

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES and ABBOTT	)	
RESPIRATORY LLC,	)	
	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
	)	
MYLAN INC. and MYLAN	)	
PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

**COMPLAINT**

Plaintiffs Abbott Laboratories and Abbott Respiratory LLC (collectively, “Abbott”), for their Complaint against Defendants Mylan Inc. and Mylan Pharmaceuticals, Inc. (collectively, “Mylan”), hereby allege as follows:

**Nature of the Action**

This is an action for patent infringement of U.S. Patent Nos. 6,080,428 (“the ’428 patent”), 6,129,930 (“the ’930 patent”), 6,406,715 (“the ’715 patent”), 6,469,035 (“the ’035 patent”), 6,676,967 (“the ’967 patent”), 6,746,691 (“the ’691 patent”), 6,818,229 (“the ’229 patent”), and 7,011,848 (“the ’848 patent”), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to Abbreviated New Drug Application (“ANDA”) No. 20-1521 filed by Mylan with the U.S. Food and Drug Administration (“FDA”) for approval to market 1000 mg / 20 mg, 750 mg / 20 mg, and 500 mg / 20 mg niacin extended release / simvastatin tablets, which are generic versions of the 1000 mg / 20 mg, 750 mg / 20 mg, and 500 mg / 20 mg forms of Abbott’s SIMCOR<sup>®</sup> drug product.

**Related Actions**

Abbott has filed several other patent infringement actions currently pending before the Court as described below:

- *Abbott Laboratories v. Lupin Ltd.*, No. 09-152-JJF-LPS (D. Del.), which relates to ANDA Nos. 90-4446, 90-860, and 90-892 filed by Lupin for approval to market generic versions of NIASPAN<sup>®</sup>, and involves the '930, '715, '967, '691, '848, '229, and '428 patents.
- *Abbott Laboratories v. Teva Pharmaceutical Industries, Ltd.*, No. 10-57-SLR-LPS (D. Del.), and *Abbott Laboratories v. Teva Pharmaceutical Industries, Ltd.*, No. 10-302-SLR-LPS (D. Del.), which relate to ANDA No. 20-0478 filed by Teva for approval to market generic versions of SIMCOR<sup>®</sup>, and involve the '930, '715, '035, '967, '691, '848, '229, and '428 patents.
- *Abbott Laboratories v. Sun Pharmaceutical Industries Ltd.*, No. 10-112-SLR (D. Del.), and *Abbott Laboratories v. Sun Pharmaceutical Industries Ltd.*, No. 10-488-SLR (D. Del.), which relate to ANDA Nos. 20-0484 and 20-1273 filed by Sun for approval to market generic versions of NIASPAN<sup>®</sup>, and involve the '428 and '035 patents.
- *Abbott Laboratories v. Watson Pharmaceuticals, Inc.*, No. 10-373-SLR (D. Del.), which relates to ANDA No. 20-0601 filed by Watson for approval to market a generic version of SIMCOR<sup>®</sup>, and involves the '930, '715, '035, '967, '691, '848, '229, and '428 patents.

- *Abbott Laboratories v. Sandoz Inc.*, No. 10-538 (D. Del.), which relates to ANDA No. 20-1403 filed by Sandoz for approval to market a generic version of NIASPAN<sup>®</sup>, and involves the '429, '035, and '229 patents.

### **Parties**

1. Abbott Laboratories is a corporation organized and existing under the laws of the State of Illinois, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

2. Abbott Respiratory LLC (“Abbott Respiratory”) is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Upon information and belief, Mylan Inc. is in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for the U.S. market through various directly or indirectly owned operating subsidiaries, including Mylan Pharmaceuticals, Inc. (“Mylan Pharmaceuticals”).

4. Upon information and belief, Mylan Pharmaceuticals is a corporation organized and existing under the laws of the State of West Virginia, with its headquarters at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc. Upon information and belief, Mylan Pharmaceuticals is in the business of, among other things, developing and manufacturing generic copies of branded pharmaceutical products for the U.S. market.

5. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals work in concert with one another, and with other Mylan subsidiaries, to develop, manufacture, and market pharmaceutical products throughout the United States, including in this judicial district.

6. Upon information and belief, following any FDA approval of ANDA No. 20-1521, Mylan Inc. and Mylan Pharmaceuticals will work in concert with one another, and with other Mylan subsidiaries, to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 20-1521 throughout the United States, and/or import such generic products into the United States.

#### **Jurisdiction and Venue**

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

8. This Court has personal jurisdiction over Mylan Inc. and Mylan Pharmaceuticals because, *inter alia*, they have each committed, or aided, abetted, actively induced, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 20-1521 that has led to foreseeable harm and injury to Abbott Respiratory, a Delaware corporation, and Abbott Laboratories, a corporation actively engaged in business in Delaware.

9. This Court also has personal jurisdiction over Mylan Inc. and Mylan Pharmaceuticals because, *inter alia*, they have purposely availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court here. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals have had persistent,

systematic and continuous contacts with Delaware, Del. Code. Ann. tit. 10, § 3104(c)(4), as set forth below, and for other reasons that will be presented to the Court if jurisdiction is challenged.

10. According to Mylan Inc.'s website, "Mylan is one of the world's leading generics and specialty pharmaceutical companies, providing products to customers in more than 140 countries and territories," and is "[t]he second largest generic pharmaceutical company in the U.S. by sales volume."

11. According to Mylan Pharmaceuticals' website, "Mylan Pharmaceuticals has one of the largest product portfolios in the U.S., consisting of more than 200 products. According to IMS Health, one of every 12 prescriptions dispensed in the U.S. is a Mylan product."

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

13. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals operate as an integrated, unitary generic pharmaceutical business. For example, Mylan Inc. includes within its Annual Report the activities of Mylan Pharmaceuticals, including the revenues earned. The Mylan website, appearing at [www.mylan.com](http://www.mylan.com), provides information about both Mylan Inc. and Mylan Pharmaceuticals. Mylan Inc. is divided into several business units, including the "Generics" business. Upon information and belief, Mylan Pharmaceuticals, in whole or in part, comprises this "Generics" business, particularly within the United States.

14. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals have overlapping officers and directors, with management and operation of Mylan Pharmaceuticals and the Generics business occurring, at least in part, at the respective headquarters of both Mylan Inc. and Mylan Pharmaceuticals. Upon information and belief, Mylan Inc. issues press releases when generic drugs are approved by the FDA or when other events concerning the commercialization of a generic drug occurs involving its Generics business.

15. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals conduct business throughout the United States, including Delaware, under the trade name “Mylan Pharmaceuticals.” Upon information and belief, Mylan Pharmaceuticals, under its “Mylan Pharmaceuticals” trade name, is registered pursuant to Del. Code Ann. tit. 24, § 2540 to distribute its generic pharmaceutical products in the Delaware and holds current and valid “Distributor/Manufacturer CSR” and “Pharmacy-Wholesale” licenses from the Delaware Board of Pharmacy. Mylan Pharmaceuticals is also registered to do business in Delaware and has appointed a registered agent in Delaware for service of process.

16. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals derive substantial revenue from generic pharmaceutical products that are sold, used, and/or consumed within Delaware.

17. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals have previously availed themselves of this forum for the purpose of litigating patent disputes. For example, in 2010, Mylan Inc. and Mylan Pharmaceuticals sought a declaratory judgment of noninfringement, unenforceability, and/or invalidity in *Mylan Pharmaceuticals Inc. v. Eurand, Inc.*, No. 10-306-SLR (D. Del.). Mylan Inc. and/or Mylan Pharmaceuticals have also submitted to this Court’s jurisdiction by asserting counterclaims in other civil actions in this jurisdiction.

Specifically, Mylan Inc. and/or Mylan Pharmaceuticals admitted jurisdiction for the purpose of the litigation and filed counterclaims in *Forest Laboratories, Inc. v. Dr. Reddy's Laboratories, Inc.*, No. 08-52-GMS-LPS (D. Del.); *AstraZeneca Pharmaceuticals LP v. Mylan Pharmaceuticals, Inc.*, No. 07-805-JJF (D. Del.); *Sciele Pharma, Inc. v. Mylan Pharmaceuticals, Inc.*, No. 07-664-GMS-LPS (D. Del.); *Sanofi-Aventis v. Actavis South Atlantic LLC*, No. 07-572-GMS (D. Del.); *Boehringer Ingelheim International GMBH v. Mylan Pharmaceuticals Inc.*, No. 05-854-JJF (D. Del.); *Janssen Pharmaceutica N.V. v. Mylan Pharmaceuticals Inc.*, No. 05-371-SLR (D. Del.); and *AstraZeneca LP v. Mylan Pharmaceuticals, Inc.*, No. 08-453-GMS (D. Del.).

#### **Patents in Suit**

18. Abbott Respiratory is the owner by assignment of the '428 patent, entitled "Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Thereof," which the U.S. Patent and Trademark Office duly and legally issued on June 27, 2000. A true and correct copy of the '428 patent is attached hereto as Exhibit A. The claims of the '428 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '428 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '428 patent.

19. Abbott Respiratory is the owner by assignment of the '930 patent, entitled "Methods and Sustained Release Nicotinic Acid Compositions for Treating Hyperlipidemia at Night," which the U.S. Patent and Trademark Office duly and legally issued on October 10, 2000. A true and correct copy of the '930 patent is attached hereto as Exhibit B. The claims of the '930 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the

'930 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '930 patent.

20. Abbott Respiratory is the owner by assignment of the '715 patent, entitled "Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia Having Unique Urinary Metabolite Profiles," which the U.S. Patent and Trademark Office duly and legally issued on June 18, 2002. A true and correct copy of the '715 patent is attached hereto as Exhibit C. The claims of the '715 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '715 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '715 patent.

21. Abbott Respiratory is the owner by assignment of the '035 patent, entitled "Methods of Pretreating Hyperlipidemic Individuals with a Flush Inhibiting Agent Prior to the Start of Single Daily Dose Nicotinic Acid Therapy to Reduce Flushing Provoked by Nicotinic Acid," which the U.S. Patent and Trademark Office duly and legally issued on October 22, 2002. A true and correct copy of the '035 patent is attached hereto as Exhibit D. The claims of the '035 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '035 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '035 patent.

22. Abbott Respiratory is the owner by assignment of the '967 patent, entitled "Methods for Reducing Flushing in Individuals Being Treated with Nicotinic Acid for Hyperlipidemia," which the U.S. Patent and Trademark Office duly and legally issued on January 13, 2004. A true and correct copy of the '967 patent is attached hereto as Exhibit E. The claims of the '967 patent are valid and enforceable. Abbott Laboratories is an exclusive

licensee of the '967 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '967 patent.

23. Abbott Respiratory is the owner by assignment of the '691 patent, entitled "Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia Having Unique Biopharmaceutical Characteristics," which the U.S. Patent and Trademark Office duly and legally issued on June 8, 2004. A true and correct copy of the '691 patent is attached hereto as Exhibit F. The claims of the '691 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '691 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '691 patent.

24. Abbott Respiratory is the owner by assignment of the '229 patent, entitled "Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia," which the U.S. Patent and Trademark Office duly and legally issued on November 16, 2004. A true and correct copy of the '229 patent is attached hereto as Exhibit G. The claims of the '229 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '229 patent with respect to SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '229 patent.

25. Abbott Respiratory is the owner by assignment of the '848 patent, which bears on its face the title "Hydrophobic Component Free Sustained Release Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Therefor," which the U.S. Patent and Trademark Office duly and legally issued on March 14, 2006. A true and correct copy of the '848 patent is attached hereto as Exhibit H. The claims of the '848 patent are valid and enforceable. Abbott Laboratories is an exclusive licensee of the '848 patent with respect to

SIMCOR<sup>®</sup>, with the right to sue for and obtain equitable relief and damages for infringement of the '848 patent.

26. Abbott Laboratories is the holder of New Drug Application (“NDA”) No. 02-2078, by which the FDA granted approval for 500 mg / 20 mg, 750 mg / 20 mg, and 1000 mg / 20 mg strength niacin extended release / simvastatin tablets, which Abbott markets in the United States under the trade name “SIMCOR<sup>®</sup>.” The formulation and dosing of SIMCOR<sup>®</sup> is covered by certain claims of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent and the '848 patent. The FDA’s official publication of approved drugs (the “Orange Book”) includes SIMCOR<sup>®</sup> together with the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent and the '848 patent.

**Infringement by Mylan**

27. By letter dated May 14, 2010 (“the Notice Letter”), Mylan notified Abbott that it had submitted ANDA No. 20-1521 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of generic niacin extended-release / simvastatin tablets before the expiration of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent, and the '848 patent. Upon information and belief, Mylan intends to engage in commercial manufacture, use, and sale of generic niacin extended-release / simvastatin tablets promptly upon receiving FDA approval to do so.

28. By filing ANDA No. 20-1521, Mylan has necessarily represented to the FDA that the components of its generic niacin extended-release / simvastatin tablets have the same active ingredients as those of the corresponding components of SIMCOR<sup>®</sup>, have the same

route of administration, dosage form, and strengths as the corresponding components of SIMCOR<sup>®</sup>, and are bioequivalent to the corresponding components of SIMCOR<sup>®</sup>.

29. In the Notice Letter, Mylan notified Abbott that its ANDA contained a “Paragraph IV certification” asserting that, in Mylan’s opinion, the ’428 patent, the ’930 patent, the ’715 patent, the ’035 patent, the ’967 patent, the ’691 patent, the ’229 patent and the ’848 patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of its generic niacin extended-release / simvastatin tablets.

30. This Complaint is being filed before the expiration of the forty-five days from the date Abbott received the Notice Letter.

**Count I (Infringement of the ’428 Patent)**

31. Each of the preceding paragraphs 1 to 30 is incorporated as if fully set forth.

32. Mylan’s submission of ANDA No. 20-1521 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the ’428 patent constitutes infringement of one or more of the claims of the ’428 patent under 35 U.S.C. § 271(e)(2)(A).

33. Upon FDA approval of Mylan’s ANDA No. 20-1521, Mylan will further infringe the ’428 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

34. Upon information and belief, Mylan had actual and constructive knowledge of the ’428 patent prior to filing ANDA No. 20-1521 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the ’428 patent.

35. If Mylan's infringement of the '428 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**Count II (Infringement of the '930 Patent)**

36. Each of the preceding paragraphs 1 to 35 is incorporated as if fully set forth.

37. Mylan's submission of ANDA No. 20-1521 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '930 patent constitutes infringement of one or more of the claims of the '930 patent under 35 U.S.C. § 271(e)(2)(A).

38. Upon FDA approval of Mylan's ANDA No. 20-1521, Mylan will further infringe the '930 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

39. Upon information and belief, Mylan had actual and constructive knowledge of the '930 patent prior to filing ANDA No. 20-1521 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '930 patent.

40. If Mylan's infringement of the '930 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**Count III (Infringement of the '715 Patent)**

41. Each of the preceding paragraphs 1 to 40 is incorporated as if fully set forth.

42. Mylan's submission of ANDA No. 20-1521 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release /

simvastatin tablets prior to the expiration of the '715 patent constitutes infringement of one or more of the claims of the '715 patent under 35 U.S.C. § 271(e)(2)(A).

43. Upon FDA approval of Mylan's ANDA No. 20-1521, Mylan will further infringe the '715 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

44. Upon information and belief, Mylan had actual and constructive knowledge of the '715 patent prior to filing ANDA No. 20-1521 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '715 patent.

45. If Mylan's infringement of the '715 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**Count IV (Infringement of the '035 Patent)**

46. Each of the preceding paragraphs 1 to 45 is incorporated as if fully set forth.

47. Mylan's submission of ANDA No. 20-1521 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '035 patent constitutes infringement of one or more of the claims of the '035 patent under 35 U.S.C. § 271(e)(2)(A).

48. Upon FDA approval of Mylan's ANDA No. 20-1521, Mylan will further infringe the '035 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

49. Upon information and belief, Mylan had actual and constructive knowledge of the '035 patent prior to filing ANDA No. 20-1521 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '035 patent.

50. If Mylan's infringement of the '035 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**Count V (Infringement of the '967 Patent)**

51. Each of the preceding paragraphs 1 to 50 is incorporated as if fully set forth.

52. Mylan's submission of ANDA No. 20-1521 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '967 patent constitutes infringement of one or more of the claims of the '967 patent under 35 U.S.C. § 271(e)(2)(A).

53. Upon FDA approval of Mylan's ANDA No. 20-1521, Mylan will further infringe the '967 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

54. Upon information and belief, Mylan had actual and constructive knowledge of the '967 patent prior to filing ANDA No. 20-1521 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '967 patent.

55. If Mylan's infringement of the '967 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**Count VI (Infringement of the '691 Patent)**

56. Each of the preceding paragraphs 1 to 55 is incorporated as if fully set forth.

57. Mylan's submission of ANDA No. 20-1521 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '691 patent constitutes infringement of one or more of the claims of the '691 patent under 35 U.S.C. § 271(e)(2)(A).

58. Upon FDA approval of Mylan's ANDA No. 20-1521, Mylan will further infringe the '691 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

59. Upon information and belief, Mylan had actual and constructive knowledge of the '691 patent prior to filing ANDA No. 20-1521 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '691 patent.

60. If Mylan's infringement of the '691 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**Count VII (Infringement of the '229 Patent)**

61. Each of the preceding paragraphs 1 to 60 is incorporated as if fully set forth.

62. Mylan's submission of ANDA No. 20-1521 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '229 patent constitutes infringement of one or more of the claims of the '229 patent under 35 U.S.C. § 271(e)(2)(A).

63. Upon FDA approval of Mylan's ANDA No. 20-1521, Mylan will further infringe the '229 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

64. Upon information and belief, Mylan had actual and constructive knowledge of the '229 patent prior to filing ANDA No. 20-1521 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '229 patent.

65. If Mylan's infringement of the '229 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**Count VIII (Infringement of the '848 Patent)**

66. Each of the preceding paragraphs 1 to 65 is incorporated as if fully set forth.

67. Mylan's submission of ANDA No. 20-1521 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic niacin extended-release / simvastatin tablets prior to the expiration of the '848 patent constitutes infringement of one or more of the claims of the '848 patent under 35 U.S.C. § 271(e)(2)(A).

68. Upon FDA approval of Mylan's ANDA No. 20-1521, Mylan will further infringe the '848 patent by making, using, offering to sell, and selling generic niacin extended-release / simvastatin tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

69. Upon information and belief, Mylan had actual and constructive knowledge of the '848 patent prior to filing ANDA No. 20-1521 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '848 patent.

70. If Mylan's infringement of the '848 patent is not enjoined, Abbott will suffer substantial and irreparable harm for which there is no remedy at law.

**Prayer for Relief**

WHEREFORE, Abbott prays that this Court grant the following relief:

a) A judgment that one or more claims of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent and the '848 patent are infringed by Mylan's submission of ANDA No. 20-1521, and that Mylan's making, using, offering to sell, or selling in the United States, or importing into the United States, of generic niacin extended-release / simvastatin tablets will infringe one or more claims of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent and the '848 patent;

b) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 20-1521 shall be a date which is not earlier than the latest expiration date of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent and the '848 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled;

c) An order permanently enjoining Mylan, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States generic niacin extended-release / simvastatin tablets until after the latest expiration date of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967

patent, the '691 patent, the '229 patent and the '848 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled;

d) Damages or other monetary relief to Abbott if Mylan engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of generic niacin extended-release / simvastatin tablets prior to the latest expiration date of the '428 patent, the '930 patent, the '715 patent, the '035 patent, the '967 patent, the '691 patent, the '229 patent and the '848 patent, including any extensions and/or additional periods of exclusivity to which Abbott is or becomes entitled.

e) Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Mary B. Graham*

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