IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
SUN PHARMACEUTICAL INDUSTRIES LIMITED,	)	
	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff AbbVie Inc. ("AbbVie" or "Plaintiff"), by its attorneys, brings this action against Defendant Sun Pharmaceutical Industries Limited ("Sun"), and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 11,690,845 ("the '845 patent") and 11,690,854 ("the '854 patent") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et. seq.*, and in particular under 35 U.S.C. § 271. This action relates to Sun'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 Plaintiff's commercial pharmaceutical product ORILISSA® (elagolix sodium oral tablets, (eq. 150 mg base and eq. 200 mg base), submitted under New Drug Application ("NDA") No. 210450), 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 ORILISSA®. Sun has submitted ANDA No. 215804 ("Sun's ANDA"), which seeks approval to market its generic version of ORILISSA®, elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base) ("Sun's Generic Product"), prior to the expiration of the '845 and '854 patents.

2. Sun has infringed one or more claims of the '845 and '854 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 215804 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Sun's Generic Product prior to the expiration of the '845 and '854 patents, or any extensions thereof. Sun will infringe one or more claims of the '845 and '854 patents under 35 U.S.C. § 271(a), (b), and/or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Sun's Generic Product prior to the expiration of the '845 and '854 patents, or any extensions thereof.

3. Plaintiff AbbVie Inc., along with AbbVie Ltd and Neurocrine Biosciences, Inc., previously filed a separate action in this Court against Sun Pharmaceutical Industries Limited for patent infringement relating to ANDA No. 215804, which included counts for infringement of U.S. Patent Nos. 7,056,927 ("the '927 patent"), 7,419,983 ("the '983 patent"), 10,537,572 ("the '572 patent"), 10,682,351 ("the '351 patent"), and 11,344,551 ("the '551 patent"). *AbbVie Inc., et al. v. Alkem Laboratories Limited, et al.,* C.A. No. 22-1423-JLH (the "First Suit") was filed on October 27, 2022. The First Suit was filed in response to a letter from Sun dated September 16, 2022 ("Sun's First Notice Letter"), purporting to be a "Notice of Certification Pursuant to Federal Food, Drug and Cosmetic Act" for ANDA No. 215804 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 as to the '927 patent, the '983 patent, the '572 patent, the '351 patent, and the '551 patent.

4. Plaintiff AbbVie Inc. also filed a separate action in this Court against Sun Pharmaceutical Industries Limited for patent infringement relating to ANDA No. 215804, which included counts for infringement of U.S. Patent No. 11,542,239 ("the '239 patent"). *AbbVie Inc. v. Sun Pharmaceutical Industries Limited*, C.A. No. 23-00684-JLH (the "Second Suit") was filed

on June 23, 2023. The Second Suit was filed in response to a letter from Sun dated May 10, 2023 ("Sun's Second Notice Letter"), purporting to be a "Notice of Certification Pursuant to Federal Food, Drug and Cosmetic Act" for ANDA No. 215804 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 as to the '239 patent. The Second Suit was consolidated with the First Suit on August 16, 2023. *See AbbVie Inc. v. Sun Pharmaceutical Industries Limited*, C.A. No. 23-00684-JLH, D.I. 10.

5. Based on information and belief, Sun is maintaining its certification as to the '927 patent, the '983 patent, the '572 patent, the '351 patent, the '551 patent, and the '239 patent set out in Sun's First and Second Notice Letters. Thus, Plaintiffs will continue to prosecute all infringement counts presented in the First and Second Suits.

ORILISSA®

6. ORILISSA® is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis. Over 80,000 women have been prescribed ORILISSA®.

7. Endometriosis occurs when tissue that normally lines the inside of the uterus grows outside of the uterus (where it does not belong). These growths are referred to as lesions. During the menstrual cycle, estrogen levels rise and can cause endometriosis lesions to grow. Then, during a period, the lesions can break down and shred, causing pain throughout the month.

8. One way to manage common symptoms of endometriosis is to reduce the amount of estrogen the body produces. ORILISSA® inhibits endogenous GnRH signaling by binding competitive to GnRH receptors in the pituitary gland. ORILISSA® dials down estrogen, which can help manage endometriosis pain.

9. ORILISSA® was approved by the FDA on July 23, 2018, pursuant to NDA No. 210450. There are 2 different FDA approved dosage forms of ORILISSA®: 150 mg (administered orally once a day for management of moderate to severe pain associated with endometriosis) or 200 mg (administered orally twice a day for management of moderate to severe pain associated with endometriosis).

10. ORILISSA® is marketed and sold in the United States by AbbVie.

11. The '845 and '854 patents are listed in the Orange Book for ORILISSA®.

THE PARTIES

12. Plaintiff AbbVie is a corporation organized and existing under the laws of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is the assignee and owner of the '845 and '854 patents. AbbVie holds NDA No. 210450 for ORILISSA®. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas, including women's health.

13. AbbVie markets, distributes, and sells therapeutic drug products, including ORILISSA®, in this judicial district and throughout the United States.

14. On information and belief, Sun is a company 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 (E), Mumbai 400063, India.

15. On information and belief, Sun is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware, either individually or in concert.

16. On information and belief, Sun caused Sun's ANDA to be submitted to FDA and seek FDA approval of Sun's ANDA.

17. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of Sun's ANDA, Sun will distribute and sell the proposed generic elagolix sodium oral tablet (eq. 150 mg base and eq. 200 mg base) products described in Sun's ANDA throughout the United States, including the State of Delaware.

JURISDICTION AND VENUE

18. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

19. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271.

20. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

21. This Court has personal jurisdiction over Defendant 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 affiliates, 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 Generic Product in the State of Delaware upon approval of ANDA No. 215804.

22. On information and belief, Sun purposefully has conducted and continues to conduct business in this judicial district by manufacturing, importing, marketing, and distributing

pharmaceutical products, including generic drug products, either by itself or through its subsidiaries, agents, and/or alter egos, throughout the United States, including in this judicial district.

23. On information and belief, Sun, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Sun's website states: "Sun Pharmaceutical Industries Ltd. (Sun Pharma) is the fourth largest specialty generic pharmaceutical company in the world with global revenues of over US$ 5.1 billion. Supported by more than 40 manufacturing facilities, we provide high-quality, affordable medicines, trusted by healthcare professionals and patients, to more than 100 countries across the globe." (https://sunpharma.com/about-us/, accessed on Jan. 25, 2024). Sun's website further states: "Over the last two decades, Sun Pharma has established itself as a leading player in the generics market in the U.S. We are the 8th largest generics pharmaceutical company in the U.S. and are ranked 2nd by prescriptions in the U.S. dermatology market. We are rapidly ramping up our presence in the specialty branded market, with dermatology, ophthalmology and oncology as key target segments. Our U.S. business makes up 30% of our global revenue." (https://sunpharma.com/usa/, accessed on Jan. 25, 2024). On information and belief, Sun derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

24. This Court also has personal jurisdiction over Sun because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Sun satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4)

"[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

25. This Court also has personal jurisdiction over Sun by virtue of the fact that, *inter alia*, Sun has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiff in this District.

26. On information and belief, Sun is subject to personal jurisdiction in this judicial district through its pursuit of regulatory approval for ANDA No. 215804 for the commercial manufacture, use, and/or sale of Sun's Generic Product, if approved, in this judicial district and to residents of this judicial district. Through at least these activities, Sun has purposely availed itself of the rights and benefits of Delaware law such that it should reasonably anticipate being haled into court in this judicial district.

27. On information and belief Sun has been, and continues to be responsible for the drafting, submission, request for approval, and maintenance of ANDA No. 215804 with a Paragraph IV certification regarding the '845 and '854 patents. On information and belief and as indicated by a letter dated December 22, 2023, sent by Sun to Plaintiff pursuant to 21 U.S.C. § 355(j)(2)(B), Sun prepared and filed its ANDA with the intention of seeking to market Sun's Generic Product nationwide, including within this judicial district.

28. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 215804, Sun will import, market, distribute, offer for sale, and/or sell Sun's Generic Product described in ANDA No. 215804

throughout the United States, including in Delaware, either by itself or through its subsidiaries, agents, and/or alter egos, and will derive substantial revenue from the use or consumption of Sun's Generic ANDA Product in the state of Delaware.

29. On information and belief, if ANDA No. 215804 is approved, Sun's Generic Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by healthcare providers practicing in Delaware; administered by healthcare providers located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

30. If ANDA No. 215804 is approved, Plaintiff will be harmed by the marketing, distribution, offer for sale, and/or sale of Sun's Generic Product, including in Delaware.

31. This Court also has personal jurisdiction over Sun because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. In particular, Defendant Sun has been sued multiple times in this District without challenging personal jurisdiction and Sun has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *Vertex Pharms. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 23-00666-RGA; *Novo Nordisk Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 22-896-CFC; *Boehringer Ingelheim Pharms., Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 21-1573-CFC; *InfoRLife SA v. Sun Pharm. Indus. Ltd.*, C.A. No. 21-1740-CFC; *Galderma Labs. L.P. v. Sun Pharm. Indus. Ltd.*, C.A. No. 18-1588-LPS; *Pfizer, Inc. v. Micro Labs USA, Inc.*, C.A. No. 17-158-LPS.

32. Alternatively, this Court has personal jurisdiction over Sun pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Sun is a foreign entity organized under the laws of India, Plaintiff's claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because,

upon information and belief, Sun has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

33. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Sun.

34. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Sun is incorporated in India and may be sued in any judicial district in the United States in which it is subject to the Court's personal jurisdiction.

FACTUAL BACKGROUND

The NDA

35. AbbVie is the holder of NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base)) Tablets.

36. The FDA approved NDA No. 210450 on July 23, 2018, for management of moderate to severe pain associated with endometriosis.

37. ORILISSA® Tablets are prescription drugs approved for the management of moderate to severe pain associated with endometriosis. Elagolix sodium is the active ingredient in the ORILISSA® Tablets.

The Asserted Patents

38. The '845 patent, titled "Methods of Administering Elagolix," was duly and legally issued by the United States Patent and Trademark Office on July 4, 2023. A true and correct copy of the '845 patent is attached as Exhibit A.

39. AbbVie owns the rights to the ’845 patent. The ’845 patent will expire on August 27, 2040.

40. The ’845 patent is listed in the FDA Orange Book in connection with NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base)) Tablets.

41. The ’854 patent, titled “Methods of Treating Heavy Menstrual Bleeding,” was duly and legally issued by the United States Patent and Trademark Office on July 4, 2023. A true and correct copy of the ’854 patent is attached as Exhibit B.

42. AbbVie owns the rights to the ’854 patent. The ’854 patent will expire on April 19, 2038.

43. The ’854 patent is listed in the FDA Orange Book in connection with NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base)) Tablets.

Sun’s ANDA No. 215804

44. On information and belief, Sun filed ANDA No. 215804 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of elagolix sodium oral tablets in eq. 150 mg base and eq. 200 mg base dosage forms, which are generic versions of Plaintiff’s ORILISSA® (elagolix sodium) Tablets.

45. ANDA No. 215804 contains Paragraph IV certifications, alleging that the claims of the ’845 and ’854 patents are invalid, unenforceable, and/or would not be infringed by Sun’s Generic Product.

46. AbbVie received a letter sent by Sun, dated December 22, 2023, purporting to be a “Notice of Certification Pursuant to Federal Food, Drug and Cosmetic Act” for ANDA No. 215804

("Sun's Third Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. Sun's Third Notice Letter notified AbbVie that Sun had filed ANDA No. 215804, seeking approval to market Sun's Generic Product prior to the expiration of the '845 and '854 patents.

47. Plaintiff commenced this action within 45 days of receiving Sun's Third Notice Letter.

48. On information and belief, following FDA approval of Sun's ANDA No. 215804, Sun will make, use, sell, or offer to sell Sun's Generic Product throughout the United States, or import such generic products into the United States before the '845 and '854 patents expire.

COUNT I
INFRINGEMENT OF THE '845 PATENT BY SUN

49. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

50. On information and belief, Sun filed Sun's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sun's Generic Product in the United States before the expiration of the '845 patent.

51. On information and belief, Sun filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '845 patent are purportedly invalid, unenforceable, and/or not infringed.

52. On information and belief, in Sun's ANDA, Sun has represented to the FDA that Sun's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiff's ORILISSA®.

53. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sun's ANDA seeking approval for the commercial manufacture, use, or sale of Sun's Generic Product before

the expiration date of the '845 patent, constitutes infringement, either literally or under the doctrine of equivalents.

54. After FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '845 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Generic Product and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of Sun's ANDA shall be no earlier than the expiration of the '845 patent and any additional periods of exclusivity.

55. On information and belief, Sun knows, or should know, and intends that healthcare providers will prescribe and patients will take Sun's Generic Product for which approval is sought in Sun's ANDA, and therefore will infringe at least one claim in the '845 patent.

56. On information and belief, Sun had knowledge of the '845 patent and, by its promotional activities and proposed package insert for Sun's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '845 patent, either literally or under the doctrine of equivalents.

57. On information and belief, Sun is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Sun's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '845 patent.

58. The offering to sell, sale, making, and/or importation of Sun's Generic Product would actively induce infringement of at least one of the claims of the '845 patent, either literally or under the doctrine of equivalents. Sun has knowledge and is aware of the '845 patent, as evidenced by Sun's Third Notice Letter.

59. On information and belief, if Sun's ANDA is approved, Sun intends to and will offer to sell, sell, and/or import in the United States Sun's Generic Product.

60. On information and belief, Sun's actions relating to Sun's ANDA complained of herein were done by and for the benefit of Sun.

61. Plaintiff will be irreparably harmed if Sun is not enjoined from infringing or actively inducing infringement of at least one claim of the '845 patent. Pursuant to 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Plaintiff does not have an adequate remedy at law.

COUNT II
INFRINGEMENT OF THE '854 PATENT BY SUN

62. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

63. On information and belief, Sun filed Sun's ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Sun's Generic Product in the United States before the expiration of the '854 patent.

64. On information and belief, Sun filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '854 patent are purportedly invalid, unenforceable, and/or not infringed.

65. On information and belief, in Sun's ANDA, Sun has represented to the FDA that Sun's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiff's ORILISSA®.

66. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Sun's ANDA seeking approval for the commercial manufacture, use, or sale of Sun's Generic Product before

the expiration date of the '854 patent, constitutes infringement, either literally or under the doctrine of equivalents.

67. After FDA approval of Sun's ANDA, Sun will infringe one or more claims of the '845 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Sun's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Sun's ANDA shall be no earlier than the expiration of the '854 patent and any additional periods of exclusivity.

68. On information and belief, Sun knows, or should know, and intends that healthcare providers will prescribe and patients will take Sun's Generic Product for which approval is sought in Sun's ANDA, and therefore will infringe at least one claim in the '854 patent.

69. On information and belief, Sun had knowledge of the '854 patent and, by its promotional activities and proposed package insert for Sun's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '854 patent, either literally or under the doctrine of equivalents.

70. On information and belief, Sun is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Sun's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '854 patent.

71. The offering to sell, sale, making, and/or importation of Sun's Generic Product would actively induce infringement of at least one of the claims of the '854 patent, either literally or under the doctrine of equivalents. Sun has knowledge and is aware of the '854 patent, as evidenced by Sun's Third Notice Letter.

72. On information and belief, if Sun's ANDA is approved, Sun intends to and will offer to sell, sell, and/or import in the United States Sun's Generic Product.

73. Sun has had and continues to have knowledge that Sun's Generic Product is especially adapted for a use that infringes the '854 patent.

74. On information and belief, Sun has had and continues to have knowledge that there is no substantial non-infringing use for Sun's Generic Product.

75. On information and belief, Sun's actions relating to Sun's ANDA complained of herein were done by and for the benefit of Sun.

76. Plaintiff will be irreparably harmed if Sun is not enjoined from infringing or actively inducing infringement of at least one claim of the '854 patent. Pursuant to 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Plaintiff does not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Sun has infringed at least one claim of the '845 and '854 patents through Sun's submission of ANDA No. 215804 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Sun's Generic Product in the United States before the expiration of the '845 and '854 patents;

B. The entry of judgment that Sun's making, using, offering to sell, selling, or importing Sun's Generic Product prior to the expiration of the '845 and '854 patents will infringe, actively induce infringement, and/or contribute to the infringement of the '845 and '854 patents under 35 U.S.C. § 271(a), (b), and/or (c);

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

D. The issuance of an order that the effective date of any FDA approval of Sun's Generic Product shall be no earlier than the expiration date of the '845 and '854 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

E. The entry of a permanent injunction, enjoining Sun and all persons acting in concert with Sun from commercially manufacturing, using, offering for sale, or selling Sun's Generic Product within the United States, or importing Sun's Generic Product into the United States, until the expiration of the '845 and '854 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The entry of a permanent injunction, enjoining Sun and all persons acting in concert with Sun from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the '845 and '854 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

G. The issuance of a declaration that this is an exceptional case and an award to Plaintiff of its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

H. An award to Plaintiff of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

I. An award to Plaintiff of any further and additional relief that this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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