Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700

OF COUNSEL:
Bruce M. Wexler
Joseph M. O'Malley, Jr.
Eric W. Dittmann
Isaac S. Ashkenazi
Leonard A. Monfredo
PAUL HASTINGS LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

Attorneys for Plaintiffs
Boehringer Ingelheim Pharma GmbH & Co. KG,
Boehringer Ingelheim International GmbH, and
Boehringer Ingelheim Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., ALKEM LABORATORIES, LTD., and MYLAN PHARMACEUTICALS INC., Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively,

"Boehringer" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Teva"); Alkem Laboratories, Ltd. ("Alkem"); and Mylan Pharmaceuticals Inc. ("Mylan") hereby allege as follows:

THE PARTIES

1. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG ("BIPKG") is a limited partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

2. Plaintiff Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

3. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

4. Defendant Teva USA is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

5. Defendant Teva USA has two places of business in the state of New Jersey.

6. Teva USA is a wholly owned subsidiary and agent of Defendant Teva Ltd.

7. Defendant Teva Ltd. is an Israeli corporation having a place of business at 5 Basel Street, Petah Tikva 49131, Israel.

8. Defendant Alkem is an Indian company, having a principal place of

business at Alkem House-Devashish, Senapati Bapat Marg, Mumbai, 400013, India.

9. Defendant Mylan is a corporation organized and existing under the laws of the state of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

NATURE OF THE ACTION

10. This is a civil action concerning United States Patent No. 6,087,380 ("the '380 patent"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

JURISDICTION AND VENUE

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

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

PERSONAL JURISDICTION OVER TEVA USA

13. Defendant Teva USA develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

14. This Court has personal jurisdiction over Teva USA because, *inter alia*, Teva USA: (1) has substantial, continuous, and systematic contacts with this State; (2) is registered to do business in the State of New Jersey under entity ID # 0100250184; (3) intends to market, sell, and/or distribute Teva's infringing Abbreviated New Drug Application ("ANDA") products (as defined in paragraph 30 *infra*) to residents of this State; (4) has two places of business in this State; (5) is licensed by the New Jersey Department of Health and Senior Services to sell generic pharmaceutical products in New Jersey; (6) maintains a broad distributorship network within this State; and (8) enjoys substantial income from sales of its

generic pharmaceutical products in this State.

15. Additionally, Teva USA has routinely consented to this Court's jurisdiction and availed itself of the protections afforded by this Court. *See, e.g.*, *Helsinn Healthcare, S.A., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-6341 (MLC)(DEA) (D.N.J. Oct. 13, 2014); *United Therapeutics Corporation v. Teva Pharmaceuticals USA, Inc.*, No. 14-5498 (PGS)(LHG) (D.N.J. Sept. 2, 2014); *Novo Nordisk Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, No. 14-4248 (MAS)(DEA) (D.N.J. July 3, 2014); *Amarin Pharma, Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, No. 14-3558 (MLC)(TJB) (D.N.J. June 4, 2014); *Teva Pharmaceuticals USA, Inc., et al. v. Doctor Reddy's Laboratories, Ltd., et al.*, No. 14-5672 (MAS)(TJB) (D.N.J. Sept. 11, 2014); *Teva Pharmaceutical Industries, Ltd., et al. v. Glenmark Generics, Inc. USA, et al.*, No. 08-4355 (GEB)(DEA) (D.N.J. Aug. 29, 2008).

PERSONAL JURISDICTION OVER TEVA LTD.

16. Defendant Teva Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

17. This Court has personal jurisdiction over Teva Ltd. because, *inter alia*, Teva Ltd.: (1) intends to market, sell, or distribute Teva's ANDA products (as defined in paragraph 30 *infra*) to residents of this State; (2) holds Drug Master File ("DMF") No. 28118 for the active pharmaceutical ingredient in Teva's ANDA products, dabigatran etexilate mesylate USP; (3) controls Defendant Teva USA; (4) makes its generic drug products available in this State through Teva USA, which has two places of business in New Jersey; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

18. Additionally, Teva Ltd. has routinely availed itself of the protections

afforded by this Court. *See, e.g.*, *Teva Pharmaceuticals USA, Inc., et al. v. Doctor Reddy's Laboratories, Ltd., et al*., No. 14-5672 (MAS)(TJB) (D.N.J. Sept. 11, 2014); *Teva Pharmaceutical Industries, Ltd., et al. v. Glenmark Generics, Inc. USA, et al.*, No. 08-4355 (GEB)(DEA) (D.N.J. Aug. 29, 2008).

19. Alternatively, to the extent the above facts do not establish personal jurisdiction over Teva Ltd., this Court may exercise jurisdiction over Teva Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Teva Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Teva Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

PERSONAL JURISDICTION OVER ALKEM

20. Defendant Alkem manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

21. This Court has personal jurisdiction over Alkem because, *inter alia*, Alkem: (1) manufactures Alkem's ANDA products (as defined in paragraph 42 *infra*) and intends to market, sell, or distribute those infringing products to residents of this State; (2) markets, sells, and distributes approved generic pharmaceutical products to residents of this State through its New Jersey subsidiary, Ascend Laboratories, LLC ("Ascend"); (3) maintains close ties to Ascend, as demonstrated by Ascend's website, http://www.ascendlaboratories.com/Products.aspx (last visited December 12, 2014) ("***Our products*** are manufactured in FDA approved state of art manufacturing plants. ***Alkem*** has

manufacturing plants in 4 cities in India. ***Our plants*** are located at Daman, Mandwa, Ankleshwar, Baddi") (emphasis added); (4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

22. Additionally, Alkem has consented to this Court's jurisdiction and availed itself of the protections afforded by this Court by asserting counterclaims against plaintiffs in this judicial district. *See* Alkem Laboratories, Ltd.'s Answer, Defenses, and Counterclaims, *Janssen Pharmaceuticals, Inc. v. Alkem Laboratories, Ltd.*, No. 13-7803 (CCC)(MF) (D.N.J. Dec. 23, 2013), ECF No. 30.

23. Alternatively, to the extent the above facts do not establish personal jurisdiction over Alkem, this Court may exercise jurisdiction over Alkem pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Alkem would be a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Alkem has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alkem satisfies due process.

PERSONAL JURISDICTION OVER MYLAN

24. Defendant Mylan develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

25. This Court has personal jurisdiction over Mylan because, *inter alia*, Mylan: (1) has substantial, continuous, and systematic contacts with this State; (2) is registered to do business in the State of New Jersey under entity ID # 0100214277; (3) intends to market,

sell, or distribute Mylan's ANDA products (as defined in paragraph 53 *infra*) to residents of this State; (4) has appointed Corporation Services Counsel of 830 Bear Tavern Road, West Trenton, New Jersey 08628 as its agent for service of process in this State; (5) intentionally markets and provides its generic pharmaceutical drug products to residents of this State; (6) maintains a broad distributorship network within this State; and (7) enjoys substantial income from sales of its generic pharmaceutical products in this State.

26. Additionally, Mylan has initiated two lawsuits in New Jersey to date in 2014, and Mylan has routinely consented to this Court's jurisdiction and avails itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Mylan Inc. and Mylan Pharmaceuticals Inc. v. Apotex Inc. and Apotex Corp.*, No. 14-4560 (JAP)(LHG) (D.N.J. July 18, 2014); *Mylan Pharmaceuticals Inc. v. Celgene Corp.*, No. 14-2094 (ES)(MAH) (D.N.J. Apr. 3, 2014); Answer, Defenses, and Counterclaims of Mylan Inc. and Mylan Pharmaceuticals Inc. to Plaintiff's Complaint for Patent Infringement, *Warner Chilcott Company, LLC v. Mylan Inc.*, No. 13-6560 (JAP)(TJB) (D.N.J. May 20, 2014), ECF No. 19; Defendants Mylan Pharmaceuticals Inc.'s and Mylan Inc.'s Answer and Counterclaims, *Aptalis Pharma US Inc. v. Mylan Pharmaceuticals Inc.*, No. 13-4158 (MLC)(LHG) (D.N.J. Aug. 23, 2013), ECF No. 11.

PATENT-IN-SUIT

27. BIPI is the holder of New Drug Application ("NDA") No. 22-512, by which the United States Food and Drug Administration ("FDA") first granted approval for 75 mg and 150 mg dabigatran etexilate mesylate capsules. The dabigatran etexilate mesylate capsules described in BIPI's NDA are prescribed, *inter alia*, to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Boehringer sells these capsules in the

United States under the trade name "PRADAXA®."

28. BIPKG owns the '380 patent, which was duly and legally issued on July 11, 2000, and is titled "Disubstituted Bicyclic Heterocycles, the Preparations and the Use Thereof as Pharmaceutical Compositions." BII and BIPI have an exclusive license under the '380 patent in the United States from BIPKG. A copy of the '380 patent is attached as Exhibit A.

ACTS GIVING RISE TO THIS ACTION

COUNT I – INFRINGEMENT OF THE '380 PATENT BY TEVA

29. Plaintiffs reallege paragraphs 1-28 as if fully set forth herein.

30. Defendant Teva filed with the FDA ANDA No. 208057, which included a certification with respect to the '380 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to engage in the manufacture, use, sale, offer for sale, and/or importation of 75 mg and 150 mg dabigatran etexilate mesylate capsules ("Teva's ANDA products") prior to the expiration of that patent.

31. On or about December 5, 2014, Teva USA sent a letter ("Teva USA's Notice Letter") to BIPI in which Teva USA represented that it had filed an ANDA for Teva's ANDA products, including the certification with respect to the '380 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

32. Teva USA's Notice Letter did not provide complete and effective notice under 21 U.S.C. § 355(j)(2)(B)(iii) because Teva has not served notice to BIPKG.

33. This action was commenced within 45 days of the receipt of Teva USA's Notice Letter.

34. Teva USA and Teva Ltd. are jointly and severally liable for any

infringement of the '380 patent because, upon information and belief, Teva USA and Teva Ltd. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 208057 and the § 355(j)(2)(A)(vii)(IV) allegations to the FDA.

35. Because Teva seeks approval of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a drug claimed in the '380 patent, and a drug the use of which is claimed in the '380 patent, before its expiration, Teva has infringed the '380 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

36. Plaintiffs are entitled to a declaration that, if Teva commercially manufactures, uses, sells, offers to sell, and/or imports any of Teva's ANDA products, or induces or contributes to any such conduct, it would further infringe the '380 patent pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

37. The commercial manufacture, use, sale, offer to sell, and/or importation of Teva's ANDA products, if approved by the FDA, prior to the expiration of the '380 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '380 patent. Boehringer is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of Teva's ANDA No. 208057 be a date that is not earlier than the expiration date of the '380 patent, or any later expiration of exclusivity for the '380 patent to which Boehringer is or may become entitled.

38. Upon information and belief, Teva was aware of the existence of the '380 patent, and was aware that the filing of its ANDA and certification with respect to the '380 patent constituted an act of infringement of that patent.

39. Teva's statement of the factual and legal bases for its opinion regarding

the invalidity of the '380 patent contained in Teva USA's Notice Letter is devoid of any objective good-faith basis in either the facts or the law.

40. Plaintiffs will be irreparably harmed by Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT II – INFRINGEMENT OF THE '380 PATENT BY ALKEM

41. Plaintiffs reallege paragraphs 1-40 as if fully set forth herein.

42. Defendant Alkem filed with the FDA ANDA No. 208040, which included a certification with respect to the '380 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to engage in the manufacture, use, sale, offer for sale, and/or importation of 75 mg and 150 mg dabigatran etexilate mesylate capsules ("Alkem's ANDA products") prior to the expiration of that patent.

43. On or about December 1, 2014, Alkem sent a letter ("Alkem's Notice Letter") to BIPKG and Boehringer Ingelheim Corporation in which Alkem represented that it had filed an ANDA for Alkem's ANDA products, including the certification with respect to the '380 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

44. Alkem's Notice Letter did not provide complete and effective notice under 21 U.S.C. § 355(j)(2)(B)(iii) because Alkem has not served notice to BIPI.

45. This action was commenced within 45 days of the receipt of Alkem's Notice Letter.

46. Because Alkem seeks approval of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a drug claimed in the '380 patent, and a drug the use of which is claimed in the '380 patent, before its expiration, Alkem has infringed the '380 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

47. Plaintiffs are entitled to a declaration that, if Alkem commercially manufactures, uses, sells, offers to sell, and/or imports any of Alkem's ANDA products, or induces or contributes to any such conduct, Alkem would further infringe the '380 patent pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

48. The commercial manufacture, use, sale, offer to sell, and/or importation of Alkem's ANDA products, if approved by the FDA, prior to the expiration of the '380 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '380 patent. Boehringer is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of Alkem's ANDA No. 208040 be a date that is not earlier than the expiration date of the '380 patent, or any later expiration of exclusivity for the '380 patent to which Boehringer is or may become entitled.

49. Upon information and belief, Alkem was aware of the existence of the '380 patent, and was aware that the filing of its ANDA and certification with respect to the '380 patent constituted an act of infringement of that patent.

50. Alkem's statement of the factual and legal bases for its opinion regarding the invalidity of the '380 patent contained in Alkem's Notice Letter is devoid of any objective good-faith basis in either the facts or the law.

51. Plaintiffs will be irreparably harmed by Alkem's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT III – INFRINGEMENT OF THE '380 PATENT BY MYLAN

52. Plaintiffs reallege paragraphs 1-51 as if fully set forth herein.

53. Defendant Mylan filed with the FDA ANDA No. 208067, which included

a certification with respect to the '380 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to engage in the manufacture, use, sale, offer for sale, and/or importation of 75 mg and 150 mg dabigatran etexilate mesylate capsules ("Mylan's ANDA products") prior to the expiration of that patent.

54. On or about December 8, 2014, Mylan sent a letter ("Mylan's Notice Letter") to BIPI, BIPKG, BII, and Boehringer Ingelheim Corporation in which Mylan represented that it had filed an ANDA for Mylan's ANDA products, including the certification with respect to the '380 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

55. This action was commenced within 45 days of the receipt of Mylan's Notice Letter.

56. Because Mylan seeks approval of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a drug claimed in the '380 patent, and a drug the use of which is claimed in the '380 patent, before its expiration, Mylan has infringed the '380 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

57. Plaintiffs are entitled to a declaration that, if Mylan commercially manufactures, uses, sells, offers to sell, and/or imports any of Mylan's ANDA products, or induces or contributes to any such conduct, it would further infringe the '380 patent pursuant to 35 U.S.C. § 271(a), (b), and/or (c).

58. The commercial manufacture, use, sale, offer to sell, and/or importation of Mylan's ANDA products, if approved by the FDA, prior to the expiration of the '380 patent, for use in accordance with its proposed labeling would infringe and/or induce and/or contribute to the infringement of the '380 patent. Boehringer is entitled to relief provided by 35 U.S.C.

§ 271(e)(4), including an Order of this Court that the effective date of the approval of Mylan's ANDA No. 208067 be a date that is not earlier than the expiration date of the '380 patent, or any later expiration of exclusivity for the '380 patent to which Boehringer is or may become entitled.

59. Upon information and belief, Mylan was aware of the existence of the '380 patent, and was aware that the filing of its ANDA and certification with respect to the '380 patent constituted an act of infringement of that patent.

60. Mylan's statement of the factual and legal bases for its opinion regarding the invalidity of the '380 patent contained in Mylan's Notice Letter is devoid of any objective good-faith basis in either the facts or the law.

61. Plaintiffs will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment be entered that Defendants Teva USA, Teva Ltd., Alkem, and Mylan have infringed the '380 patent by respectively submitting Teva's ANDA No. 208057, Alkem's ANDA No. 208040, and Mylan's ANDA No. 208067;

B. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

C. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants Teva USA, Teva Ltd., Alkem, and Mylan, and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United

States, or importation into the United States, of the drugs or methods of administering drugs claimed in the '380 patent, including any exclusivities or extensions;

D. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Teva's ANDA No. 208057, Alkem's ANDA No. 208040, and Mylan's ANDA No. 208067 be a date that is not earlier than the expiration date of the '380 patent, or any later expiration of exclusivity of the '380 patent to which Plaintiffs are or may become entitled; and

E. Such other and further relief as the Court may deem just and proper.

Dated: December 15, 2014

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com
wbaton@saul.com

OF COUNSEL:
Bruce M. Wexler
Joseph M. O'Malley, Jr.
Eric W. Dittmann
Isaac S. Ashkenazi
Leonard A. Monfredo
PAUL HASTINGS LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

Attorneys for Plaintiffs
Boehringer Ingelheim Pharma GmbH & Co. KG,
Boehringer Ingelheim International GmbH, and
Boehringer Ingelheim Pharmaceuticals, Inc.