IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WARNER-LAMBERT COMPANY LLC and PF PRISM IMB B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMA GLOBAL FZE and SUN PHARMACEUTICAL INDUSTRIES INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc.; Warner-Lambert Company LLC; and PF PRISM IMB B.V. (collectively, "Pfizer") file this Complaint for patent infringement against Sun Pharmaceutical Industries, Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. (collectively, "Sun"), and by their attorneys, hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Sun's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of IBRANCE® (palbociclib) tablets, 75 mg, 100 mg, and 125 mg, prior to the expiration of U.S. Patent No. 10,723,730 ("the '730 patent").

2. Sun notified Pfizer by letter dated January 27, 2021 ("Sun's Notice Letter") that it had submitted to the FDA ANDA No. 215569 ("Sun's ANDA"), seeking approval from the FDA

to engage in the commercial manufacture, use, and/or sale of generic palbociclib tablets, 75 mg, 100 mg, and 125 mg ("Sun's ANDA Products") prior to the expiration of the '730 patent.

PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the holder of New Drug Application ("NDA") No. 212436 for the manufacture and sale of palbociclib tablets, 75 mg, 100 mg, and 125 mg, which has been approved by the FDA.

4. Plaintiff Warner-Lambert Company LLC is a limited liability company organized and existing under the laws of the State of Delaware, and having a place of business at 235 East 42nd Street, New York, New York 10017.

5. Plaintiff PF PRISM IMB B.V. is a private limited company (*besloten venootschap*) organized under the law of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJessel, the Netherlands.

6. Upon information and belief, defendant Sun Pharmaceutical Industries Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India. Upon information and belief, Sun Pharmaceutical Industries Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Sun Pharmaceutical Industries, Inc.

7. Upon information and belief, defendant Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2 Independence Way, Princeton, New Jersey 08540.

8. Upon information and belief, defendant Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, with places of business at Office #43, Block Y, SAIF Zone, P.O. Box. No. 122304, Sharjah, United Arab Emirates, and DMCC Branch, 704 Jumeirah Business Center 1, Cluster G, JLT, P.O. Box No. 643561, Dubai, United Arab Emirates. Upon information and belief, Sun Pharma Global FZE is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

9. Upon information and belief, Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE are wholly owned subsidiaries of Sun Pharmaceutical Industries Ltd.

10. Upon information and belief, Sun Pharmaceutical Industries, Inc., Sun Pharma Global FZE, and Sun Pharmaceutical Industries Ltd. acted in concert to prepare and submit Sun's ANDA to the FDA.

11. On information and belief Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. know and intend that upon approval of Sun's ANDA, Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. will manufacture, market, sell, and distribute Sun's ANDA Products throughout the United States, including in Delaware. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Sun's ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharma Global

FZE, and Sun Pharmaceutical Industries, Inc. participated, assisted, and cooperated in carrying out the acts complained of herein.

12. Upon information and belief, following any FDA approval of Sun's ANDA, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. will act in concert to distribute and sell Sun's ANDA Products throughout the United States, including within Delaware.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

14. Sun Pharmaceutical Industries Ltd. is subject to personal jurisdiction in Delaware because, among other things, Sun Pharmaceutical Industries Ltd., itself and through its wholly owned subsidiaries Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Sun Pharmaceutical Industries Ltd., itself and through its subsidiaries Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Sun Pharmaceutical Industries Ltd. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Sun Pharmaceutical Industries, Inc. and Sun Global Pharma FZE, and therefore the activities of Sun Pharmaceutical Industries, Inc. and Sun Global Pharma FZE in this jurisdiction are attributed to Sun Pharmaceutical Industries Ltd.

15. Sun Pharma Global FZE is subject to personal jurisdiction in Delaware because, among other things, Sun Pharma Global FZE has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Sun Pharma Global FZE develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

16. Sun Pharmaceutical Industries, Inc. is subject to personal jurisdiction in this Court because, among other things, it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Sun Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and is registered to conduct business within the State of Delaware (File No. 7893212). Upon information and belief, Sun Pharmaceutical Industries, Inc. maintains in the State of Delaware a registered agent for service of process—Corporation Service Company—with an address at 251 Little Falls Drive, Wilmington, Delaware 19808. Sun Pharmaceutical Industries Inc. has therefore consented to general jurisdiction in the State of Delaware. Upon information and belief, Sun Pharmaceutical Industries, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

17. Sun has previously used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), to

challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

18. Upon information and belief, Sun, with knowledge of the Hatch-Waxman Act process, directed Sun's Notice Letter to, *inter alia*, Pfizer Inc., an entity incorporated in Delaware, and alleged in Sun's Notice Letter that Pfizer's '730 patent is invalid. Upon information and belief, Sun knowingly and deliberately challenged Pfizer's patent rights, and knew when it did so that it was triggering the forty-five day period for Pfizer to bring an action for patent infringement under the Hatch-Waxman Act.

19. Because Pfizer Inc. is incorporated in Delaware, Pfizer Inc. suffers injury and consequences from Sun's filing of Sun's ANDA challenging Pfizer's patent rights in Delaware. Upon information and belief, Sun knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Sun has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Sun's Notice Letter to Pfizer Inc., a Delaware corporation, it would be sued in Delaware for patent infringement.

20. Upon information and belief, if Sun's ANDA is approved, Sun will directly or indirectly manufacture, market, sell, and/or distribute Sun's ANDA Products within the United States, including in Delaware, consistent with Sun's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, following any FDA approval of ANDA No. 215569, Sun knows and intends that Sun's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

Upon information and belief, Sun regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Sun's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Sun's ANDA Products will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Pfizer's patent in the event that Sun's ANDA Products are approved before the patent expires.

21. Upon information and belief, Sun derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Sun and/or for which Sun is the named applicant on approved ANDAs. Upon information and belief, various products for which Sun is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

22. Venue is proper in this district as to Sun Pharmaceutical Industries, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

23. Venue is proper in this district as to Sun Pharma Global FZE pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Pharma Global FZE is a company organized and existing under the laws of the United Arab Emirates and is subject to personal jurisdiction in this judicial district.

24. Venue is proper in this district as to Sun Pharmaceutical Industries Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Pharmaceutical Industries Ltd. is a company organized and existing under the laws of the United Arab Emirates and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

25. IBRANCE®, which contains palbociclib, is approved for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer.

26. Upon information and belief, Sun's ANDA Products are a generic version of IBRANCE®.

27. Sun's Notice Letter purported to include an "Offer of Confidential Access" to Pfizer to Sun's ANDA. The offer, however, was subject to various unreasonably restrictive conditions. In an exchange of correspondence, counsel for Plaintiffs and counsel for Sun discussed the terms of Sun's Offer of Confidential Access, though the parties were unable to agree on terms under which Pfizer could review internal documents, data, and/or samples relevant to infringement, which are not publically available, on reasonable confidentiality terms.

28. Plaintiffs are filing this Complaint within forty-five days of receipt of Sun's Notice Letter.

COUNT I – INFRINGEMENT OF THE '730 PATENT

29. Pfizer incorporates each of the preceding paragraphs 1–28 as if fully set forth herein.

30. The inventors of the '730 patent are Brian Patrick Chekal and Nathan D. Ide.

31. The '730 patent, entitled "Solid Forms of a Selective Cdk4/6 Inhibitor" (attached as Exhibit A), was duly and legally issued on July 28, 2020.

32. Pfizer is the owner and assignee of the '730 patent.

33. IBRANCE® is covered by one or more claims of the '730 patent, which has been listed in connection with IBRANCE® in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as "the Orange Book").

34. In Sun's Notice Letter, Sun notified Pfizer of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sun's ANDA Products prior to the expiration of the '730 patent.

35. In Sun's Notice Letter, Sun also notified Pfizer that, as part of its ANDA, Sun had filed a certification of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv), with respect to the '730 patent. Upon information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '730 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Products.

36. Upon information and belief, Sun's ANDA Products and the use of Sun's ANDA Products are covered by one or more claims of the '730 patent, either literally or under the doctrine of equivalents.

37. As an example, claim 1 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a primary particle size distribution characterized by a D90 value of from about 30 μm to about 65 μm.

38. Upon information and belief, Sun's ANDA Products infringe claim 1 of the '730 patent, literally or under the doctrine of equivalents.

39. As an example, Claim 7 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 40 μm.

40. Upon information and belief, Sun's ANDA Products infringe claim 7 of the '730 patent, literally or under the doctrine of equivalents.

41. As an example, Claim 15 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 30 μm.

42. Upon information and belief, Sun's ANDA Products infringe claim 15 of the '730 patent, literally or under the doctrine of equivalents.

43. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Products before the expiration of the '730 patent was an act of infringement of the '730 patent under 35 U.S.C. § 271(e)(2)(A).

44. Upon information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Products immediately and imminently upon approval of its ANDA.

45. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Products would infringe one or more claims of the '730 patent, either literally or under the doctrine of equivalents.

46. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Products in accordance with, and as directed by, their proposed product labeling would infringe one or more claims of the '730 patent.

47. Upon information and belief, Sun plans and intends to, and will, actively induce infringement of the '730 patent when Sun's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '730 patent and specific intent to infringe that patent.

48. Upon information and belief, Sun knows that Sun's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '730 patent, that Sun's ANDA Products are not staple articles or commodities of commerce, and that Sun's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sun plans and intends to, and will, contribute to infringement of the '730 patent immediately and imminently upon approval of Sun's ANDA.

49. Notwithstanding Sun's knowledge of the claims of the '730 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Products with their product labeling following FDA approval of Sun's ANDA prior to the expiration of the '730 patent.

50. The foregoing actions by Sun constitute and/or will constitute infringement of the '730 patent; active inducement of infringement of the '730 patent; and contribution to the infringement by others of the '730 patent.

51. Upon information and belief, Sun has acted with full knowledge of the '730 patent and without a reasonable basis for believing that it would not be liable for infringement of the '730

patent; active inducement of infringement of the '730 patent; and/or contribution to the infringement by others of the '730 patent.

52. Pfizer will be substantially and irreparably harmed by infringement of the '730 patent.

53. Unless Sun is enjoined from infringing the '730 patent, actively inducing infringement of the '730 patent, and contributing to the infringement by others of the '730 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '730 PATENT

54. Pfizer incorporates each of the preceding paragraphs 1–53 as if fully set forth herein.

55. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on one hand and Sun on the other regarding Sun's infringement, active inducement of infringement, and contribution to the infringement by others of the '730 patent, and/or the validity of the '730 patent.

56. In Sun's Notice Letter, Sun notified Pfizer of the submission of Sun's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sun's ANDA Products prior to the expiration of the '730 patent.

57. In Sun's Notice Letter, Sun also notified Pfizer that, as part of its ANDA, Sun had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv), with respect to the '730 patent. Upon information and belief, Sun submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)

asserting that the '730 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Products.

58. Upon information and belief, Sun's ANDA Products and the use of Sun's ANDA Products are covered by one or more claims of the '730 patent.

59. As an example, claim 1 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a primary particle size distribution characterized by a D90 value of from about 30 μm to about 65 μm.

60. Upon information and belief, Sun's ANDA Products infringe claim 1 of the '730 patent, literally or under the doctrine of equivalents.

61. As an example, Claim 7 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 40 μm.

62. Upon information and belief, Sun's ANDA Products infringe claim 7 of the '730 patent, literally or under the doctrine of equivalents.

63. As an example, Claim 15 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 30 μm.

64. Upon information and belief, Sun's ANDA Products infringe claim 15 of the '730 patent, literally or under the doctrine of equivalents.

65. Upon information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Products immediately and imminently upon approval of its ANDA.

66. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Products would infringe one or more claims of the '730 patent.

67. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sun's ANDA Products in accordance with, and as directed by, their proposed labeling would infringe one or more claims of the '730 patent.

68. Upon information and belief, Sun plans and intends to, and will, actively induce infringement of the '730 patent when Sun's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sun's activities will be done with knowledge of the '730 patent and specific intent to infringe that patent.

69. Upon information and belief, Sun knows that Sun's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '730 patent, that Sun's ANDA Products are not staple articles or commodities of commerce, and that Sun's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sun plans and intends to, and will, contribute to infringement of the '730 patent immediately and imminently upon approval of Sun's ANDA.

70. Notwithstanding Sun's knowledge of the claims of the '730 patent, Sun has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sun's ANDA Products with their proposed labeling following FDA approval of Sun's ANDA prior to the expiration of the '730 patent.

71. The foregoing actions by Sun constitute and/or will constitute infringement of the '730 patent; active inducement of infringement of the '730 patent; and contribution to the infringement by others of the '730 patent.

72. Upon information and belief, Sun has acted with full knowledge of the '730 patent and without a reasonable basis for believing that it would not be liable for infringement of the '730 patent; active inducement of infringement of the '730 patent; and/or contribution to the infringement by others of the '730 patent.

73. Pfizer will be substantially and irreparably damaged by infringement of the '730 patent.

74. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Sun's ANDA Products with their proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '730 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '730 patent, and that the claims of the '730 patent are not invalid.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that the '730 patent has been infringed under 35 U.S.C. § 271(e)(2) by Sun's submission to the FDA of Sun's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Sun's ANDA Products, or any other drug product that infringes or the use of which infringes the '730 patent, be not earlier than the expiration date of the '730 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Sun, and all persons acting in concert with Sun, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sun's ANDA Products, or any other drug product covered by or whose use is covered by the '730 patent, prior to the expiration of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Sun's ANDA Products, or any other drug product which is covered by or whose use is covered by the '730 patent, prior to the expiration of that patent, will infringe, induce the infringement of, and contribute to the infringement by others of, said patent;

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

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

Attorneys for Plaintiffs

OF COUNSEL:

David I. Berl
Christopher J. Mandernach
Seth R. Bowers
Michael Xun Liu
Kevin Hoagland-Hanson
Andrew L. Hoffman
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000

February 24, 2021