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*Attorneys for Plaintiffs*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

BOEHRINGER INGELHEIM )  
PHARMACEUTICALS INC., BOEHRINGER )  
INGELHEIM INTERNATIONAL GMBH, )  
BOEHRINGER INGELHEIM CORPORATION, )  
and BOEHRINGER INGELHEIM PHARMA )  
GMBH & CO. KG, )

Plaintiffs, )

v. )

HEC PHARM GROUP, HEC PHARM CO., LTD., )  
HEC PHARM USA, MYLAN )  
PHARMACEUTICALS INC., MYLAN INC., )  
MYLAN LABORATORIES LIMITED, INTAS )  
PHARMACEUTICALS LIMITED, ACCORD )  
HEALTHCARE, INC., AUROBINDO PHARMA )  
LIMITED, AUROBINDO PHARMA USA, INC., )  
DR. REDDY'S LABORATORIES, LTD., DR. )  
REDDY'S LABORATORIES, INC., ZYDUS )  
PHARMACEUTICALS USA, INC., CADILA )  
HEALTHCARE LTD., MSN LABORATORIES )  
PRIVATE LIMITED, MSN )  
PHARMACEUTICALS, INC., PRINSTON )

Civil Action No. \_\_\_\_\_

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PHARMACEUTICAL INC., SOLCO )  
HEALTHCARE U.S., LLC, HUAHAI US INC., )  
ZHEJIANG HUAHAI PHARMACEUTICAL CO., )  
LTD., INVAGEN PHARMACEUTICALS INC., )  
SUN PHARMACEUTICAL INDUSTRIES LTD., )  
SUN PHARMA GLOBAL FZE, and SUN )  
PHARMACEUTICAL INDUSTRIES, INC. )  
 )  
Defendants )

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**COMPLAINT**

Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; Boehringer Ingelheim Corporation; and Boehringer Ingelheim Pharma GmbH & Co. KG (collectively, “Boehringer” or “Plaintiffs”), by their undersigned attorneys, for their Complaint against Defendants HEC Pharm Group; HEC Pharm Co., Ltd.; HEC Pharm USA; Mylan Pharmaceuticals Inc.; Mylan Inc.; Mylan Laboratories Limited; Intas Pharmaceuticals Limited; Accord Healthcare, Inc.; Aurobindo Pharma Limited; Aurobindo Pharma USA, Inc.; Dr. Reddy’s Laboratories, Ltd.; Dr. Reddy’s Laboratories, Inc.; Zydus Pharmaceuticals USA, Inc.; Cadila Healthcare Ltd.; MSN Laboratories Private Limited; MSN Pharmaceuticals, Inc.; Prinston Pharmaceutical Inc.; Solco Healthcare U.S. LLC; Huahai US Inc.; Zhejiang Huahai Pharmaceutical Co., Ltd.; Invagen Pharmaceuticals Inc.; Sun Pharmaceutical Industries, Ltd.; Sun Pharma Global FZE; and Sun Pharmaceutical Industries, Inc. hereby allege as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants’ submissions of Abbreviated New Drug Applications (“ANDAs”) to the Food and Drug Administration (“FDA”) seeking approval to manufacture and sell generic

versions of Plaintiffs' TRADJENTA® (linagliptin) and JENTADUETO® (linagliptin and metformin hydrochloride) tablets prior to the expiration of United States Patent Nos. 7,407,955, 8,119,648, 8,178,541, 8,673,927, 8,846,695, and 8,853,156.

### **THE PARTIES**

2. 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 Rd., Ridgefield, CT 06877.

3. 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.

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

5. Plaintiff Boehringer Ingelheim Corporation ("BIC") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, CT, 06877.

6. BIPI, BII, BIPKG and BIC are collectively referred to hereinafter as "Boehringer Ingelheim."

7. On information and belief, Defendant HEC Pharm Group ("HEC Group") is a company organized and existing under the laws of China, having a principal place of business at Dong Yang Guang Park, Shangsha, Chang'an, Dongguan, Guangdong, 523871, China.

8. On information and belief, HEC Group is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs. On information and belief, HEC Group established Defendants HEC Pharm Co., Ltd. and HEC Pharm USA Inc. for the purpose of manufacturing, distributing, marketing, and selling its generic drug products throughout the United States.

9. On information and belief, Defendant HEC Pharm Co., Ltd. (“HEC Ltd.”) is a company organized and existing under the laws of China, having a principal place of business at Binjiang Road 62, Yidu, Yichang, 443300, Hubei, China. On information and belief, HEC Ltd. develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States.

10. On information and belief, based in part on representations on their website at [www.hecpharm.com](http://www.hecpharm.com), HEC Group and HEC Ltd. hold themselves out as a unitary entity. On information and belief, HEC Group and HEC Ltd., themselves and through their U.S. agent, Defendant HEC Pharm USA Inc., manufacture and/or distribute generic drugs for sale and use throughout the United States, including in the State of New Jersey.

11. On information and belief, HEC Pharm USA Inc. (“HEC USA”) is a company organized and existing under the laws of New Jersey, having a principal place of business at 116 Village Blvd, Suite 200, Princeton, NJ 08540.

12. On information and belief, HEC USA is the U.S. agent of HEC Group and HEC Ltd., wherein following FDA approval of an ANDA, HEC Ltd. manufactures and supplies the approved generic product to HEC USA, which then markets and sells the product throughout the

United States at the direction, under the control, and for the direct benefit of HEC Ltd. and HEC Group.

13. On information and belief, Defendants HEC Ltd. and HEC USA are wholly owned subsidiaries and agents of Defendant HEC Group.

14. On information and belief, the acts of HEC Ltd. complained of herein were done with the cooperation, participation, and assistance of HEC USA and HEC Group.

15. HEC Ltd., HEC Group, and HEC USA are collectively referred to hereinafter as “HEC.”

16. On information and belief, Defendant Mylan Pharmaceuticals Inc. (“Mylan Pharms”) is a corporation 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.

17. On information and belief, Mylan Pharms is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

18. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at Robert J. Coury Global Center, 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317.

19. On information and belief, Defendant Mylan Laboratories Limited (“Mylan Labs”) is a corporation organized and existing under the laws of India and has a principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India.

20. On information and belief, Mylan Pharms is a wholly owned subsidiary of Mylan Labs, which, in turn is a wholly-owned subsidiary of Mylan Inc.

21. On information and belief, the acts of Mylan Pharms complained of herein were done with the cooperation, participation, and assistance of Mylan Inc. and Mylan Labs.

22. Mylan Pharms, Mylan Labs, and Mylan Inc. are collectively referred to herein as “Mylan.”

23. On information and belief, Defendant Accord Healthcare, Inc. (“AHI”) is a corporation organized and existing under the laws of the State of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

24. On information and belief, AHI is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

25. On information and belief, Defendant Intas Pharmaceuticals, Ltd. (“Intas”) is a corporation organized and existing under the laws of India, having a principal place of business at Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

26. On information and belief, AHI is a wholly-owned subsidiary of Intas.

27. On information and belief, the acts of AHI complained of herein were done with the cooperation, participation, and assistance of Intas.

28. Defendants AHI and Intas are collectively referred to herein as “Accord.”

29. On information and belief, Defendant Aurobindo Pharma Limited (“Aurobindo Ltd.”) is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad - 500 038, Andhra Pradesh, India.

30. On information and belief, Defendant Aurobindo Pharma USA, Inc. (“Aurobindo USA”) is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810.

31. On information and belief, Aurobindo USA is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

32. On information and belief, Aurobindo USA is a wholly-owned subsidiary of Aurobindo Ltd.

33. On information and belief, the acts of Aurobindo Ltd. complained of herein were done with the cooperation, participation, and assistance of Aurobindo USA.

34. Aurobindo USA and Aurobindo Ltd. are collectively referred to herein as “Aurobindo.”

35. On information and belief, Defendant Dr. Reddy's Laboratories, Ltd. ("DRLL") is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500 034, India.

36. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. ("DRLI") is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, NJ 08540. DRLI is registered to do business in the State of New Jersey.

37. On information and belief, DRLL is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

38. On information and belief, DRLI is a wholly-owned subsidiary of DRLL.

39. On information and belief, the acts of DRLL complained of herein were done with the cooperation, participation, and assistance of DRLI.

40. DRLI and DRLL are collectively referred to herein as "DRL"

41. On information and belief, Defendant Zydus Pharmaceuticals USA, Inc. ("Zydus USA") is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. Zydus USA is registered to do business in the State of New Jersey.

42. On information and belief, Zydus USA is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

43. On information and belief, Defendant Cadila Healthcare Ltd. (d/b/a Zydus Cadila) (“Zydus Cadila”) is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India.

44. On information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Cadila.

45. On information and belief, the acts of Zydus USA complained of herein were done with the cooperation, participation, and assistance of Zydus Cadila.

46. Zydus USA and Zydus Cadila are collectively referred to hereinafter as “Zydus.”

47. On information and belief, Defendant MSN Laboratories Private Limited (“MSN Labs”) is a corporation organized and existing under the laws of India, having a principal place of business at Sy No-317 &323, Rudraram (Village), Patancheru Mandal, Medak Dist.-502 329, Telangana, India.

48. On information and belief, Defendant MSN Pharmaceuticals, Inc. (“MSN Inc.”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 343 Thornall Street, Suite 678, Edison, NJ 08837.

49. On information and belief, MSN Labs and MSN Inc. are in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

50. On information and belief, MSN Inc. is a wholly owned subsidiary of MSN Labs.

51. On information and belief, the acts of MSN Labs complained of herein were done with the cooperation, participation, and assistance of MSN Inc.

52. MSN Inc. and MSN Labs are collectively referred to hereinafter as “MSN.”

53. On information and belief, Princeton Pharmaceutical Inc. (“Princeton”) is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.

54. On information and belief, defendant Princeton is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of New Jersey.

55. On information and belief, Defendant Solco Healthcare U.S., LLC (“Solco”) is a Delaware corporation with a principal place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.

56. On information and belief, Solco is in the business of, among other things, preparing, manufacturing, marketing, and distributing pharmaceutical products, including Princeton’s pharmaceutical products, throughout the United States, including in the State of New