

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA**

NOVEN PHARMACEUTICALS, INC.,
Plaintiff,

v.

MYLAN TECHNOLOGIES INC., MYLAN
PHARMACEUTICALS INC., MYLAN INC.,
and MYLAN N.V.,
Defendants.

Civil Action No. 1:15-CV-194 (Keeley)
Electronically filed: 10/29/2015

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Noven Pharmaceuticals, Inc. (“Noven” or “Plaintiff”), for its Complaint against Defendants Mylan Technologies Inc. (“MTI”), Mylan Pharmaceuticals Inc. (“MPI”), Mylan N.V., and Mylan Inc. (collectively, “Mylan” or “Defendants”), alleges as follows:

THE PARTIES

1. Noven Pharmaceuticals, Inc. is a Delaware corporation with a principal place of business at 11960 S.W. 144th Street, Miami, Florida 33186.
2. MTI is a corporation organized and existing under the laws of the State of West Virginia and has its principal place of business at 110 Lake Street, St. Albans, Vermont 05478.
3. MTI is a wholly-owned subsidiary of Mylan Inc. or its successor Mylan N.V.
4. MTI is engaged in the manufacture for sale of pharmaceutical products, including transdermal pharmaceutical products.
5. MPI is a corporation organized and existing under the laws of the State of West Virginia and has a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

6. MPI is a wholly-owned subsidiary of Mylan Inc. or its successor Mylan N.V.

7. Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania and has a principal place of business at Robert J. Coury Global Center, 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Mylan Inc. is a wholly-owned subsidiary of Mylan N.V.

8. Mylan N.V. is a corporation organized and existing under the laws of the Netherlands, having a place of business at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. Upon information and belief, Mylan N.V. is the corporate successor to Mylan Inc., and Mylan N.V.'s management and operations occur at the Robert J. Coury Global Center, located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Upon information and belief, Mylan N.V. was incorporated on July 7, 2014, and acquired Mylan Inc. on February 27, 2015. A Wall Street Journal article published July 14, 2014, titled "Abbott, Mylan Join Forces to Dodge U.S. Taxes" explains that "Mylan N.V. will be led by Mylan's existing management and will continue to be headquartered in Pittsburgh."

9. On information and belief, Mylan, Inc. has controlled and/or dominated defendants MTI and MPI. Upon information and belief, the control and domination exercised by Mylan Inc. over MTI and MPI prior to Mylan N.V.'s acquisition of Mylan Inc. on February 27, 2015, has been exercised by Mylan N.V. since that date.

10. Defendants are in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in West Virginia.

NATURE OF THE ACTION

11. This is a civil action for infringement of United States Patent Nos. 6,210,705 (the “705 patent”); 6,348,211 (the “211 patent”); 8,632,802 (the “802 patent”); and 9,034,370 (the “370 patent”) (collectively, the “patents-in-suit”) arising under 35 U.S.C § 100 et seq. and in particular § 271. This action relates to Abbreviated New Drug Application (“ANDA”) No. 206497, which Defendants filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration, for approval to market a generic copy of Noven’s Daytrana® product, which is sold in the United States.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, including at least 35 U.S.C. § 271(e).

13. This Court has personal jurisdiction over MPI because MPI is a corporation organized under the laws of the State of West Virginia and maintains a principal place of business at 781 Chestnut Ridge Rd., Morgantown, West Virginia 26505.

14. This court has personal jurisdiction over MTI because MTI is a corporation organized under the laws of the State of West Virginia.

15. This court also has personal jurisdiction over MTI, MPI, and Mylan Inc. because upon information and belief (1) each of the defendants MTI, MPI, and Mylan Inc. are registered to do business in the State of West Virginia and share an agent for service of process in West Virginia, the Corporation Service Company, 209 West Washington Street, Charleston, West

Virginia 25302; (2) Mylan Inc. and MPI have submitted to jurisdiction in this District in numerous patent cases; and (3) Mylan has purposefully availed itself of the privilege of doing business in the State of West Virginia and the Northern District of West Virginia by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including the State of West Virginia and the Northern District of West Virginia, and/or by selling, directly or through its agents, pharmaceutical products in the State of West Virginia and the Northern District of West Virginia.

16. This court has personal jurisdiction over Mylan N.V. at least because Mylan N.V., Mylan Inc., MPI, and MTI operate as an integrated, unitary pharmaceutical business, whereby, on information and belief, Mylan N.V. controls and/or dominates Mylan subsidiaries MTI and MPI. Mylan holds itself out and publicly represents itself as a single global entity. For example, Mylan Inc. has reported revenue on a consolidated basis that includes the revenue of its subsidiaries MTI and MPI in annual reports and S.E.C. filings. Mylan N.V. reports revenue on a consolidated basis that includes its subsidiaries MTI and MPI. Mylan N.V.'s August 6, 2015 Quarterly Report states that Mylan has a consolidated "Generics" segment that conducts business on a global basis. On information and belief, Mylan N.V. and/or Mylan Inc. issue press releases for their subsidiaries MPI and/or MTI regarding approval by the FDA of generic drugs, commercialization of generic drugs, and litigations involving the filing of ANDAs or NDAs.

17. On information and belief, Mylan N.V., Mylan Inc., MPI, and MTI have an integrated management structure, including overlapping officers and directors. For example, in an "Earnings Conference Call" on October 26, 2011, the then-Chief Executive Officer of Mylan Inc., Robert Coury, publicly stated that "Tony Mauro will be promoted to the President of [Mylan] North America while also retain[ing] his current role as President of Mylan

Pharmaceuticals,” and this arrangement constituted part of the “leadership structure” of Mylan Inc. A Mylan Inc. press release on February 24, 2012, confirmed that Tony Mauro is “president of Mylan North America and the company’s Mylan Pharmaceuticals subsidiary.” Furthermore, a Wall Street Journal company profile as of October 26, 2015, states that Mylan Inc. and Mylan N.V. share at least 13 individuals as part of their “Current Board Membership.”

18. Upon information and belief, MPI and MTI are registered pursuant to W. Va. Code § 30-5-2 (2014) to distribute generic pharmaceutical products in West Virginia and hold current and valid “Wholesale Distributor” licenses from the West Virginia Board of Pharmacy. MPI also holds a current and valid “Manufacturer” license from the West Virginia Board of Pharmacy.

19. Upon information and belief, Defendants are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products throughout the United States including in West Virginia, including the generic Methylphenidate Transdermal System that is described in Defendants’ ANDA No. 206497 (“the generic product”).

20. Upon information and belief, Defendants MPI and Mylan Inc. and/or its successor Mylan N.V. acted in concert with MTI in the preparation, development, and filing of ANDA No. 206497 and its underlying subject matter.

21. If ANDA No. 206497 is approved, the generic product will, among other things, be marketed and distributed by Defendants, directly and/or through their agents, in West Virginia, and/or prescribed by physicians practicing and dispensed by pharmacies located within West Virginia.

22. Defendants intend their generic product to be distributed and sold in the United States, including in West Virginia.

23. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

24. On October 27, 2015, Noven filed a complaint against the Mylan Defendants for patent infringement in the United States District Court for the District of Delaware based on the filing of ANDA No. 206497. The resulting Delaware action is presently pending. A copy of the complaint in the Delaware action (the “Delaware Daytrana® Action”), excluding exhibits, is attached hereto as Exhibit A. The Delaware complaint alleges essentially the same acts of infringement as the present complaint.

25. Based at least on the Mylan Defendants’ continuous and systematic business contacts with Delaware, Defendants should be subject to personal jurisdiction in the District of Delaware; however, Defendants may assert that they are not subject to such jurisdiction.

26. Noven therefore filed the instant complaint with identical infringement claims against Mylan as are included in the Delaware Daytrana® Action as a so-called Hatch-Waxman “protective suit,” to preserve its right for a 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii). Noven intends to move this Court to stay or transfer the instant action pending resolution of any jurisdictional challenge in the Delaware Daytrana® Action.

BACKGROUND

27. Noven holds New Drug Application No. N021514 for the manufacture and sale of Methylphenidate Transdermal System in 10 mg/9hr (1.1mg/hr); 15 mg/9hr (1.6 mg/hr); 20 mg/9hr (2.2 mg/hr); and 30 mg/9hr (3.3 mg/hr) dosage strengths, which was approved by the

FDA on April 6, 2006 and which Noven sells in the United States under the registered trademark Daytrana®.

28. Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(1) (“FFD&C Act”), and corresponding FDA regulations, Noven has listed the patents-in-suit in the FDA’s Orange Book as covering Daytrana® and methods for its use.

29. The ’705 patent, entitled “Compositions and methods for treatment of attention deficit disorder and attention deficit/hyperactivity disorder with methylphenidate,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on April 3, 2001. A Certificate of Correction for the ’705 patent was issued by the USPTO on December 2, 2003. Noven is the owner of all title, right, and interest in and to the ’705 patent. A true and correct copy of the ’705 patent, including its Certificate of Correction, is attached as Exhibit B.

30. The ’211 patent, entitled “Compositions and methods for treatment of attention deficit disorder and attention deficit/hyperactivity disorder with methylphenidate,” was duly and legally issued by the USPTO on February 19, 2002. A Certificate of Correction for the ’211 patent was issued by the USPTO on June 3, 2003. Noven is the owner of all title, right, and interest in and to the ’211 patent. A true and correct copy of the ’211 patent, including its Certificate of Correction, is attached as Exhibit C.

31. The ’802 patent, entitled “Device for Transdermal Administration of Drugs Including Acrylic Polymers,” was duly and legally issued by the USPTO on January 21, 2014. A Certificate of Correction for the ’802 patent was issued by the USPTO on July 22, 2014. Noven is the owner of all title, right, and interest in and to the ’802 patent. A true and correct copy of the ’802 patent, including its Certificate of Correction, is attached as Exhibit D.

32. The '370 patent, entitled "Device for Transdermal Administration of Drugs Including Acrylic Polymers," was duly and legally issued by the USPTO on May 19, 2015. Noven is the owner of all title, right, and interest in and to the '370 patent. A true and correct copy of the '370 patent, including its Certificate of Correction, is attached as Exhibit E.

33. Upon information and belief, pursuant to the FFD&C Act 21 U.S.C. § 355(j), Defendants filed ANDA No. 206497 with the FDA. Defendants' ANDA seeks FDA approval to market and sell generic Methylphenidate Transdermal Systems in 1.1 mg/hr, 1.6 mg/hr, 2.2 mg/hr, and 3.3 mg/hr dosage strengths prior to the expiration of the patents-in-suit.

34. Upon information and belief, Mylan's ANDA No. 206497 identified Noven's Daytrana® product and included a written certification, as required by the FFD&C Act 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV certification"), alleging that the claims of the patents-in-suit are invalid or will not be infringed by Mylan's generic product.

35. On or about September 14, 2015 Noven received a letter from MTI purporting to be a written notice that Mylan had filed ANDA No. 206497 seeking approval to market its generic product prior to the expiration of the patents-in-suit, pursuant to FFD&C Act, 21 U.S.C. § 505(j)(2)(B)(iv) (the "Paragraph IV letter"). Upon information and belief, the Paragraph IV letter included notice of Mylan's allegations that the patents-in-suit are invalid, unenforceable, and/or not infringed by Mylan's generic product.

36. Mylan's submission of ANDA No. 206497, including the Paragraph IV certification, to the FDA constituted infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2). Moreover, upon information and belief, Mylan's commercial manufacture, use, sale,

offer for sale, or importation of the generic product before expiration of the patents-in-suit would infringe at least one claim of each of the patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c).

37. Mylan purported to include, under the FFD&C Act, an Offer of Confidential Access (“the Mylan Offer”) to Noven to ANDA No. 206497 along with its Paragraph IV Letter. Under the FFD&C Act, 21 U.S.C. § 355(j)(5)(C)(III), an Offer of Confidential Access “shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential information.”

38. The Mylan Offer contained various restrictions, above and beyond those that would apply under a typical protective order, on who could view the ANDA and remedies in the event of a violation or breach. For example, the Mylan Offer substantially limited the fields of practice of outside and in-house counsel who might view the ANDA. In addition, the restrictions imposed by the Mylan Offer were not sufficiently directed to the purpose of protecting trade secrets and other confidential business information.

39. Since receiving Mylan’s Paragraph IV letter, Noven has attempted to negotiate with Mylan to procure a copy of the ANDA and to reach agreement on the terms and conditions of the Mylan Offer. These negotiations have been unsuccessful and the parties did not reach an agreement. For example, Mylan’s most recent proposal continues to unduly limit the fields of practice and other activities of outside and in-house counsel who would accept access to the ANDA, and goes beyond such restrictions as would apply had a protective order been entered.

40. Noven is commencing this action within 45 days of receiving the Paragraph IV letter.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 6,210,705

41. The contents of Paragraphs 1 through 40 are incorporated by reference as if specifically set forth herein.

42. Mylan's submission of ANDA No. 206497 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '705 patent constituted patent infringement under 35 U.S.C. § 271(e)(2).

43. Upon information and belief, Mylan will infringe the '705 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the United States upon the FDA's approval of ANDA No. 206497, either literally or under the doctrine of equivalents.

44. Upon information and belief, Mylan will infringe the '705 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '705 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 206497.

45. Upon information and belief, Mylan will infringe the '705 patent under 35 U.S.C. § 271(c) by selling and offering to sell the generic product in the United States, with knowledge of the '705 patent and that there is no substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 206497.

46. The foregoing actions by Mylan constitute and/or will constitute infringement of the '705 patent, active inducement of infringement of the '705 patent, and contribution to the infringement by others of the '705 patent.

47. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '705 patent. Further, Noven does not have an adequate remedy at law.

48. Upon information and belief, Mylan was aware of the '705 patent prior to filing ANDA No. 206497, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '705 patent.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 6,348,211

49. The contents of Paragraphs 1 through 48 are incorporated by reference as if specifically set forth herein.

50. Mylan's submission of ANDA No. 206497 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '211 patent constituted patent infringement under 35 U.S.C. § 271(e)(2).

51. Upon information and belief, Mylan will infringe the '211 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the

United States upon the FDA's approval of ANDA No. 206497, either literally or under the doctrine of equivalents.

52. Upon information and belief, Mylan will infringe the '211 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '211 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 206497.

53. Upon information and belief, Mylan will infringe the '211 patent under 35 U.S.C. § 271(c) by selling and offering to sell the generic product in the United States, with knowledge of the '211 patent and that there is no substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 206497.

54. The foregoing actions by Mylan constitute and/or will constitute infringement of the '211 patent, active inducement of infringement of the '211 patent, and contribution to the infringement by others of the '211 patent.

55. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '211 patent. Further, Noven does not have an adequate remedy at law.

56. Upon information and belief, Mylan was aware of the '211 patent prior to filing ANDA No. 206497, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '211 patent.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 8,632,802

57. The contents of Paragraphs 1 through 56 are incorporated by reference as if specifically set forth herein.

58. Mylan's submission of ANDA No. 206497 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '802 patent constituted patent infringement under 35 U.S.C. § 271(e)(2).

59. Upon information and belief, Mylan will infringe the '802 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the United States upon the FDA's approval of ANDA No. 206497, either literally or under the doctrine of equivalents.

60. Upon information and belief, Mylan will infringe the '802 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '802 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 206497.

61. Upon information and belief, Mylan will infringe the '802 patent under 35 U.S.C. § 271(c) by selling and offering to sell the generic product in the United States, with knowledge of the '802 patent and that there is no substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 206497.

62. The foregoing actions by Mylan constitute and/or will constitute infringement of the '802 patent, active inducement of infringement of the '802 patent, and contribution to the infringement by others of the '802 patent.

63. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '802 patent. Further, Noven does not have an adequate remedy at law.

64. Upon information and belief, Mylan was aware of the '802 patent prior to filing ANDA No. 206497, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '802 patent.

**COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 9,034,370**

65. The contents of Paragraphs 1 through 64 are incorporated by reference as if specifically set forth herein.

66. Mylan's submission of ANDA No. 206497 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '370 patent constituted patent infringement under 35 U.S.C. § 271(e)(2).

67. Upon information and belief, Mylan will infringe the '370 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the

United States upon the FDA's approval of ANDA No. 206497, either literally or under the doctrine of equivalents.

68. Upon information and belief, Mylan will infringe the '370 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '370 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 206497.

69. Upon information and belief, Mylan will infringe the '370 patent under 35 U.S.C. § 271(c) by selling and offering to sell the generic product in the United States, with knowledge of the '370 patent and that there is no substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 206497.

70. The foregoing actions by Mylan constitute and/or will constitute infringement of the '370 patent, active inducement of infringement of the '370 patent, and contribution to the infringement by others of the '370 patent.

71. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '370 patent. Further, Noven does not have an adequate remedy at law.

72. Upon information and belief, Mylan was aware of the '370 patent prior to filing ANDA No. 206497, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '370 patent.

PRAYER FOR RELIEF

WHEREFORE, Noven prays for judgment and seeks relief as follows:

A. A judgment that Defendants have infringed the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 206497 to the FDA, and that the commercial manufacture, use, sale, offer for sale, and/or importation of the generic product before the expiration of the patents-in-suit would constitute infringement by Defendants of one or more claims of the patents-in-suit;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 206497 shall be no earlier than the date on which the last of the patents-in-suit will expire, including any extensions;

C. An injunction under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283, permanently enjoining Defendants, their officers, agents, servants employees, , representatives, attorneys, and all other persons acting in active concert with them or acting on their behalf, from engaging in the commercial manufacture, use, sale, offer to sell, within the United States and importation into the United States of any pharmaceutical product covered by the patents-in-suit;

D. An award of damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C) and/or 35 U.S.C. § 284 as if Defendants commercially manufacture, use, sell, offer to sell, or import the generic product;

E. A finding that this is an exceptional case under 35 U.S.C. § 285, and that Noven be awarded reasonable attorneys' fees and costs; and

F. An award of any such other and further relief as the Court may deem just and proper.

Dated: October 28, 2015

Respectfully submitted:

By: /s/ David A. Barnette
David A. Barnette (WV Bar # 242)
Vivian H. Basdekis (WV Bar #10587)
JACKSON KELLY PLLC
500 Lee Street East, Suite 1600
Charleston, WV 25301-3202
Telephone: (304) 340-1327
dbarnette@jacksonkelly.com
vhbasdekis@jacksonkelly.com

Attorneys for Plaintiff, Noven
Pharmaceuticals, Inc.

Of Counsel:

Steve J. Lee
Michael K. Levy
Christopher J. Coulson
Kulsoom Z. Hasan
KENYON & KENYON LLP
One Broadway
New York, NY 10004
Telephone: 212.425.7200