UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., and JANSSEN PHARMACEUTICA N.V., *Plaintiffs,* v. TORRENT PHARMACEUTICALS LTD., TORRENT PHARMA INC., WATSON LABORATORIES, INC. (NV), WATSON LABORATORIES, INC. (DE), WATSON LABORATORIES, INC. (NY), WATSON LABORATORIES, INC. (CT), WATSON PHARMA, INC., WATSON PHARMACEUTICALS INC., AMERIGEN PHARMACEUTICALS, INC., AMERIGEN PHARMACEUTICALS LTD., GLENMARK GENERICS INC., GLENMARK GENERICS INC., USA, GLENMARK GENERICS LTD., GLENMARK PHARMACEUTICALS LTD., HETERO USA INC., and HETERO LABS LTD. *Defendants.*	Civil Action No. _____

COMPLAINT

Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and Janssen Pharmaceutica N.V. (collectively, "Plaintiffs"), 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 filing of Abbreviated New Drug Applications ("ANDAs") by Defendants Torrent Pharmaceuticals Ltd., Watson Laboratories, Inc., Amerigen Pharmaceuticals, Inc., Glenmark Generics Inc., USA (a.k.a., Glenmark Generics

Inc.), and Hetero USA Inc. (or Hetero Labs Ltd.) with the United States Food and Drug Administration ("FDA") for approval to manufacture and sell generic versions of Plaintiffs' Bystolic® drug products prior to the expiration of U.S. Patent No. 6,545,040 (the " '040 Patent").

PARTIES

2. Plaintiff Forest Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 909 Third Avenue, New York, NY 10022.

3. Plaintiff Forest Laboratories Holdings, Ltd. is a corporation organized and existing under the laws of the Ireland, with a place of business at Milner House, 18 Parliament Street, Hamilton HM 11, Bermuda (referred to herein, together with Forest Laboratories, Inc., as "Forest").

4. Plaintiff Janssen Pharmaceutica N.V. is a corporation organized and existing under the laws of Belgium, with its principal place of business at Turnhoutseweg 30, B2340 Beerse, Belgium.

5. On information and belief, Defendant Torrent Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Off. Ashram Road, Ahmedabad - 380 009, Gujarat, India.

6. On information and belief, Defendant Torrent Pharma Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 5380 Holiday Terrace, Suite 40, Kalamazoo, MI 49009.

7. On information and belief, Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals Ltd.

8. On information and belief, Torrent Pharma Inc. acts as the agent of Torrent Pharmaceuticals Ltd.

9. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. hereinafter are referred to collectively as "Torrent."

10. On information and belief, Torrent manufactures and sells various generic drug products and regularly conducts business throughout the United States, including in the State of Delaware.

11. On information and belief, Defendant "Watson Laboratories, Inc. (NV)" is a corporation operating under the name Watson Laboratories, Inc., and is organized and existing under the laws of the State of Nevada, having places of business at 132 Business Center Drive, Corona, CA 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

12. On information and belief, Defendant "Watson Laboratories, Inc. (DE)" is a corporation operating under the name Watson Laboratories, Inc., and is organized and existing under the laws of the State of Delaware, having places of business at 311 Bonnie Circle, Corona, CA 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

13. On information and belief, Defendant "Watson Laboratories, Inc. (NY)" is a corporation operating under the name Watson Laboratories, Inc., and is organized and existing under the laws of the State of New York, having places of business at 311 Bonnie Circle, Corona, CA 92880 and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

14. On information and belief, Defendant "Watson Laboratories, Inc. (CT)" is a corporation operating under the name Watson Laboratories, Inc., and is organized and existing under the laws of the State of Connecticut, having places of business at 131 West St., Danbury,

CT 06810, 311 Bonnie Circle, Corona, CA 92880, and Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

15. On information and belief, Defendant Watson Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

16. On information and belief, Defendant Watson Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Nevada, having places of business at 311 Bonnie Circle, Corona, CA 92880 and 360 Mount Kemble Avenue, Morristown, NJ 07962, and its corporate headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

17. On information and belief, Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), and Watson Pharma, Inc. are wholly-owned subsidiaries of Watson Pharmaceuticals Inc. On information and belief, Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Watson Pharmaceuticals Inc. have officers and directors in common.

18. On information and belief, Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), and Watson Pharma, Inc. act as agents of Watson Pharmaceuticals Inc.

19. Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), and Watson Laboratories, Inc. (CT) hereinafter are referred to collectively or individually as "Watson Laboratories, Inc." Watson Laboratories, Inc., Watson

Pharma, Inc., and Watson Pharmaceuticals Inc. hereinafter are referred to collectively as "Watson."

20. On information and belief, Watson manufactures and sells various generic drug products and regularly conducts business throughout the United States, including in the State of Delaware.

21. On information and belief, Defendant Amerigen Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 197 State Route 18S, Suite 306N, East Brunswick, NJ 08816.

22. On information and belief, Defendant Amerigen Pharmaceuticals Ltd. is a Chinese company having places of business at 197 State Route 18S, Suite 306N, East Brunswick, NJ 08816 and No. 58, Qunxing Yi Road, Suzhou Industrial Park, PRC. 215006.

23. On information and belief, Amerigen Pharmaceuticals Inc. is a wholly-owned subsidiary of Amerigen Pharmaceuticals Ltd.

24. On information and belief, Amerigen Pharmaceuticals Inc. acts as the agent of Amerigen Pharmaceuticals Ltd.

25. Amerigen Pharmaceuticals Inc. and Amerigen Pharmaceuticals Ltd. hereinafter are referred to collectively as "Amerigen."

26. On information and belief, Defendant Glenmark Generics Inc., USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, NJ 07430.

27. On information and belief, Defendant Glenmark Generics Inc. is the same entity as Defendant Glenmark Generics Inc., USA. To the extent Glenmark Generics Inc. is a an entity

separate and apart from Glenmark Generics Inc., USA, any allegations in this Complaint relating to Glenmark Generics Inc., USA shall apply equally to Glenmark Generics Inc.

28. On information and belief, Defendant Glenmark Generics Ltd. is an Indian company having a place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India.

29. On information and belief, Defendant Glenmark Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India.

30. On information and belief, Glenmark Generics Inc., USA and Glenmark Generics Ltd. are wholly-owned subsidiaries of Glenmark Pharmaceuticals Ltd. On information and belief, Glenmark Generics Inc., USA is the North American division of Glenmark Generics Ltd. On information and belief, Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals Ltd. have officers and directors in common.

31. On information and belief, Glenmark Generics Inc., USA acts as the agent of Glenmark Generics Ltd. and Glenmark Pharmaceuticals Ltd.

32. Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals Ltd. hereinafter are referred to collectively as "Glenmark."

33. On information and belief, Glenmark manufactures and sells various generic drug products and regularly conducts business throughout the United States, including in the State of Delaware.

34. On information and belief, Defendant Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854.

35. On information and belief, Defendant Hetero Labs Ltd. is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estate, Sanathnagar Hyderabad 500018 Andhra Pradesh, India.

36. On information and belief, Hetero USA Inc. is a wholly-owned subsidiary of Hetero Labs Ltd.

37. On information and belief, Hetero USA Inc. acts as the agent of Hetero Labs Ltd.

38. Hetero USA Inc. and Hetero Labs Ltd. hereinafter are referred to collectively as "Hetero."

39. On information and belief, Hetero manufactures and sells various generic drug products and regularly conducts business throughout the United States, including in the State of Delaware.

JURISDICTION AND VENUE

40. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally, and 35 U.S.C. § 271(e)(2) specifically.

41. This action arises under the patent laws of the United States of America, and this Court has jurisdiction over the subject matter of this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

43. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable

harm and injury to a Delaware corporation, Plaintiff Forest Laboratories, Inc., in Delaware. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

44. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. have submitted to the personal jurisdiction of the United States District Court for the District of Delaware at least in *Wyeth v. Torrent Pharms. Ltd., et al.,* 1:09-cv-00019 (JJF); *Teva Pharm. Indus. Ltd., et al. v. Torrent Pharms. Ltd. et al.,* 1:07-cv-00332 (GMS); and *Sanofi-Aventis v. Actavis South Atlantic LLC, et al.,* 1:07-cv-00572 (GMS).

45. On information and belief, Torrent Pharmaceuticals Ltd., directly or through Torrent Pharma Inc. and/or through one or more of its subsidiaries, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Torrent Pharmaceuticals Ltd., either directly or through Torrent Pharma Inc. and/or through one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware.

46. On information and belief, Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. operate as an integrated business ultimately controlled by Torrent Pharmaceuticals Ltd. For example, Torrent Pharmaceuticals Ltd.'s website, located at http://www.torrentpharma.com/international%20offices.php, lists Torrent Pharma Inc. as the international office for Torrent Pharmaceuticals Ltd. in the United States.

47. On information and belief, this Court has personal jurisdiction over Torrent Pharmaceuticals Ltd. by virtue of, among other things: (1) its presence in Delaware; (2) its sale of a substantial volume of prescription drugs in Delaware; (3) its prior consent to be sued in

Delaware; (4) its systematic and continuous contacts with Delaware, including those made through Torrent Pharma Inc.; and (5) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

48. On information and belief, Torrent Pharma Inc. is in the business of marketing and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Torrent Pharma Inc., either directly or through one or more of its subsidiaries, agents, and/or distributors, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware. On information and belief, the acts of Torrent Pharma Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Torrent Pharmaceuticals Ltd. In its letter dated February 1, 2012, notifying Plaintiffs of its submission to the FDA of ANDA No. 203966 for Torrent's generic nebivolol hydrochloride tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg (the "Torrent Notice Letter"), Torrent Pharmaceuticals Ltd. identified Torrent Pharma Inc. as its "U.S. Agent."

49. On information and belief, this Court has personal jurisdiction over Torrent Pharma Inc. by virtue of, among other things: (1) its incorporation in the state of Delaware; (2) its registration to do business in Delaware, including its appointment of a registered agent in Delaware (located at Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, DE 19808) for the receipt of service of process; (3) its sale of a substantial volume of prescription drugs in Delaware; (4) its prior consent to be sued in Delaware; (5) its systematic and continuous contacts with Delaware; and (6) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

50. In *Cephalon Inc. v. Watson Pharmaceuticals, Inc.*, 629 F. Supp. 2d 338 (D. Del. 2009), this Court found general personal jurisdiction over Watson Laboratories, Inc. due to their extensive contacts with Delaware. Watson Laboratories, Inc., Watson Pharmaceuticals Inc., and Watson Pharma, Inc. have submitted to the personal jurisdiction of the United States District Court for the District of Delaware at least in *Novartis Pharms. Corp., et al. v. Watson Labs., Inc., et al.*, 1:11-cv-01112 (SLR); and *Alcon Pharms. Ltd. et al. v. Watson Labs., Inc., et al.*, 1:11-cv-00293 (SLR).

51. On information and belief, Watson Laboratories, Inc. is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Watson Laboratories, Inc., either directly or through Watson Pharma, Inc. and/or one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware. On information and belief, the acts of Watson Laboratories, Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Watson Pharmaceuticals Inc. and/or Watson Pharma, Inc.

52. Upon information and belief, Watson Laboratories, Inc. acts under the direction, control, and influence of Watson Pharmaceuticals Inc. with respect to, at least, the acts and conduct alleged in this Complaint.

53. On information and belief, this Court has personal jurisdiction over Watson Laboratories, Inc. by virtue of, among other things: (1) its presence in Delaware; (2) its sale of a substantial volume of prescription drugs in Delaware; (3) its prior consent to be sued in Delaware; (4) its systematic and continuous contacts with Delaware, including those made

through Watson Pharma, Inc.; and (5) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

54. On information and belief, Watson Pharma, Inc. is in the business of marketing and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Watson Pharma, Inc., either directly or through one or more of its subsidiaries, agents, and/or distributors, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware. On information and belief, the acts of Watson Pharma, Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Watson Pharmaceuticals Inc. and/or Watson Laboratories, Inc.

55. Upon information and belief, Watson Pharma, Inc. acts under the direction, control, and influence of Watson Pharmaceuticals Inc. and/or Watson Laboratories, Inc. with respect to, at least, the acts and conduct alleged in this Complaint.

56. On information and belief, this Court has personal jurisdiction over Watson Pharma, Inc. by virtue of, among other things: (1) its incorporation in the state of Delaware; (2) its registration to do business in Delaware, including its appointment of a registered agent in Delaware (located at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801) for the receipt of service of process; (3) its sale of a substantial volume of prescription drugs in Delaware; (4) its prior consent to be sued in Delaware; (5) its systematic and continuous contacts with Delaware; and (6) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

57. On information and belief, Watson Pharmaceuticals Inc., directly or through Watson Laboratories, Inc., Watson Pharma, Inc. and/or through one or more of its subsidiaries, is

in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Watson Pharmaceuticals Inc., either directly or through Watson Laboratories, Inc., Watson Pharma, Inc. and/or through one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware.

58. Upon information and belief, Watson Pharmaceuticals Inc. is an integrated pharmaceutical company engaged in the development, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, whose largest commercial market is the United States. Upon information and belief, Watson Pharmaceuticals Inc. operates and manages its business as three operating segments, including Global Generics, which markets approximately 160 generic pharmaceutical product families primarily under the Watson Laboratories, Inc. and Watson Pharmaceuticals Inc. labels. Upon information and belief, Watson Pharmaceuticals Inc.'s generic business in the U.S. provides the dominant source of its revenue. Upon information and belief, Watson Pharmaceuticals Inc. engages in continuous and systemic contacts in Delaware, including, but not limited to, Watson Pharmaceuticals Inc.'s direction of the operations and management of Watson Pharma, Inc.

59. On information and belief, Watson Laboratories, Inc., Watson Pharmaceuticals Inc., and Watson Pharma, Inc. operate as an integrated business ultimately controlled by Watson Pharmaceuticals Inc.

60. Watson Laboratories Inc.'s and Watson Pharma, Inc.'s acts and continuous and systematic contacts with the State of Delaware, as an agent of Watson Pharmaceuticals Inc., are also attributable to Watson Pharmaceuticals Inc. for jurisdictional purposes.

61. On information and belief, this Court has personal jurisdiction over Watson Pharmaceuticals Inc. by virtue of, among other things: (1) its presence in Delaware; (2) its sale of a substantial volume of prescription drugs in Delaware; (3) its prior consent to be sued in Delaware; (4) its systematic and continuous contacts with Delaware, including those made through Watson Laboratories, Inc. and Watson Pharma, Inc.; and (5) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

62. On information and belief, Amerigen Pharmaceuticals, Inc. is in the business of marketing and selling generic prescription pharmaceutical drugs that it distributes, or plans to distribute, in Delaware and throughout the United States. On information and belief, the acts of Amerigen Pharmaceuticals, Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Amerigen Pharmaceuticals Ltd. In its letter dated February 16, 2012, notifying Plaintiffs of its submission to the FDA of ANDA No. 203659 for Amerigen's generic nebivolol hydrochloride tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg (the "Amerigen Notice Letter"), Amerigen Pharmaceuticals Inc. stated that it in filing its ANDA, it was "acting as the US Agent for Amerigen Pharmaceuticals Ltd."

63. In its press releases (*see, e.g.*, http://www.amerigenpharma.com/?p=1192), Amerigen describes itself as "a group of companies engaged in all phases of the generic pharmaceutical business, with operations in the US and China." Its press releases also state that the "US regulatory and commercial activities within the group are conducted by Amerigen Pharmaceuticals Inc., based in East Brunswick, NJ, USA," and that the Amerigen group of companies "is controlled by Amerigen Pharmaceuticals Limited." Its press releases also state

that the "group has an active portfolio of products under development, filed, or intended for filing, as ANDA's with the US FDA."

64. On information and belief, this Court has personal jurisdiction over Amerigen Pharmaceuticals, Inc. by virtue of, among other things: (1) its incorporation in the state of Delaware; (2) its registration to do business in Delaware, including its appointment of a registered agent in Delaware (located at Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, DE 19808) for the receipt of service of process; and (3) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

65. On information and belief, Amerigen Pharmaceuticals Ltd., directly or through Amerigen Pharmaceuticals, Inc. and/or through one or more of its subsidiaries, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes, or plans to distribute, in Delaware and throughout the United States.

66. Amerigen Pharmaceuticals, Inc.'s acts and continuous and systematic contacts with the State of Delaware, as an agent of Amerigen Pharmaceuticals Ltd., are also attributable to Amerigen Pharmaceuticals Ltd. for jurisdictional purposes.

67. On information and belief, Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd. operate as an integrated business ultimately controlled by Amerigen Pharmaceuticals Ltd. For example, in its press releases (*see, e.g.*, http://www.amerigenpharma.com/?p=1192), Amerigen describes itself as "a group of companies engaged in all phases of the generic pharmaceutical business, with operations in the US and China," and that the Amerigen group of companies, including Amerigen Pharmaceuticals, Inc., "is controlled by Amerigen Pharmaceuticals Limited."

68. On information and belief, this Court has personal jurisdiction over Amerigen Pharmaceuticals Ltd. by virtue of, among other things: (1) its presence in Delaware, including through Amerigen Pharmaceuticals Inc.; and (2) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

69. Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals Ltd. have submitted to the personal jurisdiction of the United States District Court for the District of Delaware at least in *Daiichi Sankyo, Inc., et al. v. Impax Labs., Inc., et al.*, 1:10-cv-0097 (NLH) (AMD).

70. In its letter dated February 17, 2012, notifying Plaintiffs of its submission to the FDA of ANDA No. 203821 for Glenmark's generic nebivolol hydrochloride tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg (the "Glenmark Notice Letter"), Glenmark stated that "Glenmark Generics, Inc." submitted the ANDA, and the letter was signed by Dr. Vijay Soni, "Executive Vice President - IP, Glenmark Generics, Inc." The letterhead on which the Glenmark Notice Letter was written displayed "Glenmark Generics Inc., USA." On information and belief, Glenmark Generics Inc., USA submitted ANDA No. 203821 with the FDA, and references in the Glenmark Notice Letter to "Glenmark Generics Inc." referred to Glenmark Generics Inc., USA.

71. On information and belief, Glenmark Generics Inc., USA is in the business of marketing and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Glenmark Generics Inc., USA, either directly or through one or more of its subsidiaries, agents, and/or distributors, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware. On information and belief, the acts of Glenmark Generics Inc., USA complained of herein were

done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Glenmark Generics Ltd. and Glenmark Pharmaceuticals Ltd.

72. On information and belief, this Court has personal jurisdiction over Glenmark Generics Inc., USA by virtue of, among other things: (1) its incorporation in the state of Delaware; (2) its registration to do business in Delaware, including its appointment of a registered agent in Delaware (located at National Registered Agents, Inc., 160 Greentree Drive, Suite 101, Dover, DE 19904) for the receipt of service of process; (3) its sale of a substantial volume of prescription drugs in Delaware; (4) its prior consent to be sued in Delaware; (5) its systematic and continuous contacts with Delaware; and (6) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

73. On information and belief, Glenmark Generics Ltd., directly or through Glenmark Generics Inc., USA and/or through one or more of its subsidiaries, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Glenmark Generics Ltd., either directly or through Glenmark Generics Inc., USA and/or through one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware.

74. On information and belief, this Court has personal jurisdiction over Glenmark Generics Ltd. by virtue of, among other things: (1) its presence in Delaware; (2) its sale of a substantial volume of prescription drugs in Delaware; (3) its prior consent to be sued in Delaware; (4) its systematic and continuous contacts with Delaware, including those made through Glenmark Generics Inc., USA; and (5) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

75. On information and belief, Glenmark Pharmaceuticals Ltd., directly or through Glenmark Generics Inc., USA, Glenmark Generics Ltd., and/or through one or more of its subsidiaries, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Glenmark Pharmaceuticals Ltd., either directly or through Glenmark Generics Inc., USA, Glenmark Generics Ltd., and/or through one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware.

76. On information and belief, Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals Ltd. operate as an integrated business ultimately controlled by Glenmark Pharmaceuticals Ltd. For example, the "About Us" page of Glenmark Generics Inc., USA's website, located at http://us.glenmark-generics.com/, states that "Glenmark Generics Inc. (CGI), USA is the North American division of Glenmark Generics Ltd." In its press releases (*see, e.g.*, http://www.glenmark-generics.com/Media/ViewRelease/d499e48e-614f-4d80-ba65-17bb859324e6), Glenmark states that Glenmark Generics Inc., USA is a "subsidiary of Glenmark Generics Ltd.," and that Glenmark Generics Ltd. "is a subsidiary of Glenmark Pharmaceuticals Limited and aims to be a global integrated Generic and API leader."

77. On information and belief, this Court has personal jurisdiction over Glenmark Pharmaceuticals Ltd. by virtue of, among other things: (1) its presence in Delaware; (2) its sale of a substantial volume of prescription drugs in Delaware; (3) its prior consent to be sued in Delaware; (4) its systematic and continuous contacts with Delaware, including those made through Glenmark Generics Inc., USA and/or Glenmark Generics Ltd.; and (5) its course of

conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

78. On information and belief, Hetero USA Inc. is in the business of marketing and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Hetero USA Inc., either directly or through one or more of its subsidiaries, agents, and/or distributors, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware. On information and belief, the acts of Hetero USA Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Hetero Labs Ltd. In its letter dated February 17, 2012, notifying Plaintiffs of its submission to the FDA of ANDA No. 203825 for Hetero's generic nebivolol hydrochloride tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg (the "Hetero Notice Letter"), Hetero USA Inc. described itself as "the U.S. Regulatory Agent for Hetero Labs Limited Unit III."

79. On information and belief, this Court has personal jurisdiction over Hetero USA Inc. by virtue of, among other things: (1) its incorporation in the state of Delaware; (2) its registration to do business in Delaware, including its appointment of a registered agent in Delaware (located at W/K Incorporating Services, Inc., 3500 South Dupont Highway, Dover, DE 19901) for the receipt of service of process; and (3) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

80. On information and belief, Hetero Labs Ltd., directly or through Hetero USA Inc. and/or through one or more of its subsidiaries, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Hetero Labs Ltd., either directly or

through Hetero USA Inc. and/or through one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware.

81. On information and belief, Hetero Labs Limited Unit III is a division or part of Hetero Labs Ltd. Hetero Labs Ltd.'s website, located at http://www.heterodrugs.com/mfg-infrastructure.shtml, describes Unit III as a manufacturing facility of Hetero Labs Ltd.

82. Hetero USA Inc.'s acts and continuous and systematic contacts with the State of Delaware, as an agent of Hetero Labs Ltd., are also attributable to Hetero Labs Ltd. for jurisdictional purposes.

83. On information and belief, Hetero USA Inc. and Hetero Labs Ltd. operate as an integrated business ultimately controlled by Hetero Labs Ltd.

84. On information and belief, this Court has personal jurisdiction over Hetero Labs Ltd. by virtue of, among other things: (1) its presence in Delaware, including through Hetero USA Inc.; and (2) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware.

BACKGROUND

85. Bystolic® contains nebivolol hydrochloride (a beta-adrenergic blocking agent or "beta blocker"). According to its approved label, Nebivolol is a racemate composed of d-Nebivolol and l-Nebivolol with the stereochemical designations of [SRRR]-nebivolol and [RSSS]-nebivolol, respectively. Bystolic® "is indicated for the treatment of hypertension, to lower blood pressure."

INFRINGEMENT OF U.S. PATENT NO. 6,545,040

86. Plaintiffs incorporate each of the preceding paragraphs 1-85 as if fully stated herein.

87. On April 8, 2003, the United States Patent and Trademark Office ("USPTO") issued the '040 Patent to Janssen Pharmaceutica N.V. A true and correct copy of the '040 Patent is attached hereto as **Exhibit A**. The '040 Patent was submitted to the USPTO for *ex parte* reexamination on January 26, 2007. On February 17, 2009, the USPTO issued an *Ex Parte* Reexamination Certificate for the '040 Patent, attached hereto as part of **Exhibit A**, stating that "no amendments have been made to the patent," and that the "patentability of claims 1-6 is confirmed."

88. Plaintiff Janssen Pharmaceutica N.V. is the assignee of the '040 Patent.

89. Plaintiff Forest is the exclusive licensee of the '040 Patent. Plaintiff Forest holds New Drug Application ("NDA") No. 021742 for Bystolic® brand nebivolol hydrochloride tablets.

90. Forest is the exclusive distributor of Bystolic® in the United States.

91. Plaintiffs own all rights, title and interest in the '040 Patent, including all rights needed to bring this action in Plaintiffs' own names.

92. Bystolic® and its use in the treatment of hypertension are covered by one or more claims of the '040 Patent, and the '040 Patent has been listed in connection with Bystolic® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book," as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Bystolic®.

93. In the Torrent Notice Letter, Torrent Pharmaceuticals Ltd. notified Plaintiffs that it had submitted to the FDA ANDA No. 203966, for Torrent's nebivolol hydrochloride, 2.5 mg, 5 mg, 10 mg, and 20 mg, drug products that are generic versions of Bystolic® ("Torrent's ANDA

Products"). The purpose of the submission of the ANDA was to obtain permission under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent's ANDA Products prior to the expiration of the '040 Patent. Plaintiffs received the Torrent Notice Letter on or around February 2, 2012.

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

95. In the Torrent Notice Letter, Torrent also notified Plaintiffs that, as a part of its ANDA, Torrent had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '040 Patent. On information and belief, Torrent submitted ANDA No. 203966 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '040 Patent is invalid and/or will not be infringed by the manufacture, use, offer for sale, or sale of Torrent's ANDA Products.

96. Torrent's ANDA Products are covered by one or more claims of the '040 Patent.

97. Torrent's filing of ANDA No. 203966 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent's ANDA Products before the expiration date of the '040 Patent is an act of infringement of the '040 Patent, under 35 U.S.C. § 271(e)(2)(A).

98. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Torrent's ANDA Products would infringe one or more claims of the '040 Patent.

99. On information and belief, the use of Torrent's ANDA Products in accordance with and as directed by Torrent's proposed labeling for that product would infringe one or more claims of the '040 Patent.

100. On information and belief, unless enjoined by this Court, Torrent intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Torrent's ANDA Products with its proposed labeling immediately and imminently upon approval of ANDA No. 203966.

101. On information and belief, unless enjoined by this Court, Torrent plans and intends to, and will, actively induce infringement of the '040 Patent when its ANDA No. 203966 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

102. Torrent had knowledge of the '040 Patent when it submitted ANDA No. 203966.

103. On information and belief, Torrent knows that Torrent's ANDA Products and its proposed labeling are especially made or adapted for use in infringing the '040 Patent, and that Torrent's ANDA Products and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, unless enjoined by this Court, Torrent plans and intends to, and will, contribute to the infringement of the '040 Patent immediately and imminently upon approval of ANDA No. 203966.

104. The foregoing actions by Torrent constitute and/or will constitute infringement of the '040 Patent, active inducement of infringement of the '040 Patent, and/or contribution to the infringement by others of the '040 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

105. On information and belief, Torrent acted without a reasonable basis for believing that it would not be liable for infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement by others of the '040 Patent.

106. Unless Torrent is enjoined from infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement of the '040 Patent, Plaintiffs will suffer irreparable injury.

107. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 203966 to be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent, or any extension of that expiration date that might arise after the filing of this Complaint.

108. In its letter dated February 10, 2012, notifying Plaintiffs of its submission to the FDA of ANDA No. 203683 for Watson's generic nebivolol hydrochloride tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg (the "Watson Notice Letter"), Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), or Watson Laboratories, Inc. (CT) notified Plaintiffs that it had submitted to the FDA ANDA No. 203683, for Watson's nebivolol hydrochloride, 2.5 mg, 5 mg, 10 mg, and 20 mg, drug products that are generic versions of Bystolic® ("Watson's ANDA Products"). The purpose of the submission of the ANDA was to obtain permission under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Watson's ANDA Products prior to the expiration of the '040 Patent. Plaintiffs received the Watson Notice Letter on or around February 13, 2012.

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

110. In the Watson Notice Letter, Watson also notified Plaintiffs that, as a part of its ANDA, Watson had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '040 Patent. On information

and belief, Watson submitted ANDA No. 203683 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '040 Patent is invalid and/or will not be infringed by the manufacture, use, offer for sale, or sale of Watson's ANDA Products.

111. Watson's ANDA Products are covered by one or more claims of the '040 Patent.

112. Watson's filing of ANDA No. 203683 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Watson's ANDA Products before the expiration date of the '040 Patent is an act of infringement of the '040 Patent, under 35 U.S.C. § 271(e)(2)(A).

113. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Watson's ANDA Products would infringe one or more claims of the '040 Patent.

114. On information and belief, the use of Watson's ANDA Products in accordance with and as directed by Watson's proposed labeling for that product would infringe one or more claims of the '040 Patent.

115. On information and belief, unless enjoined by this Court, Watson intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Watson's ANDA Products with its proposed labeling immediately and imminently upon approval of ANDA No. 203683.

116. On information and belief, unless enjoined by this Court, Watson plans and intends to, and will, actively induce infringement of the '040 Patent when its ANDA No. 203683 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

117. Watson had knowledge of the '040 Patent when it submitted ANDA No. 203683.

118. On information and belief, Watson knows that Watson's ANDA Products and its proposed labeling are especially made or adapted for use in infringing the '040 Patent, and that Watson's ANDA Products and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, unless enjoined by this Court, Watson plans and intends to, and will, contribute to the infringement of the '040 Patent immediately and imminently upon approval of ANDA No. 203683.

119. The foregoing actions by Watson constitute and/or will constitute infringement of the '040 Patent, active inducement of infringement of the '040 Patent, and/or contribution to the infringement by others of the '040 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

120. On information and belief, Watson acted without a reasonable basis for believing that it would not be liable for infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement by others of the '040 Patent.

121. Unless Watson is enjoined from infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement of the '040 Patent, Plaintiffs will suffer irreparable injury.

122. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 203683 to be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent, or any extension of that expiration date that might arise after the filing of this Complaint.

123. In the Amerigen Notice Letter, Amerigen Pharmaceuticals, Inc. notified Plaintiffs that it had submitted to the FDA ANDA No. 203659, for Amerigen's nebivolol hydrochloride, 2.5 mg, 5 mg, 10 mg, and 20 mg, drug products that are generic versions of Bystolic®

("Amerigen's ANDA Products"). The purpose of the submission of the ANDA was to obtain permission under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Amerigen's ANDA Products prior to the expiration of the '040 Patent. Plaintiffs received the Amerigen Notice Letter on or around February 16, 2012.

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

125. In the Amerigen Notice Letter, Amerigen also notified Plaintiffs that, as a part of its ANDA, Amerigen had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '040 Patent. On information and belief, Amerigen submitted ANDA No. 203659 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '040 Patent is invalid and/or will not be infringed by the manufacture, use, offer for sale, or sale of Amerigen's ANDA Products.

126. Amerigen's ANDA Products are covered by one or more claims of the '040 Patent.

127. Amerigen's filing of ANDA No. 203659 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Amerigen's ANDA Products before the expiration date of the '040 Patent is an act of infringement of the '040 Patent, under 35 U.S.C. § 271(e)(2)(A).

128. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Amerigen's ANDA Products would infringe one or more claims of the '040 Patent.

129. On information and belief, the use of Amerigen's ANDA Products in accordance with and as directed by Amerigen's proposed labeling for that product would infringe one or more claims of the '040 Patent.

130. On information and belief, unless enjoined by this Court, Amerigen intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Amerigen's ANDA Products with its proposed labeling immediately and imminently upon approval of ANDA No. 203659.

131. On information and belief, unless enjoined by this Court, Amerigen plans and intends to, and will, actively induce infringement of the '040 Patent when its ANDA No. 203659 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

132. Amerigen had knowledge of the '040 Patent when it submitted ANDA No. 203659.

133. On information and belief, Amerigen knows that Amerigen's ANDA Products and its proposed labeling are especially made or adapted for use in infringing the '040 Patent, and that Amerigen's ANDA Products and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, unless enjoined by this Court, Amerigen plans and intends to, and will, contribute to the infringement of the '040 Patent immediately and imminently upon approval of ANDA No. 203659.

134. The foregoing actions by Amerigen constitute and/or will constitute infringement of the '040 Patent, active inducement of infringement of the '040 Patent, and/or contribution to the infringement by others of the '040 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

135. On information and belief, Amerigen acted without a reasonable basis for believing that it would not be liable for infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement by others of the '040 Patent.

136. Unless Amerigen is enjoined from infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement of the '040 Patent, Plaintiffs will suffer irreparable injury.

137. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 203659 to be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent, or any extension of that expiration date that might arise after the filing of this Complaint.

138. In the Glenmark Notice Letter, Glenmark Generics Inc. notified Plaintiffs that it had submitted to the FDA ANDA No. 203821, for Glenmark's nebivolol hydrochloride, 2.5 mg, 5 mg, 10 mg, and 20 mg, drug products that are generic versions of Bystolic® (''Glenmark's ANDA Products''). The purpose of the submission of the ANDA was to obtain permission under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Glenmark's ANDA Products prior to the expiration of the '040 Patent. Plaintiffs received the Glenmark Notice Letter on or around February 20, 2012.

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

140. In the Glenmark Notice Letter, Glenmark also notified Plaintiffs that, as a part of its ANDA, Glenmark had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '040

Patent. On information and belief, Glenmark submitted ANDA No. 203821 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '040 Patent is invalid and/or will not be infringed by the manufacture, use, offer for sale, or sale of Glenmark's ANDA Products.

141. Glenmark's ANDA Products are covered by one or more claims of the '040 Patent.

142. Glenmark's filing of ANDA No. 203821 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Glenmark's ANDA Products before the expiration date of the '040 Patent is an act of infringement of the '040 Patent, under 35 U.S.C. § 271(e)(2)(A).

143. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Glenmark's ANDA Products would infringe one or more claims of the '040 Patent.

144. On information and belief, the use of Glenmark's ANDA Products in accordance with and as directed by Glenmark's proposed labeling for that product would infringe one or more claims of the '040 Patent.

145. On information and belief, unless enjoined by this Court, Glenmark intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Glenmark's ANDA Products with its proposed labeling immediately and imminently upon approval of ANDA No. 203821.

146. On information and belief, unless enjoined by this Court, Glenmark plans and intends to, and will, actively induce infringement of the '040 Patent when its ANDA No. 203821

is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

147. Glenmark had knowledge of the '040 Patent when it submitted ANDA No. 203821.

148. On information and belief, Glenmark knows that Glenmark's ANDA Products and its proposed labeling are especially made or adapted for use in infringing the '040 Patent, and that Glenmark's ANDA Products and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, unless enjoined by this Court, Glenmark plans and intends to, and will, contribute to the infringement of the '040 Patent immediately and imminently upon approval of ANDA No. 203821.

149. The foregoing actions by Glenmark constitute and/or will constitute infringement of the '040 Patent, active inducement of infringement of the '040 Patent, and/or contribution to the infringement by others of the '040 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

150. On information and belief, Glenmark acted without a reasonable basis for believing that it would not be liable for infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement by others of the '040 Patent.

151. Unless Glenmark is enjoined from infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement of the '040 Patent, Plaintiffs will suffer irreparable injury.

152. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 203821 to be a date which is not earlier than December 17, 2021, the current expiration date of

the '040 Patent, or any extension of that expiration date that might arise after the filing of this Complaint.

153. In the Hetero Notice Letter, Hetero USA Inc. notified Plaintiffs that it had submitted to the FDA ANDA No. 203825, for Hetero's nebivolol hydrochloride, 2.5 mg, 5 mg, 10 mg, and 20 mg, drug products that are generic versions of Bystolic® ("Hetero's ANDA Products"). The purpose of the submission of the ANDA was to obtain permission under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Hetero's ANDA Products prior to the expiration of the '040 Patent. Plaintiffs received the Hetero Notice Letter on or around February 20, 2012.

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

155. In the Hetero Notice Letter, Hetero also notified Plaintiffs that, as a part of its ANDA, Hetero had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '040 Patent. On information and belief, Hetero submitted ANDA No. 203825 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '040 Patent is invalid and/or will not be infringed by the manufacture, use, offer for sale, or sale of Hetero's ANDA Products.

156. Hetero's ANDA Products are covered by one or more claims of the '040 Patent.

157. Hetero's filing of ANDA No. 203825 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Hetero's ANDA Products before the expiration date of the '040 Patent is an act of infringement of the '040 Patent, under 35 U.S.C. § 271(e)(2)(A).

158. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Hetero's ANDA Products would infringe one or more claims of the '040 Patent.

159. On information and belief, the use of Hetero's ANDA Products in accordance with and as directed by Hetero's proposed labeling for that product would infringe one or more claims of the '040 Patent.

160. On information and belief, unless enjoined by this Court, Hetero intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Hetero's ANDA Products with its proposed labeling immediately and imminently upon approval of ANDA No. 203825.

161. On information and belief, unless enjoined by this Court, Hetero plans and intends to, and will, actively induce infringement of the '040 Patent when its ANDA No. 203825 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

162. Hetero had knowledge of the '040 Patent when it submitted ANDA No. 203825.

163. On information and belief, Hetero knows that Hetero's ANDA Products and its proposed labeling are especially made or adapted for use in infringing the '040 Patent, and that Hetero's ANDA Products and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, unless enjoined by this Court, Hetero plans and intends to, and will, contribute to the infringement of the '040 Patent immediately and imminently upon approval of ANDA No. 203825.

164. The foregoing actions by Hetero constitute and/or will constitute infringement of the '040 Patent, active inducement of infringement of the '040 Patent, and/or contribution to the infringement by others of the '040 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

165. On information and belief, Hetero acted without a reasonable basis for believing that it would not be liable for infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement by others of the '040 Patent.

166. Unless Hetero is enjoined from infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement of the '040 Patent, Plaintiffs will suffer irreparable injury.

167. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 203825 to be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent, or any extension of that expiration date that might arise after the filing of this Complaint.

168. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

A. A declaration that the '040 Patent is valid and enforceable;

B. A judgment that the '040 Patent would be infringed by Torrent's ANDA Products; that submission of ANDA No. 203966 is an act of infringement of the '040 Patent; and that Torrent's making, using, offering to sell, selling, marketing, distributing, or importing Torrent's ANDA Products, or any product or compound that infringes the '040 Patent, prior to the expiration date of the '040 Patent, would infringe, actively induce infringement, and contribute to the infringement of the '040 Patent;

C. An Order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Torrent's ANDA No. 203966, or any product or compound that infringes

the '040 Patent, shall be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent, or any extensions thereof;

D. An Order permanently enjoining Torrent, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Torrent's ANDA Products, or any other product or compound, not colorably different, that infringes the '040 Patent, or inducing or contributing to the infringement of the '040 Patent until after the expiration of the '040 Patent;

E. Damages or other monetary relief, including prejudgment interest, if Torrent engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Torrent's ANDA Products, or any product or compound that infringes the '040 Patent, or the inducement or contribution of the foregoing, prior to the expiration of the '040 Patent;

F. A judgment that the '040 Patent would be infringed by Watson's ANDA Products; that submission of ANDA No. 203683 is an act of infringement of the '040 Patent; and that Watson's making, using, offering to sell, selling, marketing, distributing, or importing Watson's ANDA Products, or any product or compound that infringes the '040 Patent, prior to the expiration date of the '040 Patent, would infringe, actively induce infringement, and contribute to the infringement of the '040 Patent;

G. An Order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Watson's ANDA No. 203683, or any product or compound that infringes the '040 Patent, shall be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent, or any extensions thereof;

H. An Order permanently enjoining Watson, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Watson's ANDA Products, or any other product or compound, not colorably different, that infringes the '040 Patent, or inducing or contributing to the infringement of the '040 Patent until after the expiration of the '040 Patent;

I. Damages or other monetary relief, including prejudgment interest, if Watson engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Watson's ANDA Products, or any product or compound that infringes the '040 Patent, or the inducement or contribution of the foregoing, prior to the expiration of the '040 Patent;

J. A judgment that the '040 Patent would be infringed by Amerigen's ANDA Products; that submission of ANDA No. 203659 is an act of infringement of the '040 Patent; and that Amerigen's making, using, offering to sell, selling, marketing, distributing, or importing Amerigen's ANDA Products, or any product or compound that infringes the '040 Patent, prior to the expiration date of the '040 Patent, would infringe, actively induce infringement, and contribute to the infringement of the '040 Patent;

K. An Order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Amerigen's ANDA No. 203659, or any product or compound that infringes the '040 Patent, shall be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent, or any extensions thereof;

L. An Order permanently enjoining Amerigen, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Amerigen's ANDA Products, or any other product

or compound, not colorably different, that infringes the '040 Patent, or inducing or contributing to the infringement of the '040 Patent until after the expiration of the '040 Patent;

M. Damages or other monetary relief, including prejudgment interest, if Amerigen engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Amerigen's ANDA Products, or any product or compound that infringes the '040 Patent, or the inducement or contribution of the foregoing, prior to the expiration of the '040 Patent;

N. A judgment that the '040 Patent would be infringed by Glenmark's ANDA Products; that submission of ANDA No. 203821 is an act of infringement of the '040 Patent; and that Glenmark's making, using, offering to sell, selling, marketing, distributing, or importing Glenmark's ANDA Products, or any product or compound that infringes the '040 Patent, prior to the expiration date of the '040 Patent, would infringe, actively induce infringement, and contribute to the infringement of the '040 Patent;

O. An Order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Glenmark's ANDA No. 203821, or any product or compound that infringes the '040 Patent, shall be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent, or any extensions thereof;

P. An Order permanently enjoining Glenmark, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Glenmark's ANDA Products, or any other product or compound, not colorably different, that infringes the '040 Patent, or inducing or contributing to the infringement of the '040 Patent until after the expiration of the '040 Patent;

Q. Damages or other monetary relief, including prejudgment interest, if Glenmark engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Glenmark's ANDA Products, or any product or compound that infringes the '040 Patent, or the inducement or contribution of the foregoing, prior to the expiration of the '040 Patent;

R. A judgment that the '040 Patent would be infringed by Hetero's ANDA Products; that submission of ANDA No. 203825 is an act of infringement of the '040 Patent; and that Hetero's making, using, offering to sell, selling, marketing, distributing, or importing Hetero's ANDA Products, or any product or compound that infringes the '040 Patent, prior to the expiration date of the '040 Patent, would infringe, actively induce infringement, and contribute to the infringement of the '040 Patent;

S. An Order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Hetero's ANDA No. 203825, or any product or compound that infringes the '040 Patent, shall be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent, or any extensions thereof;

T. An Order permanently enjoining Hetero, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Hetero's ANDA Products, or any other product or compound, not colorably different, that infringes the '040 Patent, or inducing or contributing to the infringement of the '040 Patent until after the expiration of the '040 Patent;

U. Damages or other monetary relief, including prejudgment interest, if Hetero engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Hetero's ANDA Products, or any product or compound that infringes the '040

Patent, or the inducement or contribution of the foregoing, prior to the expiration of the '040 Patent;

V. A declaration that this is an exceptional case and an award of attorneys' fees to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

W. Plaintiffs' reasonable costs of suit incurred; and

X. Such other and further relief as this Court may deem just and proper.

Dated: March 13, 2012

Respectfully submitted,

/s/ Mary W. Bourke
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