IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WYETH LLC, PFIZER PHARMACEUTICALS LLC, PF PRISM C.V. and PFIZER MANUFACTURING HOLDINGS LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MYLAN INC., MYLAN N.V., MYLAN LABORATORIES LTD. and MYLAN PHARMACEUTICALS INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc., Wyeth LLC, Pfizer Pharmaceuticals LLC, PF PRISM C.V., and Pfizer Manufacturing Holdings LLC, (collectively "Pfizer"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendants Mylan Inc. ("Mylan"), Mylan N.V. ("MNV"), Mylan Laboratories Ltd. ("MLL"), and Mylan Pharmaceuticals Inc. ("MPI") (collectively "Defendants") of New Drug Application ("NDA") No. 208461 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Pfizer's TYGACIL® tigecycline injectable IV infusion, ("TYGACIL®") prior to the expiration of U.S. Patent No. 7,879,828 ("the '828 patent"), U.S. Patent No. 8,372,995 ("the '995 patent"), and U.S. Patent No. 8,975,242 ("the '242 patent").

PARTIES

2. 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.

3. Plaintiff Wyeth 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. Wyeth LLC's sole member is Pfizer Inc.

4. Plaintiff Pfizer Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware and having a place of business at Bo. Carmelitas, Road 689, Km 1.9, Vega Baja, Puerto Rico 00693. Pfizer Pharmaceuticals LLC is a wholly-owned subsidiary of PF PRISM C.V.

5. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456 and that for all purposes is represented by and acting through its general partner Pfizer Manufacturing Holdings LLC, a limited liability company organized under the laws of the State of Delaware, and having its address at 235 East 42nd Street, New York, New York 10017, registered in the register held by the Secretary of State of the State of Delaware under number 4869755. PF PRISM C.V. is the holder of NDA No. 21821, which has been approved by the FDA.

6. Plaintiff Pfizer Manufacturing Holdings 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. Pfizer Manufacturing Holdings LLC is a general partner of PF PRISM C.V.

7. Upon information and belief, defendant Mylan is a corporation organized and existing under the laws of the State of Pennsylvania, having a place of business at Robert J. Coury Global Center, 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Mylan is a wholly-owned subsidiary and is controlled by MNV.

8. Upon information and belief, defendant MNV is a corporation organized and existing under the laws of the Netherlands, having a place of business at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. Upon information and belief, MNV is the corporate successor to Mylan, and MNV's management and operations occur at Mylan's headquarters at Robert J. Coury Global Center, 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

9. Upon information and belief, defendant MLL is a corporation organized and existing under the laws of India, with a place of business at Strides House, Opp. to IIM, Bilekalli, Bannerghatta Road, Bangalore – 560 076, Karnataka, India. MLL is a wholly-owned subsidiary of and is controlled by Mylan.

10. Upon information and belief, defendant MPI is a corporation organized and existing under the laws of the State of West Virginia, with a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. MPI is a wholly-owned subsidiary of and is controlled by Mylan.

11. Upon information and belief, MLL's preparation and submission of NDA No. 208461 was done at the direction, under the control, and for the direct benefit of Mylan,

MNV, and/or MPI. Upon information and belief, Mylan, MNV and/or MPI directed MLL to submit NDA No. 208461.

12. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of NDA No. 208461, Defendants will act in concert to distribute and sell the generic product described in NDA No. 208461 throughout the United States and within Delaware.

JURISDICTION AND VENUE

13. Jurisdiction and venue are proper in this District pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, 1400(b), and 2201.

14. Defendants are subject to personal jurisdiction in Delaware because, among other things, they regularly transact and/or solicit business in Delaware and have purposefully availed themselves of this forum such that they should reasonably anticipate being haled into court here.

15. Upon information and belief, Defendants together are in the business of manufacturing drug products, which Defendants manufacture, distribute, sell, or offer to sell throughout the United States, including in Delaware; they derive substantial revenue from services or things used or consumed in Delaware; as part of their ordinary business practice of engaging in U.S. patent litigation, they have regularly and routinely litigated NDA and abbreviated new drug application ("ANDA") cases without contesting jurisdiction in this judicial district; they have, directly or through an agent, filed an NDA, and/or been actively involved in the preparation and submission of an NDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in NDA No. 208461 in the United States, including in Delaware; upon receiving FDA approval, they intend to offer to sell and sell the generic product described in NDA No. 208461

in the United States, including in Delaware, and thereby cause Pfizer to lose sales in Delaware; and by offering to sell or selling the generic product described in NDA No. 208461, Defendants would infringe a patent or patents owned by Pfizer, a Delaware corporation, and therefore would harm Pfizer in Delaware.

16. Upon information and belief, Mylan, MNV, MLL, and/or MPI regularly do business in Delaware and have engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware. Mylan, MNV, MLL, and MPI have done so with each other's authorization, participation, or assistance, or acting in concert with each other.

17. Upon information and belief, MNV was incorporated on July 7, 2014, and acquired Mylan on February 27, 2015. Upon information and belief, after MNV acquired Mylan, MNV issued MNV shares in the place of Mylan stock to Mylan shareholders, adopted Mylan's stock ticker symbol, and became Mylan's parent company. For example, a Mylan Annual Report dated March 2, 2015, published on MNV's website, describes the transaction in part as follows: "Mylan merged with a wholly owned subsidiary of [MNV] . . . , with Mylan becoming a wholly owned indirect subsidiary of [MNV]," and "Mylan's outstanding common stock was exchanged on a one to one basis for [MNV] ordinary shares." Furthermore, according to MNV's website, for the purposes of public filings MNV is the "successor registrant to Mylan Inc. as of February 27, 2015." Upon information and belief, upon MNV's incorporation, Mylan's officers and directors also became the officers and directors of MNV, and MNV's management and operations continue to be run from Mylan's headquarters. For example, a Wall Street Journal article published July 14, 2014, titled "Abbott, Mylan Join Forces to Dodge U.S.

Taxes" explains that "Mylan N.V. will be led by Mylan's existing management and will continue to be headquartered in Pittsburgh." Furthermore, the above-described March 2 Mylan Annual Report was signed on Mylan's behalf by Heather Bresch as Chief Executive Officer and Director and John D. Sheehan as Executive Vice President and Chief Financial Officer, and a MNV Quarterly Report dated August 6, 2015, also published on MNV's website, was signed on MNV's behalf by the same two individuals holding the same positions in MNV as they do in Mylan. The same August 6 Quarterly Report states that MNV's "global headquarters are located in Canonsburg, Pennsylvania." And, furthermore, a Wall Street Journal company profile as of October 21, 2015, listed 14 individuals as MNV's "Current Board Membership" and listed the same 14 individuals as Mylan's "Current Board Membership." Upon information and belief, the control and direction exercised by Mylan over the Defendants prior to MNV's incorporation on February 27, 2015, has been exercised by MNV since that date.

18. According to MNV's website (www.mylan.com), MNV is "one of the largest generics and specialty pharmaceutical companies in the world," and MNV applies "one global quality standard across [its] facilities and across [its] product line . . . regardless of the market." Upon information and belief, MNV applies its single global quality standard to Mylan, MLL, and MPI.

19. Upon information and belief, Mylan, MNV, MLL, and MPI operate as an integrated, unitary generic pharmaceutical business. For example, Mylan includes in its Annual Reports, published on MNV's website, the activities of MLL and MPI, including the revenue earned and other financial information, and lists MLL and MPI as subsidiaries. Furthermore, MNV included in its August 6 Quarterly Report, published on MNV's website, the activities of Mylan, MLL, and MPI, including the revenue earned and other financial information, and states

that MNV "operate[s] a global vertically-integrated manufacturing platform" that includes Mylan, MLL, and MPI. MNV's website provides information about Mylan, MNV, MLL, and MPI, such as stating that MNV's "global manufacturing platform" includes locations in India, where MLL is incorporated, and Morgantown, West Virginia, where MPI is located. Mylan, MLL, and MPI do not maintain separate websites. Mylan and MNV are divided into a number of business units, including the "Generics" segment. Upon information and belief, MLL and MPI in whole or in part comprise this "Generics" segment.

20. Upon information and belief, Mylan, MNV, MLL, and MPI have overlapping officers and directors, with management and operation of Mylan, MNV, MLL, MPI, and the Generics segment occurring, at least in part, at the respective headquarters of Mylan, MNV, MLL, and/or MPI. For example, in an "Earnings Conference Call" on October 26, 2011, the then-Chief Executive Officer of Mylan, Robert Coury, publicly stated that "Tony Mauro will be promoted to the President of [Mylan] North America while also retaining his current role as President of Mylan Pharmaceuticals," and this arrangement constituted part of the "leadership structure" of Mylan. A Mylan press release on February 24, 2012, confirmed that Tony Mauro is "president of Mylan North America and the company's Mylan Pharmaceuticals subsidiary." Furthermore, the above-described Wall Street Journal company profile as of October 21, 2015, states that Mylan and MNV share 14 individuals as part of their "Current Board Membership." Upon information and belief, MNV has adopted Mylan's management and leadership structure.

21. Upon information and belief, MNV issues press releases for Mylan, MLL, and MPI, and Mylan issues press releases for MLL and MPI, when generic drugs are approved by the FDA, when other events concerning the commercialization of a generic drug occur, and when they and their subsidiaries—including MLL and MPI—are involved in litigation in connection

with filing NDAs and ANDAs. For example, MNV issued a press release on April 13, 2015, "announc[ing] that its subsidiaries Mylan Inc. and Mylan Pharmaceuticals Inc." had settled patent litigation and that, as a result, would "be able to launch [their] ANDA products." Furthermore, when Mylan and MPI together were sued with regard to an ANDA for a generic version of NEXAVAR®, Mylan issued a press release dated February 9, 2015, "confirm[ing] that it and its subsidiary" MPI had been sued and, although MPI was the entity that filed the ANDA, stating that "Mylan believes it is the first company to have filed a substantially complete ANDA." Furthermore, Mylan issued a press release dated December 4, 2014, when MLL received tentative approval for two NDAs, which Mylan stated would make Mylan's products "eligible for purchase."

22. Upon information and belief, when the FDA inspects and issues warning letters regarding MLL and MPI manufacturing facilities, the FDA sends the warning letters to Mylan and/or MNV. For example, the FDA sent a letter dated August 6, 2015, to Mylan and MNV President Rajiv Malik to notify him of regulatory violations it found when it inspected an MLL facility in Bangalore, India. And, upon information and belief, when MLL produces defective drugs that must be recalled, Mylan, MNV, and/or MPI notify consumers of the recall and consumers are directed to contact Mylan Customer Service with concerns. For example, on July 7, 2014, MPI initiated a recall of "Metoprolol Succinate Extended-release Tables, USP 50mg manufactured by Mylan Laboratories Limited."

23. Upon information and belief, Mylan recently acquired MLL, and Mylan and MNV have since represented to the public that MLL, Mylan, and MNV now operate as a single entity. For example, a Mylan Annual Report dated March 2, 2015, published on MNV's website, states that Mylan previously "acquire[d]" Mylan Laboratories Limited, that Mylan's

active pharmaceutical ingredient ("API") "business is conducted through Mylan Laboratories Limited," and that Mylan includes MLL in its "Rest of World" category and classifies MLL as part of its "Generics segment." A Mylan Annual Report issued on February 28, 2013, published on MNV's website, states that MLL is "Mylan's Indian subsidiary," goes on to describe MLL revenues as part of its "Generics Segment," and reports short-term borrowings by MLL. Furthermore, in the above-described MNV August 6 Quarterly Report, published on MNV's website, MNV states that it operates "one of the world's largest [API] operations" and that "[o]ur API business is conducted through Mylan Laboratories Limited ('Mylan India'), which is included within Rest of World in our Generics segment." Furthermore, in the March 2 Annual Report, Mylan explains that it was found by the European Commission jointly and severally liable with MLL for antitrust violations related to Mylan's PERINDOPRIL® drug product, but that Mylan alone paid the judgment of "approximately $21.7 million" and is appealing the decision. In the above-described August 6 Quarterly Report, MNV adopts Mylan's statement and indicates that "[MNV] paid approximately $21.7 million."

24. Upon information and belief, Mylan has publicly represented that it operates as a single entity with MLL because it exercises control over, and has acted to merge other subsidiaries into, MLL, and Mylan represents that by merging those subsidiaries into MLL they are now integrated into Mylan. In its Annual Reports, published on MNV's website, Mylan explains that it recently acquired two "wholly owned subsidiaries, Agila Specialties Private Limited and Onco Therapies Limited," and "receiv[ed] approvals in 2014 from the relevant Indian regulatory authorities to legally merge [them] into Mylan Laboratories Limited." Mylan further explains in its Annual Reports that the "Agila Acquisition involves the integration of Agila with our existing businesses" and that Mylan will "devote significant management attention and resources to integrating Agila," and that integrating Agila will "combin[e] corporate cultures." Mylan's CEO

publicly commented that the acquisition involved "taking the Agila pipeline, assets, capacity, [and] marrying that up with [Mylan's] infrastructure." A recent press release on February 3, 2014, states the number of ANDAs that Mylan has pending FDA approval, and included in that number "ANDAs associated with Mylan's recent acquisition of Agila." Mylan's President publicly stated that the "acquisition of Agila transforms Mylan into a global powerhouse," and that "the combination strengthens Mylan's existing platform in developed markets, such as the U.S., where Mylan can now offer customers an even more comprehensive portfolio of high quality products." Mylan's Executive Chairman publicly "welcome[d] Agila's employees to Mylan," and noted that they would "be able to integrate our businesses seamlessly and efficiently." Upon information and belief, the above-referenced Mylan businesses into which Agila is being and/or has been integrated include MLL and MPI. Upon information and belief, because MNV is Mylan's corporate successor and corporate parent as of February 27, 2015, since that date MNV has exercised and continues to exercise the same degree of control over MLL as Mylan.

25. Upon information and belief, Defendants conduct business throughout the United States, including Delaware, under the trade name "Mylan Pharmaceuticals."

26. Upon information and belief, MPI, under its "Mylan Pharmaceuticals" trade name, has a registered agent in Delaware (Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808) and is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer CSR" and "Pharmacy - Wholesale" pursuant to 24 Del. C. § 2540.

27. By offering to sell or selling the generic product described in NDA No. 208461, Defendants would infringe a patent or patents owned by Pfizer, a Delaware corporation.

28. By letter dated September 11, 2015, Defendants notified Pfizer pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") that MLL had filed NDA No. 208461 (the

"Notice Letter"). By sending their Notice Letter to Pfizer, a Delaware corporation, Defendants purposefully directed their activities at Pfizer in Delaware and therefore the consequences of their activities are suffered by Pfizer in Delaware.

29. Upon information and belief, Defendants have availed themselves of the legal protections of the state of Delaware by bringing civil actions in this Court. *See, e.g., Mylan Pharms. Inc. and Mylan Inc. v. Eurand, Inc., et al.,* C.A. No. 10-306 (D. Del.); *Mylan Pharms. Inc. v. Ethypharm S.A., et al.*, C.A. No. 10-1064 (D. Del.).

30. Upon information and belief, Defendants have availed themselves of the legal protections of the state of Delaware by filing counterclaims affirmatively seeking relief in other prior actions in this Court. *See, e.g., Millenium Pharms. Inc. v. Mylan Labs. Ltd. and Agila Specialties Inc.*, C.A. No. 15-40 (D. Del.); *AbbVie Inc. v. Mylan Pharms. Inc. and Mylan Labs. Ltd.*, C.A. No. 14-1236 (D. Del.); *Cubist Pharms. LLC v. Agila Specialties Inc. and Mylan Labs. Ltd.*, C.A. No. 13-1679 (D. Del.); *Forest Labs., Inc., et al. v. Mylan Inc. and Mylan Pharms. Inc.*, C.A. No. 13-1605 (D. Del.); *Alcon Research Ltd. v. Mylan Pharms. Inc. and Mylan Inc.*, C.A. No. 13-1332 (D. Del.); *UCB Inc. et al. v. Mylan Pharms. Inc. and Mylan Inc.*, C.A. No. 13-1214 (D. Del.); *AbbVie Inc., et al. v. Mylan Pharms. Inc. and Mylan Labs. Ltd.*, C.A. No. 13-1072 (D. Del.); *Santarus, Inc., et al. v. Mylan Inc. and Mylan Pharms. Inc.*, C.A. No. 13-145 (D. Del.); *ViiV Healthcare Co., et al. v. Mylan Inc. and Mylan Pharms. Inc.*, C.A. No. 12-1065 (D. Del.).

BACKGROUND

31. TYGACIL® is a tetracycline class antibacterial indicated for the treatment of complicated skin and skin structure infections, complicated intra-abdominal infections, and community-acquired bacterial pneumonia, in adults. Each TYGACIL® vial contains 50 mg

tigecycline lyophilized powder for reconstitution for intravenous infusion and 100 mg of lactose monohydrate.

32. The ’828 patent, entitled “Tigecycline Compositions and Methods of Preparation” (Exhibit A hereto), was duly and legally issued on February 1, 2011 to Wyeth LLC, as assignee, and subject to the exclusive license referenced herein. TYGACIL® and the use thereof are covered by one or more claims of the ’828 patent, which has been listed in connection with TYGACIL® in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the “Orange Book.”

33. The ’995 patent, entitled “Crystalline Solid Forms of Tigecycline and Methods of Preparing Same” (Exhibit B hereto), was duly and legally issued on February 12, 2013 to Wyeth LLC, as assignee, and subject to the exclusive license referenced herein. TYGACIL® and the use thereof are covered by one or more claims of the ’995 patent, which has been listed in connection with TYGACIL® in the Orange Book.

34. The ’242 patent, entitled “Tigecycline Compositions and Methods of Preparation” (Exhibit C hereto), was duly and legally issued on March 10, 2015 to Wyeth LLC, as assignee, and subject to the exclusive license referenced herein. TYGACIL® and the use thereof are covered by one or more claims of the ’242 patent, which has been listed in connection with TYGACIL® in the Orange Book.

35. In 2011, PF PRISM C.V. took an exclusive license to the ’828 patent, patent application no. 11/440,032 (which later issued as the ’995 patent), and all continuations of existing patents and patent applications relating to TYGACIL® (which includes the ’242 patent). Thereafter, PF PRISM C.V. contributed its rights under the exclusive license to Pfizer Pharmaceuticals LLC.

36. Pfizer has all right, title, and interest in the '828 patent, the '995 patent, and the '242 patent, including the right to sue for infringement thereof.

37. Defendants notified Pfizer in the Notice Letter that Defendants had submitted to the FDA NDA No. 208461 for a tigecycline injectable product for IV infusion containing 50 mg tigecycline ("Defendants' NDA Product"). Defendants' NDA Product is a drug product that is a generic version of TYGACIL®.

38. The purpose of Defendants' submission of NDA No. 208461 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' NDA Product prior to the expiration of the '828 patent, the '995 patent, and the '242 patent.

39. In the Notice Letter, Defendants also notified Pfizer that, as part of their NDA No. 208461, Defendants had filed certifications of the type described in Section 505(b)(2)(A)(iv) of the FDCA, with respect to the '828 patent, the '995 patent, and the '242 patent. Upon information and belief, Defendants submitted NDA No. 208461 to the FDA containing a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) asserting that the '828 patent, the '995 patent, and the '242 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Defendants' NDA Product, or alternatively, that these patents are invalid.

40. In an exchange of correspondence, counsel for Defendants and counsel for Pfizer discussed the terms of Pfizer's Request for Confidential Access. The parties were unable to agree on terms under which Pfizer could review Defendants' NDA and certain portions of the Drug Master File referred to therein, and Defendants refused to produce other internal documents and data relevant to infringement.

41. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 7,879,828 UNDER 35 U.S.C. § 271(e)(2)

42. Pfizer incorporates each of the preceding paragraphs 1–41 as if fully set forth herein.

43. Defendants' submission of NDA No. 208461 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' NDA Product prior to the expiration of the '828 patent was an act of infringement of the '828 patent under 35 U.S.C. § 271(e)(2)(A).

44. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' NDA Product would infringe one or more claims of the '828 patent, either literally or under the doctrine of equivalents.

45. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' NDA Product with its proposed labeling upon approval of NDA No. 208461.

46. Upon information and belief, the use of Defendants' NDA Product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '828 patent.

47. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '828 patent when NDA No. 208461 is approved, and plan and intend to, and will, do so after approval.

48. Upon information and belief, Defendants know that their NDA Product and its proposed labeling are especially made or adapted for use in infringing the '828 patent, and that

their NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the ’828 patent after approval of NDA No. 208461.

49. Upon information and belief, after approval of NDA No. 208461, Defendants will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the ’828 patent prior to the expiration of the patent.

50. The foregoing actions by Defendants constitute and/or will constitute infringement of the ’828 patent, active inducement of infringement of the ’828 patent, and contribution to the infringement by others of the ’828 patent.

51. Upon information and belief, Defendants have acted with full knowledge of the ’828 patent and without a reasonable basis for believing that they would not be liable for infringing the ’828 patent, actively inducing infringement of the ’828 patent, and contributing to the infringement by others of the ’828 patent.

52. Unless Defendants are enjoined from infringing the ’828 patent, actively inducing infringement of the ’828 patent, and contributing to the infringement by others of the ’828 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 8,372,995 UNDER 35 U.S.C. § 271(e)(2)

53. Pfizer incorporates each of the preceding paragraphs 1–52 as if fully set forth herein.

54. Defendants’ submission of NDA No. 208461 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Defendants' NDA Product prior to the expiration of the '995 patent was an act of infringement of the '995 patent under 35 U.S.C. § 271(e)(2)(A).

55. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' NDA Product would infringe one or more claims of the '995 patent, either literally or under the doctrine of equivalents.

56. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' NDA Product with its proposed labeling upon approval of NDA No. 208461.

57. Upon information and belief, the use of Defendants' NDA Product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '995 patent.

58. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '995 patent when NDA No. 208461 is approved, and plan and intend to, and will, do so after approval.

59. Upon information and belief, Defendants know that their NDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, and that their NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '995 patent after approval of NDA No. 208461.

60. Upon information and belief, after approval of NDA No. 208461, Defendants will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '995 patent prior to the expiration of the patent.

61. The foregoing actions by Defendants constitute and/or will constitute infringement of the ’995 patent, active inducement of infringement of the ’995 patent, and contribution to the infringement by others of the ’995 patent.

62. Upon information and belief, Defendants have acted with full knowledge of the ’995 patent and without a reasonable basis for believing that it would not be liable for infringing the ’995 patent, actively inducing infringement of the ’995 patent, and contributing to the infringement by others of the ’995 patent.

63. Unless Defendants are enjoined from infringing the ’995 patent, actively inducing infringement of the ’995 patent, and contributing to the infringement by others of the ’995 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 8,975,242 UNDER 35 U.S.C. § 271(e)(2)

64. Pfizer incorporates each of the preceding paragraphs 1–63 as if fully set forth herein.

65. Defendants’ submission of NDA No. 208461 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ NDA Product prior to the expiration of the ’242 patent was an act of infringement of the ’242 patent under 35 U.S.C. § 271(e)(2)(A).

66. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product would infringe one or more claims of the ’242 patent, either literally or under the doctrine of equivalents.

67. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product with its proposed labeling upon approval of NDA No. 208461.

68. Upon information and belief, the use of Defendants' NDA Product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '242 patent.

69. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '242 patent when NDA No. 208461 is approved, and plan and intend to, and will, do so after approval.

70. Upon information and belief, Defendants know that their NDA Product and its proposed labeling are especially made or adapted for use in infringing the '242 patent, and that their NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '242 patent after approval of NDA No. 208461.

71. Upon information and belief, after approval of NDA No. 208461, Defendants will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '242 patent prior to the expiration of the patent.

72. The foregoing actions by Defendants constitute and/or will constitute infringement of the '242 patent, active inducement of infringement of the '242 patent, and contribution to the infringement by others of the '242 patent.

73. Upon information and belief, Defendants have acted with full knowledge of the '242 patent and without a reasonable basis for believing that they would not be liable for infringing the '242 patent, actively inducing infringement of the '242 patent, and contributing to the infringement by others of the '242 patent.

74. Unless Defendants are enjoined from infringing the ’242 patent, actively inducing infringement of the ’242 patent, and contributing to the infringement by others of the ’242 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,879,828

75. Pfizer incorporates each of the preceding paragraphs 1–74 as if fully set forth herein.

76. Defendants have knowledge of the ’828 patent.

77. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product would infringe one or more claims of the ’828 patent, either literally or under the doctrine of equivalents.

78. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product with its proposed labeling after approval of NDA No. 208461.

79. Upon information and belief, the use of Defendants’ NDA Product in accordance with and as directed by Defendants’ proposed labeling for that product would infringe one or more claims of the ’828 patent.

80. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’828 patent when NDA No. 208461 is approved, and plan and intend to, and will, do so after approval.

81. Upon information and belief, Defendants know that their NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’828 patent, and that their NDA Product and its proposed labeling are not suitable for substantial noninfringing use.

Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the ’828 patent after approval of NDA No. 208461.

82. Upon information and belief, after approval of NDA No. 208461, Defendants will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the ’828 patent prior to the expiration of the patent.

83. The foregoing actions by Defendants constitute and/or will constitute infringement of the ’828 patent, active inducement of infringement of the ’828 patent, and contribution to the infringement by others of the ’828 patent.

84. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringing the ’828 patent, actively inducing infringement of the ’828 patent, and contributing to the infringement by others of the ’828 patent.

85. Unless Defendants are enjoined from infringing the ’828 patent, actively inducing infringement of the ’828 patent, and contributing to the infringement by others of the ’828 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT V – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,372,995

86. Pfizer incorporates each of the preceding paragraphs 1–85 as if fully set forth herein.

87. Defendants have knowledge of the ’995 patent.

88. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product would infringe one or more claims of the ’995 patent, either literally or under the doctrine of equivalents.

89. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' NDA Product with its proposed labeling after approval of NDA No. 208461.

90. Upon information and belief, the use of Defendants' NDA Product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '995 patent.

91. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '995 patent when NDA No. 208461 is approved, and plan and intend to, and will, do so after approval.

92. Upon information and belief, Defendants know that their NDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, and that their NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '995 patent after approval of NDA No. 208461.

93. Upon information and belief, after approval of NDA No. 208461, Defendants will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '995 patent prior to the expiration of the patent.

94. The foregoing actions by Defendants constitute and/or will constitute infringement of the '995 patent, active inducement of infringement of the '995 patent, and contribution to the infringement by others of the '995 patent.

95. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringing the ’995 patent, actively inducing infringement of the ’995 patent, and contributing to the infringement by others of the ’995 patent.

96. Unless Defendants are enjoined from infringing the ’995 patent, actively inducing infringement of the ’995 patent, and contributing to the infringement by others of the ’995 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,975,242

97. Pfizer incorporates each of the preceding paragraphs 1–96 as if fully set forth herein.

98. Defendants have knowledge of the ’242 patent.

99. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product would infringe one or more claims of the ’242 patent, either literally or under the doctrine of equivalents.

100. Upon information and belief, Defendants will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ NDA Product with its proposed labeling after approval of NDA No. 208461.

101. Upon information and belief, the use of Defendants’ NDA Product in accordance with and as directed by Defendants’ proposed labeling for that product would infringe one or more claims of the ’242 patent.

102. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’242 patent when NDA No. 208461 is approved, and plan and intend to, and will, do so after approval.

103. Upon information and belief, Defendants know that their NDA Product and its proposed labeling are especially made or adapted for use in infringing the ’242 patent, and that their NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the ’242 patent after approval of NDA No. 208461.

104. Upon information and belief, after approval of NDA No. 208461, Defendants will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the ’242 patent prior to the expiration of the patent.

105. The foregoing actions by Defendants constitute and/or will constitute infringement of the ’242 patent, active inducement of infringement of the ’242 patent, and contribution to the infringement by others of the ’242 patent.

106. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringing the ’242 patent, actively inducing infringement of the ’242 patent, and contributing to the infringement by others of the ’242 patent.

107. Unless Defendants are enjoined from infringing the ’242 patent, actively inducing infringement of the ’242 patent, and contributing to the infringement by others of the ’242 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that Defendants have infringed the ’828 patent, the ’995 patent, and the ’242 patent;

(b) A judgment ordering that the effective date of any FDA approval for Defendants to make, use, offer for sale, sell, market, distribute, or import Defendants’ NDA

Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the ’828 patent, the ’995 patent, or the ’242 patent be not earlier than the expiration date of the ’828 patent, the ’995 patent, or the ’242 patent respectively, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Defendants, their officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Defendants’ NDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the ’828 patent, the ’995 patent, or the ’242 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’828 patent, the ’995 patent, or the ’242 patent, respectively, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Defendants’ NDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the ’828 patent, the ’995 patent, or the ’242 patent prior to the expiration date of the ’828 patent, the ’995 patent, or the ’242 patent respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the ’828 patent, the ’995 patent, or the ’242 patent;

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

(f) An award of Pfizer’s costs and expenses in this action; and

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

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