18. On information and belief, Cipla Limited holds Drug Master File ("DMF") No. 31728 for ibrutinib.

19. On information and belief, Cipla Limited and Cipla USA Inc. acted collaboratively in the preparation and submission of ANDA No. 211249 and DMF No. 31728 and continue to act collaboratively in pursuing FDA approval of ANDA No. 211249 and seeking to market the proposed generic ibrutinib capsules.

20. On information and belief, Cipla USA Inc. acts as the U.S. agent for Cipla Limited for purposes of regulatory submissions to FDA in seeking approval for generic drugs.

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

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

JURISDICTION AND VENUE

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

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

25. This Court has personal jurisdiction over Cipla USA Inc. because Cipla USA Inc. is a corporation organized and existing under the laws of Delaware. On information and belief,

Cipla USA Inc. is registered to do business as a domestic corporation in Delaware (File Number 5207954).

26. Additionally, this Court has personal jurisdiction over Cipla because, on information and belief, Cipla, *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 Cipla's ANDA Product in the State of Delaware upon approval of ANDA No. 211249.

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

28. On information and belief, Cipla 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.

29. Cipla 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 December 29, 2017 sent by Cipla Limited to, *inter alia*, Pharmacyclics pursuant to 21 U.S.C. § 355(j)(2)(B) ("Cipla's Notice Letter"), Cipla prepared and filed its ANDA with the

intention of seeking to market the ANDA Product nationwide, including within this judicial district.

30. On information and belief, Cipla 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.

31. On information and belief, Cipla 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. Cipla intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed ANDA Product.

32. Cipla Limited regularly invokes 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.*, *Meda Pharmaceuticals Inc. et al. v. Apotex Inc.*, 14-cv-01453 D.I. 1 (D. Del. Dec. 2, 2014); *Cipla Ltd. v. Sunovion Pharmaceuticals Inc.*, 15-cv-00424, D.I. 1 (D. Del. May 26, 2015). Cipla Limited and Cipla USA Inc. also have not contested personal jurisdiction or venue in patent litigation concerning FDA-approved drug products in this judicial district. *See, e.g.*, *Alcon Research, Ltd. v. Cipla Limited et al.*, 17-cv-01244, D.I. 9 (D. Del. Dec. 5, 2017); *Biogen International GmbH et al v. Cipla Limited et al.*, 17-cv-00851, D.I. 10 (D. Del. Oct. 16, 2017); *Onyx Therapeutics, Inc. v. Cipla Limited et al.*, 16-cv-00988, D.I. 15 (D. Del. Jan. 25, 2017); *Amgen Inc. v. Cipla Limited et al.*, 16-cv-00880, D.I. 8 (D. Del. Oct. 26, 2016); *Bristol-Myers Squibb Company v. Cipla USA, Inc. et al.*, 16-cv-00074, D.I. 8 (D. Del. Mar. 4, 2016).

33. Alternatively, this Court has personal jurisdiction over Cipla Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Cipla Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Cipla Limited has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Cipla's ANDA, preparing and submitting DMF No. 31728 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 Cipla Limited satisfies due process.

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

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

THE ASSERTED PATENTS

36. 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 A.

37. 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 B.

38. The '382 Patent, entitled "Crystalline Forms of a Bruton's Tyrosine Kinase Inhibitor," was duly and lawfully issued by the USPTO on January 10, 2017. A true and correct copy of the '382 Patent is attached hereto as Exhibit C.

39. 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 D.

40. 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 E.

41. 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 F.

CIPLA’S ANDA NO. 211249

42. On information and belief, Cipla has submitted ANDA No. 211249 to FDA, or caused ANDA No. 211249 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, ’382, ’617, ’090, and ’889 Patents.

43. On information and belief, FDA has not approved Cipla’s ANDA.

44. On information and belief, Cipla sent Pharmacyclics a Notice Letter dated December 29, 2017. Cipla’s Notice Letter represented that Cipla had submitted to FDA ANDA No. 211249 and a purported Paragraph IV certification for the ’753, ’455, ’382, ’617, ’090, and ’889 Patents.

45. In Cipla’s Notice Letter, Cipla purported to offer confidential access to portions of its ANDA No. 211249 on terms and conditions set forth in Cipla’s Notice Letter (“the Cipla Offer”). Cipla requested that Pharmacyclics accept the Cipla Offer before receiving access to ANDA No. 211249. The Cipla Offer contained unreasonable restrictions on who could view the

ANDA, well beyond those that would apply under a protective order. The Cipla Offer did not permit any of Pharmacyclics' in-house attorneys to access ANDA No. 211249. Nor did it permit any scientific experts to access ANDA No. 211249. Nor did it permit outside counsel, in-house attorneys, or scientific experts for Plaintiff Janssen to access Cipla's ANDA. Additionally, the Cipla Offer contained provisions that unreasonably restricted the ability of counsel receiving access to ANDA No. 211249 to engage in any patent prosecution or work before or involving the FDA. The restrictions the Cipla Offer placed on access to ANDA No. 211249 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).

46. Beginning with correspondence on January 8, 2018, outside counsel for Pharmacyclics negotiated in good faith with counsel for Cipla in an attempt to reach agreement on reasonable terms of confidential access to the ANDA. The parties did not reach agreement until February 9, 2018. Cipla produced portions of its ANDA that afternoon, three days before the filing of this Complaint. To date, Pharmacyclics and Janssen have not received a complete copy of Cipla's ANDA.

47. According to applicable regulations, Notice Letters such as Cipla'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.

48. For at least one claim of each of the '753, '455, '090, and '889 Patents, Cipla'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.

49. On information and belief, if FDA approves Cipla's ANDA, Cipla 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 Cipla's ANDA Product will directly infringe the '753, '455, '382, '617, '090, and '889 Patents, either literally or under the doctrine of equivalents, and Cipla will actively induce and/or contribute to their infringement.

50. This action is being brought within forty-five days of Plaintiffs' receipt of Cipla's Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). 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 '753 PATENT BY CIPLA

51. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–50 as if fully set forth herein.

52. On information and belief, Cipla submitted or caused the submission of ANDA No. 211249 to FDA, and thereby seeks FDA approval of Cipla's ANDA Product.

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

54. Cipla's ANDA Product infringes one or more claims of the '753 Patent.

55. Cipla did not contest infringement of at least claims 1–15 and 17 of ’753 Patent in Cipla’s Notice Letter. If Cipla had a factual or legal basis to contest infringement of the claims of the ’753 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.

56. Cipla has infringed one or more claims of the ’753 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211249 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’753 Patent.

57. On information and belief, the importation, manufacture, sale, offer for sale, or use of Cipla’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), and/or Cipla 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).

58. Cipla had actual and constructive notice of the ’753 Patent prior to filing ANDA No. 211249, and was aware that the filing of ANDA No. 211249 with the request for FDA approval prior to the expiration of the ’753 Patent would constitute an act of infringement of the ’753 Patent.

59. Cipla 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. Cipla’s conduct in certifying invalidity 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.

60. Plaintiffs will be irreparably harmed if Cipla 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 Cipla, 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 ’455 PATENT BY CIPLA

61. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–60 as if fully set forth herein.

62. On information and belief, Cipla submitted or caused the submission of ANDA No. 211249 to FDA, and thereby seeks FDA approval of Cipla’s ANDA Product.

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

64. Cipla’s ANDA Product infringes one or more claims of the ’455 Patent.

65. Cipla did not contest infringement of claims 1–13 of the ’455 Patent in Cipla’s Notice Letter. If Cipla had a factual or legal basis to contest infringement of the claims of the ’455 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.

66. Cipla has infringed one or more claims of the ’455 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211249 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’455 Patent.

67. On information and belief, the importation, manufacture, sale, offer for sale, or use of Cipla’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), and/or Cipla 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).

68. Cipla had actual and constructive notice of the ’455 Patent prior to filing ANDA No. 211249, and was aware that the filing of ANDA No. 211249 with the request for FDA approval prior to the expiration of the ’455 Patent would constitute an act of infringement of the ’455 Patent.

69. Cipla 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. Cipla’s conduct in certifying invalidity 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.

70. Plaintiffs will be irreparably harmed if Cipla 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 Cipla, 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 ’382 PATENT BY CIPLA

71. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–70 as if fully set forth herein.

72. On information and belief, Cipla submitted or caused the submission of ANDA No. 211249 to FDA, and thereby seeks FDA approval of Cipla’s ANDA Product.

73. Plaintiffs own all rights, title, and interest in and to the ’382 Patent.

74. Cipla's ANDA Product infringes one or more claims of the '382 Patent literally or under the doctrine of equivalents.

75. Cipla has infringed one or more claims of the '382 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211249 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '382 Patent.

76. On information and belief, the importation, manufacture, sale, offer for sale, or use of Cipla's ANDA Product prior to the expiration of the '382 Patent would infringe one or more claims of the '382 Patent under 35 U.S.C. § 271(a), and/or Cipla would induce the infringement of and/or contribute to the infringement of one or more claims of the '382 Patent under 35 U.S.C. § 271 (b) and/or (c).

77. Cipla had actual and constructive notice of the '382 Patent prior to filing ANDA No. 211249, and was aware that the filing of ANDA No. 211249 with the request for FDA approval prior to the expiration of the '382 Patent would constitute an act of infringement of the '382 Patent.

78. Cipla filed its ANDA without adequate justification for asserting that the '382 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Cipla's conduct in certifying invalidity and/or non-infringement with respect to the '382 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.

79. Plaintiffs will be irreparably harmed if Cipla is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '382 Patent. Plaintiffs do not

have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Cipla, 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 ’617 PATENT BY CIPLA

80. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–79 as if fully set forth herein.

81. On information and belief, Cipla submitted or caused the submission of ANDA No. 211249 to FDA, and thereby seeks FDA approval of Cipla’s ANDA Product.

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

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

84. Cipla has infringed one or more claims of the ’617 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211249 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the ’617 Patent.

85. On information and belief, the importation, manufacture, sale, offer for sale, or use of Cipla’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), and/or Cipla 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).

86. Cipla had actual and constructive notice of the ’617 Patent prior to filing ANDA No. 211249, and was aware that the filing of ANDA No. 211249 with the request for FDA

approval prior to the expiration of the ’617 Patent would constitute an act of infringement of the ’617 Patent.

87. Cipla 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. Cipla’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.

88. Plaintiffs will be irreparably harmed if Cipla 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 Cipla, 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 ’090 PATENT BY CIPLA

89. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–88 as if fully set forth herein.

90. On information and belief, Cipla submitted or caused the submission of ANDA No. 211249 to FDA, and thereby seeks FDA approval of Cipla’s ANDA Product.

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

92. Cipla’s ANDA Product infringes one or more claims of the ’090 Patent.

93. Cipla did not contest infringement of claims 1–2 of the ’090 Patent in Cipla’s Notice Letter. If Cipla 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.

94. Cipla has infringed one or more claims of the '090 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211249 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '090 Patent.

95. On information and belief, the importation, manufacture, sale, offer for sale, or use of Cipla'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 Cipla 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).

96. Cipla had actual and constructive notice of the '090 Patent prior to filing ANDA No. 211249, and was aware that the filing of ANDA No. 211249 with the request for FDA approval prior to the expiration of the '090 Patent would constitute an act of infringement of the '090 Patent.

97. Cipla 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. Cipla'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.

98. Plaintiffs will be irreparably harmed if Cipla 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 Cipla, 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 '889 PATENT BY CIPLA

99. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–98 as if fully set forth herein.

100. On information and belief, Cipla submitted or caused the submission of ANDA No. 211249 to FDA, and thereby seeks FDA approval of Cipla's ANDA Product.

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

102. Cipla's ANDA Product infringes one or more claims of the '889 Patent.

103. Cipla did not contest infringement of claims 1–2 of the '889 Patent in Cipla's Notice Letter. If Cipla 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.

104. Cipla has infringed one or more claims of the '889 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211249 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '889 Patent.

105. On information and belief, the importation, manufacture, sale, offer for sale, or use of Cipla'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 Cipla 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).

106. Cipla had actual and constructive notice of the ’889 Patent prior to filing ANDA No. 211249, and was aware that the filing of ANDA No. 211249 with the request for FDA approval prior to the expiration of the ’889 Patent would constitute an act of infringement of the ’889 Patent.

107. Cipla 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. Cipla’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.

108. Plaintiffs will be irreparably harmed if Cipla 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 Cipla, 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 Cipla has infringed the ’753, ’455, ’382, ’617, ’090 and ’889 Patents under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Cipla’s ANDA shall be no earlier than the last expiration date of any of the ’753, ’455, ’382, ’617, ’090, or ’889 Patents, or any later expiration of exclusivity for any of the ’753, ’455, ’382, ’617, ’090, or ’889 Patents, including any extensions or regulatory exclusivities;

(C) Entry of a permanent injunction enjoining Cipla, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Cipla 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, '382, '617, '090, and '889 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the '753, '455, '382, '617, '090, and '889 Patents;

(D) A judgment declaring that making, using, selling, offering to sell, or importing Cipla's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the '753, '455, '382, '617, '090, and '889 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

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

(F) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Cipla 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, '382, '617, '090, or '889 Patents, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

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

(H) Costs and expenses in this action; and

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

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