IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC and JANSSEN BIOTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SUN PHARMA GLOBAL FZE and SUN PHARMACEUTICAL INDUSTRIES LTD.,	)	
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 Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. (collectively, "Sun"), 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 Sun's recent submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Applications ("ANDA") seeking approval to market a generic version of Plaintiffs' highly successful pharmaceutical product IMBRUVICA®, prior to the expiration of a patent listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for IMBRUVICA®. Sun has submitted ANDA No. 211319 ("Sun's ANDA") which seeks approval to market a generic version of IMBRUVICA®, prior to the expiration of U.S. Patent No. 10,004,746 ("the '746 Patent").

THE RELATED LITIGATION

2. This is a civil action for infringement of the '746 Patent.

3. One other patent infringement action relating to Sun's ANDA and IMBRUVICA® is pending in this judicial district between Plaintiffs and Sun: *Pharmacyclics LLC et al. v. Shilpa Medicare Limited et al.*, Civil Action No. 18-237-CFC (the "Related Action"). The Related Action is coordinated with three other cases, each of which also arises from a defendant's submission of an ANDA seeking approval to market a generic version of IMBRUVICA®: *Pharmacyclics LLC et al. v. Fresenius Kabi USA, LLC et al.*, Civil Action No. 18-192-CFC; *Pharmacyclics LLC et al. v. Cipla Ltd.*, Civil Action No. 18-247-CFC; and, *Pharmacyclics LLC et al. v. Zydus Worldwide DMCC et al.*, Civil Action No. 18-275-CFC.

IMBRUVICA®

4. 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.

5. 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.

6. 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®.

7. 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.

8. 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.

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

10. IMBRUVICA® has gained widespread acceptance in the medical community with approximately 100,000 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.

11. The '746 Patent is listed in the Orange Book for IMBRUVICA®.

THE PARTIES

12. 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 '746 Patent. Pharmacyclics holds New Drug Application ("NDA") No. 205552 for IMBRUVICA®.

13. 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®.

14. On information and belief, Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, with a principal place of business at Office 43 Block Y, Sharjah Airport International Free Zone, P.O. Box 122304, Sharjah, United Arab Emirates.

15. On information and belief, Sun Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of India, with a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra 400063, India.

16. On information and belief, Sun Pharma Global FZE is a wholly owned subsidiary of Sun Pharmaceutical Industries Ltd.

17. On information and belief, Sun Pharma Global FZE acts at the direction, and for the benefit, of Sun Pharmaceutical Industries Ltd., and is controlled and/or dominated by Sun Pharmaceutical Industries Ltd.

18. On further information and belief, Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE 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.

19. On information and belief, Sun caused ANDA No. 211319 to be submitted to FDA and seeks FDA approval of ANDA No. 211319.

20. On information and belief, Sun Pharmaceutical Industries Ltd. holds Drug Master File ("DMF") No. 31547 for ibrutinib.

21. On information and belief, Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE acted collaboratively in the preparation and submission of ANDA No. 211319 and DMF No. 31547 and continue to act collaboratively in pursuing FDA approval of ANDA No. 210896 and seeking to market the proposed generic ibrutinib capsules.

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

23. On information and belief, Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. rely on material assistance from one another to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of Delaware. On information and belief, Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Sun's ANDA Product, in the event FDA approves Sun's ANDA.

JURISDICTION AND VENUE

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

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

26. This Court has personal jurisdiction over Sun because, on information and belief, Sun, *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Sun's ANDA Product in the State of Delaware upon approval of ANDA No. 211319.

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

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

29. Sun has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to 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 August 23, 2018 sent by Sun Pharma Global FZE to, *inter alia*, Pharmacyclics and Janssen pursuant to 21 U.S.C. § 355(j)(2)(B) ("Sun's Notice Letter"), Sun 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, Sun 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, Sun 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. Sun intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed ANDA Product.

32. Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE have engaged in patent litigation concerning FDA-approved drug products in this judicial district and have not contested personal jurisdiction or venue in this judicial district in such litigation. *See also, e.g.*, *Biogen MA Inc. v. Sun Pharma Global FZE*, 17-848, D.I. 9 (D. Del. Oct. 16, 2017); *Bristol-*

Myers Squibb Co. et al v. Sun Pharmaceutical Industries, Inc. et al., 17-409, D.I. 10 (D. Del. May 12, 2017); *Amgen Inc. v. Sun Pharmaceutical Industries, Ltd., et al.*, 16-882, D.I. 14 (D. Del. Nov. 16, 2016).

33. Sun does not contest personal jurisdiction in this judicial district in the Related Action. *See Pharmacyclics LLC et al. v. Shilpa Medicare Limited et al.*, 18-237-CFC, D.I. 14, Answer ¶ 41 (Apr. 6, 2018) ("Sun does not contest personal jurisdiction in this Court for the purpose of this action only.").

34. Sun has invoked the jurisdiction of this judicial district as a Counterclaimant in the Related Action. *See Pharmacyclics LLC et al. v. Shilpa Medicare Limited et al.*, 18-237-CFC, D.I. 14, Counterclaims ¶ 10 (Apr. 6, 2018).

35. Alternatively, this Court has personal jurisdiction over Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE have sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Sun's ANDA to FDA, preparing and submitting DMF No. 31547 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 Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE satisfies due process.

36. Venue is proper in this district for Sun Pharma Global FZE pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Pharma Global FZE is a corporation organized and

existing under the laws of the United Arab Emirates and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

37. Venue is proper in this district for Sun Pharmaceutical Industries Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Pharmaceutical Industries Ltd. 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).

38. Sun does not contest venue in this judicial district in the Related Action. *See Pharmacyclics LLC et al. v. Shilpa Medicare Limited et al.*, 18-237-CFC, D.I. 14, Answer ¶ 45 (Apr. 6, 2018) ("Sun does not contest venue in this Court for the purpose of this action only.").

THE ASSERTED PATENT

39. The '746 Patent, entitled "Use of Inhibitors of Bruton's Tyrosine Kinase (BTK)," was duly and lawfully issued by the USPTO on June 26, 2018. A true and correct copy of the '746 Patent is attached hereto as Exhibit A.

SUN'S ANDA NO. 211319

40. On information and belief, Sun has submitted ANDA No. 211319 to FDA, or caused ANDA No. 211319 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 '746 Patent.

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

42. On information and belief, Sun sent Pharmacyclics and Janssen a Notice Letter dated August 23, 2018. Sun's Notice Letter represented that Sun had submitted to FDA ANDA No. 211319 and a purported Paragraph IV certification for the '746 Patent.

43. According to applicable regulations, Notice Letters such as Sun's must contain a detailed statement of the factual and legal basis for the applicant's opinion that the patent is

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

44. Sun's Notice Letter did not allege that any claim of the '746 Patent is not infringed.

45. On information and belief, if FDA approves Sun's ANDA, Sun will manufacture, offer for sale, or sell its ANDA Product, within the United States, including within the State of Delaware, or will import its ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Sun's ANDA Product will directly infringe the '746 Patent and Sun will actively induce and/or contribute to its infringement.

46. This action is being brought within forty-five days of Plaintiffs' receipt of Sun's Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C).

COUNT I
INFRINGEMENT OF THE '746 PATENT BY SUN

47. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–46 as if fully set forth herein.

48. On information and belief, Sun submitted or caused the submission of ANDA No. 211319 to FDA, and thereby seeks FDA approval of Sun's ANDA Product.

49. Plaintiffs own all rights, title, and interest in and to the '746 Patent.

50. Sun's ANDA Product infringes one or more claims of the '746 Patent.

51. Sun has infringed one or more claims of the '746 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211319 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '746 Patent.

52. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '746 Patent would infringe one or more claims of the '746 Patent under 35 U.S.C. § 271(a), and/or Sun would induce the infringement of and/or contribute to the infringement of one or more claims of the '746 Patent under 35 U.S.C. § 271 (b) and/or (c).

53. Sun had actual and constructive notice of the '746 Patent prior to filing ANDA No. 211319, and was aware that the filing of ANDA No. 211319 with the request for FDA approval prior to the expiration of the '746 Patent would constitute an act of infringement of the '746 Patent.

54. Sun filed its ANDA without adequate justification for asserting that the '746 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Sun's conduct in certifying invalidity and/or non-infringement with respect to the '746 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.

55. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '746 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and

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

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment that Sun has infringed the '746 Patent 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 Sun's ANDA shall be no earlier than the expiration date of the '746 Patent, or any later expiration of exclusivity for the '746 Patent, including any extensions or regulatory exclusivities;

(C) Entry of a permanent injunction enjoining Sun, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Sun or on its behalf from commercially manufacturing, using, offering for sale, or selling its ANDA Product within the United States, or importing its ANDA Product into the United States, until the day after the expiration of the '746 Patent, including any additional exclusivity period applicable to this patent, and from otherwise infringing the claims of the '746 Patent;

(D) A judgment declaring that making, using, selling, offering to sell, or importing Sun's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the '746 Patent pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(E) A declaration under 28 U.S.C. § 2201 that if Sun, 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 Sun'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 Sun engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product, or any product that infringes the '746 Patent, or induces or contributes to such conduct, prior to the expiration of the patent including any additional exclusivity period applicable to the patent;

(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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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

Attorneys for Plaintiffs

OF COUNSEL:

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

Attorneys for Pharmacyclics

Gregory L. Diskant
Irena Royzman
Jordan M. Engelhardt
Lachlan Campbell-Verduyn
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
(212) 336-2000

Attorneys for Janssen Biotech, Inc.

October 5, 2018