IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| JAVELIN PHARMACEUTICALS, INC., HOSPIRA, INC., and JANSSEN PHARMACEUTICA N.V., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| MYLAN LABORATORIES LIMITED, MYLAN INC., and MYLAN PHARMACEUTICALS INC., | ) | |
| Defendants. | ) | |

**COMPLAINT**

Plaintiffs Javelin Pharmaceuticals, Inc. and Hospira, Inc. (collectively, "Javelin Plaintiffs") and Janssen Pharmaceutica N.V. (together with the Javelin Plaintiffs, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Mylan Laboratories Limited, Mylan Inc., and Mylan Pharmaceuticals Inc. (collectively, "Mylan" or "Defendants") herein allege:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from Mylan's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA"), seeking approval to market a generic copy of Javelin Plaintiffs' pharmaceutical product, Dyloject®, prior to the expiration of United States Patent Nos. 6,407,079 ("the '079 patent") and 8,946,292 ("the '292 patent"), which cover, *inter alia*, Dyloject® and/or its use.

**THE PARTIES**

2. Plaintiff Javelin Pharmaceuticals, Inc. ("Javelin") is a corporation organized and existing under the laws of Delaware with its principal place of business at 275 North Field Drive, Lake Forest, IL 60045. Javelin is a wholly-owned subsidiary of Hospira, Inc.

3. Plaintiff Hospira, Inc. ("Hospira") is a corporation organized and existing under the laws of Delaware with is principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

4. Plaintiff Janssen Pharmaceutica N.V. ("Janssen") is a corporation organized and existing under the laws of Belgium with its principal place of business at Turnhoutseweg 30, B-2340, Beerse, Belgium.

5. Upon information and belief, defendant Mylan Laboratories Limited ("Mylan Labs") is a company organized and existing under the laws of India, with a place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad – 500034, India. Upon information and belief, Mylan Labs is a wholly-owned subsidiary of and is controlled by Mylan Inc. and is an agent or affiliate of Mylan Pharmaceuticals Inc.

6. Upon information and belief, defendant Mylan Inc. is a company organized and existing under the laws of the Commonwealth of Pennsylvania with its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Upon information and belief, Mylan Inc. is in the business of, among other things, marketing and selling generic copies of branded pharmaceutical products for the United States market, alone and/or through its wholly-owned subsidiaries and agents.

7. Upon information and belief, defendant Mylan Pharmaceuticals Inc. ("Mylan Pharms") is a company organized and existing under the laws of the State of West

Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505-4310. Upon information and belief, Mylan Pharms is in the business of manufacturing and selling generic copies of pharmaceutical products for the United States market. Upon information and belief, Mylan Pharms is a wholly-owned subsidiary of and is controlled by Mylan Inc. and is an agent or affiliate of Mylan Labs.

## THE PATENTS-IN-SUIT

8. On June 18, 2002, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '079 patent, entitled "Pharmaceutical Compositions Containing Drugs Which Are Instable or Sparingly Soluble in Water and Methods for Their Preparation." On October 16, 2014, the USPTO issued an ex parte reexamination certificate for the '079 patent. A copy of the '079 patent, along with the ex parte reexamination certificate, is attached to this Complaint as **Exhibit A**.

9. Janssen is the lawful owner of and holds right, title, and interest in the '079 patent, including, along with Javelin as the exclusive licensee in this field-of-use, the right to sue and to recover for infringement thereof.

10. Javelin holds an exclusive license to the '079 patent within a particular field of use, and is specifically licensed to make, have made, use and sell intramuscular and intravenous injectable formulations of pharmaceutical products containing a hydroxypropyl derivative of beta-cyclodextrin, with diclofenac sodium as the active ingredient (the "Javelin License"). Javelin is a wholly-owned subsidiary of Hospira. Pursuant to the Javelin License, Hospira distributes and sells Dyloject® in the United States.

11. On February 3, 2015, the USPTO duly and legally issued the '292 patent, entitled "Formulations of Low Dose Diclofenac and Beta-Cyclodextrin." At the time of its issue,

the ’292 patent was assigned to Javelin, which also currently holds title to the ’292 patent. A copy of the ’292 patent is attached to this Complaint as **Exhibit B**.

12. Javelin is the lawful owner of all right, title, and interest in the ’292 patent, including the right to sue and to recover for infringement thereof.

**DYLOJECT®**

13. Javelin holds approved New Drug Application No. 022396 (the “Dyloject® NDA”) for an injectable diclofenac sodium product, in a 37.5 mg dose, injected with 1 mL of liquid, which the Javelin Plaintiffs sell under the trade name Dyloject®.

14. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ’079 and ’292 patents are listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to Dyloject®.

**MYLAN’S ANDA**

15. Upon information and belief, Mylan has submitted ANDA No. 20-8786 (“Mylan’s ANDA”) to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a generic injectable diclofenac sodium product, in a 37.5 mg dose, injected with 1 mL of liquid (“Mylan’s Product”), which is based on Javelin’s Dyloject® product, before the expiration of the ’079 and ’292 patents.

16. Mylan Labs is the holder of Mylan’s ANDA.

17. Upon information and belief, Mylan Inc., Mylan Pharms, and Mylan Labs collaborated in the development of Mylan’s Product and preparation and filing of Mylan’s ANDA.

18. Upon information and belief, Mylan's ANDA refers to and relies upon the Dyloject® NDA and contains data that, according to Mylan, demonstrates the equivalence of Mylan's Product and Dyloject®.

19. By letter to Javelin (c/o Hospira) and Janssen, dated February 22, 2016, Mylan stated that Mylan's ANDA contained certifications, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '079 and '292 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation of Mylan's Product (the "Paragraph IV Certifications"). Mylan attached a memorandum to its February 22, 2016 letter, in which it purported to allege the factual and legal bases for its Paragraph IV Certifications (the "Paragraph IV Notice Letter"). Mylan did not dispute infringement of claims 1-5, 12-16, 18-19, 23, and 26-28 of the '079 patent.

20. Upon information and belief, if the FDA approves Mylan's ANDA, Mylan Labs, Mylan Inc., and Mylan Pharms plan to and will act in concert to manufacture, distribute, import, offer for sale and/or sell Mylan's Product throughout the United States, including within the State of Delaware.

## JURISDICTION AND VENUE

21. This is a civil action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271 and 21 U.S.C. § 355.

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

23. Upon information and belief, Mylan operates as a single, integrated generic pharmaceutical manufacturer. The Mylan website, for example, describes its "Global Manufacturing" as including facilities in "Morgantown, West Virginia" (the location of Mylan

Pharms) and "Hyderabad" India (the location of Mylan Labs). *See* MYLAN, *Company*, available at http://www.mylan.com/en/company. Mylan's website, as a further example, includes contact information and addresses for Mylan Labs and Mylan Inc. *See, e.g.*, MYLAN, *Contact Us*, available at http://www.mylan.in/en/company/contact-us. Furthermore, the FDA issues warning letters to Mylan Inc. for problems arising at Mylan Labs' manufacturing facilities. *See, e.g.*, Letter from Thomas J. Cosgrove, FDA to Mr. Rajiv Malik, President of Mylan Inc. (Aug. 6, 2015), available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458363.htm. And, Mylan Pharms issues recalls for products, *i.e.* "Metoprolol Succinate Extended-release Tablets, USP 50 mg," which were "manufactured by Mylan Laboratories Limited." Metoprolol Succinate Recall Notice (July 7, 2014), available at http://www.smithdrug.com/uploads/recalls/metoprolol_07112014.pdf.

24. Upon information and belief, Mylan Pharms, Mylan Inc., and/or Mylan Labs are subject to personal jurisdiction in the State of Delaware due to, *inter alia*, their regular transaction and/or solicitation of business in this State. Furthermore, by continuously placing their products into the stream of commerce for distribution and consumption in the State of Delaware, and throughout the United States, Mylan has engaged in the regular conduct of business within this judicial district.

25. This Court has personal jurisdiction over Mylan Pharms because, upon information and belief, Mylan Pharms 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, Mylan Pharms has had persistent and continuous contact with this judicial district, including by developing, manufacturing, and/or selling generic pharmaceutical products that are distributed and sold in this district.

26. Upon information and belief, Mylan Pharms derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

27. Upon information and belief, Mylan Pharms is registered to do business in Delaware, and has thereby consented to suit in Delaware.

28. Upon information and belief, Mylan Pharms has appointed Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware, 19808, as its registered agent for the receipt of service of process.

29. Upon information and belief, Mylan Pharms is registered with the Delaware Board of Pharmacy as a "Pharmacy-Wholesale[r]" and a "Distributor/Manufacturer CSR." *See Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, 78 F. Supp. 3d 572, 577 (D. Del. 2015).

30. This Court has repeatedly exercised jurisdiction over Mylan Pharms in prior cases under the Hatch-Waxman Act. *See, e.g., Bayer Healthcare LLC v. Mylan Pharmaceuticals Inc.*, 1:15-cv-0114, D.I. 60 (D. Del. Mar. 30, 2016); *Acorda Therapeutics*, 78 F. Supp. 3d at 583-97; *Forest Laboratories, Inc. v. Amneal Pharmaceuticals, LLC*, 1:14-cv-0508, D.I. 127 (D. Del. Mar. 30, 2015); *Novartis Pharmaceuticals. Corp. v. Mylan Inc.*, 1:14-cv-0820, D.I. 56 (D. Del. Mar. 16, 2015); *AstraZeneca AB v. Mylan Pharmaceuticals Inc.*, 1:14-cv-0696, D.I. 26 (D. Del. Nov. 5, 2014).

31. Mylan Pharms has regularly engaged in patent litigation in this judicial district, including cases concerning its filing of an ANDA, without contesting jurisdiction. Mylan Pharms has previously consented to personal jurisdiction in this Court and availed itself of the benefits and protections of Delaware's laws by filing suit in this jurisdiction in, *inter alia*,

the following matters: *Pfizer Inc., et al. v. Mylan Inc., et al.*, 1:15-cv-0026 (D. Del.) (defendants Mylan Inc. and Mylan Pharms filing counterclaims in this district); *AbbVie Inc. v. Mylan Pharmaceuticals Inc., et al.*, 1:14-cv-1236 (D. Del.) (defendants Mylan Pharms and Mylan Labs filing counterclaims in this district); *AbbVie Inc. v. Mylan Pharmaceuticals Inc.*, 1:13-cv-1072 (D. Del.) (defendants Mylan Pharms and Mylan Labs consenting to personal jurisdiction and filing counterclaims in this district); *Forest Laboratories, Inc. et al. v. Mylan Inc.*, et al., 1:13-cv-1605 (D. Del.) (defendants Mylan Inc. and Mylan Pharms consenting to personal jurisdiction and filing counterclaims in this district); and *Mylan Pharmaceuticals Inc., et al. v. Eurand, Inc., et al.*, 1:10-cv-0306 (D. Del.) (defendants Mylan Pharms and Mylan Inc. filed suit seeking a declaratory judgment in this district).

32. This Court has personal jurisdiction over Mylan Pharms for the reasons articulated by the United States Court of Appeals for the Federal Circuit on March 18, 2016 in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 2015-1456 (Fed. Cir. March 18, 2016). There, the Federal Circuit held that a generic drug company such as Mylan is subject to personal jurisdiction in Delaware when it "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at Delaware (and, it is undisputed, elsewhere)." *Acorda*, slip op. at 8.

33. This Court has personal jurisdiction over Mylan Inc. because, upon information and belief, Mylan Inc. 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, Mylan Inc. has had persistent and continuous contact with this judicial

district, including by developing, manufacturing, and/or selling generic pharmaceutical products that are distributed and sold in this district.

34. Upon information and belief, Mylan Inc. derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

35. Upon information and belief, Mylan Inc., directly and/or through Mylan Pharms, has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers, and distributors in this judicial district.

36. Upon information and belief, Mylan Inc. has at least 20 subsidiaries incorporated in the State of Delaware. *See Acorda Therapeutics*, 78 F. Supp. 3d at 578.

37. Upon information and belief, Mylan Pharms and Mylan Labs act as the agents of Mylan Inc., and have submitted regulatory filings for generic pharmaceutical products to the FDA on behalf of Mylan Inc.

38. Mylan Inc. has regularly engaged in patent litigation in this judicial district, including cases concerning its filing of an ANDA, without contesting jurisdiction. Mylan Inc. has previously consented to personal jurisdiction in this Court and availed itself of the benefits and protections of Delaware's laws by filing suit in this jurisdiction in, *inter alia*, the following matters: *Pfizer Inc., et al. v. Mylan Inc., et al.*, 1:15-cv-0026 (D. Del.) (defendants Mylan Inc. and Mylan Pharms filing counterclaims in this district); *Forest Laboratories, Inc. et al. v. Mylan Inc.*, et al., 1:13-cv-1605 (D. Del.) (defendants Mylan Inc. and Mylan Pharms consenting to personal jurisdiction and filing counterclaims in this district); and *Mylan Pharmaceuticals Inc., et al. v. Eurand, Inc., et al.*, 1:10-cv-0306 (D. Del.) (defendants Mylan Pharms and Mylan Inc. filed suit seeking a declaratory judgment in this district).

39. This Court has personal jurisdiction over Mylan Inc. for the reasons articulated by the United States Court of Appeals for the Federal Circuit on March 18, 2016 in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 2015-1456 (Fed. Cir. March 18, 2016). There, the Federal Circuit held that a generic drug company such as Mylan is subject to personal jurisdiction in Delaware when it "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at Delaware (and, it is undisputed, elsewhere)." *Acorda*, slip op. at 8.

40. Upon information and belief, this Court has personal jurisdiction over Mylan Labs because Mylan Labs 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, Mylan Labs has had persistent and continuous contact with this judicial district, including by developing, manufacturing, and/or selling generic pharmaceutical products that are distributed and sold in this district. Although this Court has personal jurisdiction over Mylan Labs for at least the reasons set forth in Paragraphs 40 through 44, in the absence of such personal jurisdiction in any single state a foreign entity such as Mylan Labs is subject to jurisdiction throughout the United States. *See* Fed. R. Civ. P. 4(k)(2); *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1293-94 (Fed. Cir. 2012).

41. Upon information and belief, Mylan Labs derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

42. Mylan Labs has regularly engaged in patent litigation in this judicial district, including cases concerning its filing of an ANDA, without contesting jurisdiction.

Mylan Labs has previously consented to personal jurisdiction in this Court and availed itself of the benefits and protections of Delaware's laws by filing suit in this jurisdiction in, *inter alia*, the following matters: *AbbVie Inc. v. Mylan Pharmaceuticals Inc., et al.*, 1:14-cv-1236 (D. Del.) (defendants Mylan Pharms and Mylan Labs filing counterclaims in this district); *AbbVie Inc. v. Mylan Pharmaceuticals Inc.*, 1:13-cv-1072 (D. Del.) (defendants Mylan Pharms and Mylan Labs consenting to personal jurisdiction and filing counterclaims in this district).

43. This Court has personal jurisdiction over Mylan Labs for the reasons articulated by the United States Court of Appeals for the Federal Circuit on March 18, 2016 in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 2015-1456 (Fed. Cir. March 18, 2016). There, the Federal Circuit held that a generic drug company such as Mylan is subject to personal jurisdiction in Delaware when it "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at Delaware (and, it is undisputed, elsewhere)." *Acorda*, slip op. at 8.

44. Upon information and belief, Mylan has engaged in Delaware-related activities in connection with its efforts to obtain FDA approval to market its generic copies of Dyloject®. Upon information and belief, Mylan Labs, as the agent/affiliate of Mylan Inc. and Mylan Pharms, prepared and filed the Mylan ANDA, seeking approval to commercially market, use, offer for sale, or sell Mylan's Product in the United States, including within the State of Delaware, and because, as set forth in Paragraph 19, Mylan Labs sent the Paragraph IV Certifications to Javelin, a Delaware corporation.

45. If Mylan Pharms, Mylan Inc., and/or Mylan Labs commercially markets, uses, offers for sale, or sells Mylan's Product in the State of Delaware, or anywhere within the

United States, before the expiration of the ’079 and ’292 patents, Mylan will infringe and/or actively induce or contribute to the infringement of the ’079 and ’292 patents, causing harm to the Plaintiffs in the State of Delaware.

46. Venue is proper in the District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**COUNT I**
**INFRINGEMENT OF U.S. PATENT NO. 6,407,079**

47. Plaintiffs incorporate each of the preceding Paragraphs 1 through 46 as if fully set forth herein.

48. Mylan has infringed one or more claims of the ’079 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan’s ANDA, by which Mylan seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan’s Product prior to the expiration of the ’079 patent.

49. Mylan’s sale, offer for sale, use, or commercial manufacture of Mylan’s Product within the United States, or importation of Mylan’s Product into the United States, during the term of the ’079 patent would infringe, contribute to the infringement of, and/or induce the infringement of the ’079 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Mylan will infringe or aid another in the infringement of at least one or more of the following claims of the ’079 patent: claims 1-5, 12-16, and 25-35.

50. Mylan’s Paragraph IV Notice Letter does not dispute that Mylan’s Product infringes claims 1-5, 12-16, 18, 19, 23, and 26-28 of the ’079 patent.

51. Upon information and belief, Mylan has acted with full knowledge of the ’079 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the ’079 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution

and/or importation of Mylan's Product with its proposed labeling immediately and imminently upon approval of Mylan's ANDA. Upon information and belief, through such activities, Mylan specifically intends infringement of the '079 patent.

52. Upon information and belief, if the FDA approves Mylan's ANDA, Mylan plans and intends to, and will, infringe, actively induce infringement of, and contribute to the infringement of the '079 patent, and plans and intends to, and will, do so immediately and imminently upon approval.

53. Upon information and belief, Mylan knows that Mylan's Product is especially made or adapted for use in infringing the '079 patent, and that Mylan's Product is not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '079 patent immediately and imminently upon approval of Mylan's ANDA.

54. Plaintiffs will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '079 patent.

55. Plaintiffs have no adequate remedy at law.

56. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT II**
**INFRINGEMENT OF U.S. PATENT NO. 8,946,292**

57. Javelin Plaintiffs incorporate each of the preceding Paragraphs 1 through 46 as if fully set forth herein.

58. Mylan has infringed one or more claims of the '292 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the

FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product prior to the expiration of the '292 patent.

59. Mylan's sale, offer for sale, use, or commercial manufacture of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '292 patent would infringe, contribute to the infringement of, and/or induce the infringement of the '292 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Mylan will infringe or aid another in the infringement of at least one or more of the following claims of the '292 patent: claims 1 through 5.

60. Upon information and belief, the proposed labeling for Mylan's Product directs the use of Mylan's Product for one or more of the following indications: management of mild to moderate pain and/or management of moderate to severe pain alone or in combination with opioid analgesics.

61. Upon information and belief, Mylan has acted with full knowledge of the '292 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement, induced infringement, and contributory infringement of the '292 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Mylan's Product with its proposed labeling immediately and imminently upon approval of Mylan's ANDA. Upon information and belief, through such activities, Mylan specifically intends infringement of the '292 patent.

62. Upon information and belief, if the FDA approves Mylan's ANDA, Mylan plans and intends to, and will, infringe, actively induce infringement of, and contribute to the

infringement of the ’292 patent, and plans and intends to, and will, do so immediately and imminently upon approval.

63. Upon information and belief, Mylan knows that Mylan’s Product is especially made or adapted for use in infringing the ’292 patent, and that Mylan’s Product is not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the ’292 patent immediately and imminently upon approval of Mylan’s ANDA.

64. Javelin Plaintiffs will be harmed substantially and irreparably if Mylan is not enjoined from infringing the ’292 patent.

65. Javelin Plaintiffs have no adequate remedy at law.

66. Javelin Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys’ fees under 35 U.S.C. § 285.

**COUNT III**
**DECLARATORY JUDGMENT OF**
**INFRINGEMENT OF U.S. PATENT NO. 6,407,079**

67. Plaintiffs incorporate each of the preceding Paragraphs 1 through 56 as if fully set forth herein.

68. A definite and concrete, real and substantial justiciable controversy of sufficient immediacy exists between Plaintiffs and Mylan regarding infringement of the ’079 patent.

69. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States a product patented by the ’079 patent before the expiration of the ’079 patent. If those substantial and meaningful preparations lead to Mylan’s sale, offer for sale, use, or commercial manufacture of Mylan’s Product within the United States, or importation of

Mylan's Product into the United States, during the term of the '079 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the '079 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

70. Mylan's actions, including but not limited to the filing of Mylan's ANDA, and systematically attempting to meet the applicable regulatory requirements for approval of that ANDA, indicate a refusal to change its course of action.

71. Upon information and belief, Mylan's manufacture, importation, use, sale and/or offer to sell Mylan's Product prior to the expiration of the '079 patent would infringe at least claims 1-5, 12-16, and 25-35 of the '079 patent under at least 35 U.S.C. § 271(a), (b), and/or (c).

72. Upon information and belief, Mylan has acted with full knowledge of the '079 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement of the '079 patent.

73. Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of Mylan's Product will constitute infringement of the '079 patent under at least 35 U.S.C. § 271 (a), (b), and/or (c).

74. Plaintiffs will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '079 patent.

75. Plaintiffs have no adequate remedy at law.

76. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT IV**
**DECLARATORY JUDGMENT OF**
**INFRINGEMENT OF U.S. PATENT NO. 8,946,292**

77. Javelin Plaintiffs incorporate each of the preceding Paragraphs 1 through 46 and 57 through 66 as if fully set forth herein.

78. A definite and concrete, real and substantial justiciable controversy of sufficient immediacy exists between the Javelin Plaintiffs and Mylan regarding infringement of the ’292 patent.

79. Mylan has made and will continue to make substantial and meaningful preparations to import into the United States and/or manufacture, offer to sell, sell, and/or use within the United States a product covered by the ’292 patent before the expiration of the ’292 patent. If those substantial and meaningful preparations lead to Mylan’s sale, offer for sale, use, or commercial manufacture of Mylan’s Product within the United States, or importation of Mylan’s Product into the United States, during the term of the ’292 patent, then Mylan would infringe, contribute to the infringement of, and/or induce the infringement of the ’292 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

80. Mylan’s actions, including but not limited to the filing of Mylan’s ANDA, and systematically attempting to meet the applicable regulatory requirements for approval of that ANDA, indicate a refusal to change its course of action.

81. Upon information and belief, Mylan’s manufacture, importation, use, sale and/or offer to sell Mylan’s Product prior to the expiration of the ’292 patent would infringe at least claims 1-5 of the ’292 patent under at least 35 U.S.C. § 271(a), (b), and/or (c).

82. Upon information and belief, Mylan has acted with full knowledge of the ’292 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement, induced infringement, or contributory infringement of the ’292 patent.

83. Javelin Plaintiffs should be granted a judicial declaration that the importation into the United States and/or manufacture, use, offer for sale, and/or sale in the United States of Mylan's Product will constitute infringement of the '292 patent under at least 35 U.S.C. § 271(a), (b), and/or (c).

84. Javelin Plaintiffs will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '292 patent.

85. Javelin Plaintiffs have no adequate remedy at law.

86. Javelin Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

**PRAYER FOR RELIEF**

WHEREFORE, Javelin Pharmaceuticals, Inc., Hospira, Inc., and Janssen Pharmaceutica N.V. pray for a judgment in their favor and against Mylan Laboratories Limited, Mylan Inc., and Mylan Pharmaceuticals Inc., and respectfully request the following relief:

A. A judgment that Mylan has infringed the '079 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Mylan has infringed the '292 patent under 35 U.S.C. § 271(e)(2)(A);

C. A judgment declaring that the making, using, offering to sell, selling or importing of Mylan's Product described in ANDA 20-8786 would constitute infringement by Mylan of the '079 and '292 patents, or inducing or contributing to such conduct, pursuant to 35 U.S.C. § 271;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Mylan, its officers, agents, servants, and employees, and those persons in

active concert with any of them, from manufacturing, using, offering to sell, or selling Mylan's Product within the United States, or importing Mylan's Product into the United States, prior to the expiration of the '079 and '292 patents, including any extensions;

E. A judgment ordering, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 20-8786, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '079 and '292 patents, including any extensions;

F. If Mylan commercially manufactures, uses, offers to sell, or sells Mylan's Product within the United States, or imports Mylan's Product into the United States, prior to the expiration of the '079 or '292 patents, including any extensions, a judgment awarding Plaintiffs monetary relief, together with interest;

G. A declaration that this case is exceptional;

H. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

I. Costs and expenses in this action; and

J. Such other relief as the Court deems just and proper.

CONNOLLY GALLAGHER LLP

*/s/ Arthur G. Connolly III*

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April 4, 2016