IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVEN PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 17-1777 (LPS)
	)	
MYLAN TECHNOLOGIES INC., MYLAN PHARMACEUTICALS INC., MYLAN INC., and MYLAN N.V.	)	
	)	
Defendants.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Noven Pharmaceuticals, Inc. ("Noven" or "Plaintiff"), for its First Amended Complaint for Patent Infringement against Defendants Mylan Technologies Inc. ("MTI"), Mylan Pharmaceuticals Inc. ("MPI"), Mylan, Inc., and Mylan N.V. (collectively, "Mylan" or "Defendants") alleges as follows:

THE PARTIES

1. Noven is a Delaware corporation with a principal place of business at 11960 S.W. 144th Street, Miami, Florida 33186.

2. Upon information and belief, Defendant MTI is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 110 Lake Street, St. Albans, Vermont 92618.

3. Upon information and belief, Defendant MTI is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including Delaware.

4. Upon information and belief, Defendant MTI is a wholly-owned subsidiary of Defendant Mylan Inc.

5. Upon information and belief, Defendant MPI is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

6. Upon information and belief, Defendant MPI is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including Delaware.

7. Upon information and belief, Defendant MPI is a wholly-owned subsidiary of Defendant Mylan Inc.

8. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

9. Upon information and belief, Defendant Mylan Inc. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including Delaware.

10. Upon information and belief, Defendant Mylan Inc. is an indirectly wholly-owned subsidiary of Mylan N.V.

11. Upon information and belief, Defendant Mylan Inc. controls and/or dominates Defendants MTI and MPI.

12. Upon information and belief, Defendant Mylan N.V. is a corporation organized and existing under the laws of the Netherlands, having a principal place of business at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England.

13. Upon information and belief, Defendant Mylan N.V. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including Delaware.

14. Upon information and belief, Defendant Mylan N.V. is the corporate successor to Defendant Mylan Inc.

15. Upon information and belief, Defendant Mylan N.V.'s global headquarters are located at Canonsburg, Pennsylvania.

16. Upon information and belief, Defendant Mylan N.V. is led by Mylan Inc.'s management located at Canonsburg, Pennsylvania.

17. According to a Wall Street Journal article published on July 14, 2014, titled "Abbott, Mylan Join Forces to Dodge U.S. Taxes" states that "Abbott will transfer the assets to a new publicly traded company that will be called Mylan N.V. and that will become the parent company of the current Mylan," and that "Mylan N.V. will be led by Mylan's existing management and will continue to be headquartered in Pittsburgh." (Exhibit A, available at https://www.marketwatch.com/story/abbott-mylan-join-forces-to-dodge-us-taxes-2014-07-14, last accessed on December 7, 2017.)

NATURE OF THE ACTION

18. This is a civil action for infringement of U.S. Patent Nos. 9,730,900 ("the '900 patent"); 9,724,310 ("the '310 patent"); and 9,833,419 ("the '419 patent") (collectively, "patents-in-suit") arising under the United States Patent Laws, Title 35, United States Code § 100, *et. seq.*, and in particular under 35 U.S.C. § 271.

19. This action relates to Abbreviated New Drug Application ("ANDA") No. 206685, which Defendants filed or caused to be filed under 21 U.S.C. § 355(j) with the United States

Food and Drug Administration ("FDA"), for approval to market throughout the United States, Estradiol Transdermal System, USP "Twice-Weekly" 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day ("Mylan's ANDA Product"), which is a generic copy of Noven's Minivelle® product (Estradiol Transdermal System) in 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day dosage strengths.

JURISDICTION

20. This is a civil action for infringement arising under the Patent Laws of the United States, including 35 U.S.C. § 271.

21. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a), and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

22. Upon information and belief, Defendant MTI is engaged in the business of challenging patents held by branded pharmaceutical companies, including in this Judicial District. Defendant MTI has consented to jurisdiction and venue in this Court, and availed itself of the protections afforded by this Court, including by asserting counterclaims in this Court.

23. In addition, this Court has personal jurisdiction over Defendant MTI by virtue of the fact that Defendant MTI has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in the State of Delaware, including acts of patent infringement with respect to Mylan's ANDA Product. These acts have led and will lead to foreseeable harm and injury to Noven, a Delaware corporation, in this Judicial District. For example, upon information and belief, upon receiving approval from the FDA, Defendant MTI will make, use, import, sell, and/or offer for sale Mylan's ANDA

Product, throughout the United States, including in the State of Delaware, prior to the expiration of the patents-in-suit.

24. Upon information and belief, Defendant MTI has substantial, continuous, and systematic contacts with the State of Delaware including Defendant MTI's engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

25. Upon information and belief, Defendant MTI, and/or its subsidiaries, affiliates or agents, intends to engage in the commercial manufacture and sale of Mylan's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

26. Upon information and belief, Defendant MTI, and/or its subsidiaries, affiliates or agents, intends to place Mylan's ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in this Judicial District.

27. Upon information and belief, Defendant MTI regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in this State, and/or derives substantial revenues from the services or products used or consumed in the State of Delaware.

28. Defendant MTI has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted claims and counterclaims in this jurisdiction, including, *inter alia*, in the matters of *Indivior Inc. et al. v. Mylan Technologies Inc. et al.*, C.A. No. 15-cv-1016 (D. Del.); *UCB, Inc. et al. v. Mylan Technologies Inc. et al.*, C.A. No. 17-cv-322 (D. Del.); *Noven Pharmaceuticals, Inc. v. Mylan*

Technologies Inc. et al., C.A. No. 15-cv-979 (D. Del.); *Noven Pharmaceuticals, Inc. et al. v. Mylan Technologies Inc. et al*., C.A. No. 15-cv-328 (D. Del.); *Novartis Pharmaceuticals Corporation et al. v. Mylan Pharmaceuticals Inc. et al*., C.A. No. 14-cv-777 (D. Del.); and *Endo Pharmaceuticals Inc. v. Mylan Technologies Inc. et al.*, C.A. No. 11-cv-220 (D. Del.).

29. Upon information and belief, Defendant MTI holds a current and valid Delaware "Pharmacy-Wholesale" drug registration under License No. A4-0002022.

30. Upon information and belief, Defendant MTI holds a current and valid Delaware "Distributor/Manufacturer CSR" registration for controlled substances under License No. DM-0009694.

31. Upon information and belief, Defendant MPI is engaged in the business of challenging patents held by branded pharmaceutical companies, including in this Judicial District. Defendant MPI has consented to jurisdiction and venue in this Court, and availed itself of the protections afforded by this Court, including by asserting counterclaims in this Court.

32. In addition, this Court has personal jurisdiction over Defendant MPI by virtue of the fact that Defendant MPI has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, and intends a future course of conduct that includes acts of patent infringement in the State of Delaware, including acts of patent infringement with respect to Mylan's ANDA Product. These acts have led and will lead to foreseeable harm and injury to Noven, a Delaware corporation, in this Judicial District. For example, upon information and belief, upon receiving approval from the FDA, Defendant MPI will make, use, import, sell, and/or offer for sale Mylan's ANDA Product, throughout the United States, including in the State of Delaware, prior to the expiration of the patents-in-suit.

33. Upon information and belief, Defendant MPI has substantial, continuous, and systematic contacts with the State of Delaware including Defendant MPI's engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

34. Upon information and belief, Defendant MPI, and/or its subsidiaries, affiliates or agents, intends to engage in the commercial manufacture and sale of Mylan's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

35. Upon information and belief, Defendant MPI, and/or its subsidiaries, affiliates or agents, intends to place Mylan's ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in this Judicial District.

36. Upon information and belief, Defendant MPI regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in this State, and/or derives substantial revenues from the services or products used or consumed in the State of Delaware.

37. Upon information and belief, Defendant MPI has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted claims and counterclaims in this jurisdiction, including, *inter alia*, in over a hundred matters within the last ten years in this Judicial District, including, for example *Indivior Inc. et al. v. Mylan Technologies Inc. et al.*, C.A. No. 15-cv-1016 (D. Del.); *UCB, Inc. et al. v. Mylan Technologies Inc. et al.*, C.A. No. 17-cv-322 (D. Del.); *Noven Pharmaceuticals, Inc. v. Mylan Technologies Inc. et al.*, C.A. No. 15-cv-979 (D. Del.); *Noven Pharmaceuticals, Inc. et al.*

v. Mylan Technologies Inc. et al., C.A. No. 15-cv-328 (D. Del.); *Novartis Pharmaceuticals Corporation et al. v. Mylan Pharmaceuticals Inc. et al*., C.A. No. 14-cv-777 (D. Del.); and *Endo Pharmaceuticals Inc. v. Mylan Technologies Inc. et al.*, C.A. No. 11-cv-220 (D. Del.).

38. Upon information and belief, Defendant MPI is registered to do business in the State of Delaware, and has appointed an agent for service of process, Corporation Services Company located at 251 Little Falls Drive, Wilmington, DE 19808.

39. Upon information and belief, Defendant MPI holds current and valid Delaware "Pharmacy-Wholesale" drug registrations under License Nos. A4-0000741 and A4-0001719.

40. Upon information and belief, Defendant MPI holds current and valid Delaware "Distributor/Manufacturer CSR" registrations for controlled substances under License Nos. DS0342 and DM-0007571.

41. Upon information and belief, Defendant Mylan Inc. is engaged in the business of challenging patents held by branded pharmaceutical companies, including in this Judicial District. Defendant Mylan Inc. has consented to jurisdiction and venue in this Court, and availed itself of the protections afforded by this Court, including by asserting counterclaims in this Court.

42. Upon information and belief, Defendant Mylan Inc. has substantial, continuous, and systematic contacts with the State of Delaware including Defendant Mylan Inc.'s engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

43. In addition, this Court has personal jurisdiction over Defendant Mylan Inc. by virtue of the fact that Defendant Mylan Inc. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, and intends a

future course of conduct that includes acts of patent infringement in the State of Delaware, including acts of patent infringement with respect to Mylan's ANDA Product. These acts have led and will lead to foreseeable harm and injury to Noven, a Delaware corporation, in this Judicial District. For example, upon information and belief, upon receiving approval from the FDA, Defendant Mylan Inc. will make, use, import, sell, and/or offer for sale Mylan's ANDA Product, throughout the United States, including in the State of Delaware, prior to the expiration of the patents-in-suit.

44. Upon information and belief, Defendant Mylan Inc., and/or its subsidiaries, affiliates or agents, intends to engage in the commercial manufacture and sale of Mylan's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

45. Upon information and belief, Defendant Mylan Inc., and/or its subsidiaries, affiliates or agents, intends to place Mylan's ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in this Judicial District.

46. Upon information and belief, Defendant Mylan Inc. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in this State, and/or derives substantial revenues from the services or products used or consumed in the State of Delaware.

47. Upon information and belief, Defendant Mylan Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted claims and counterclaims in this jurisdiction, including, *inter alia*, in over a hundred matters within the last ten years in this Judicial District, including, for example

Indivior Inc. et al. v. Mylan Technologies Inc. et al., C.A. No. 15-cv-1016 (D. Del.); *UCB, Inc. et al. v. Mylan Technologies Inc. et al.*, C.A. No. 17-cv-322 (D. Del.); *Noven Pharmaceuticals, Inc. v. Mylan Technologies Inc. et al.*, C.A. No. 15-cv-979 (D. Del.); *Noven Pharmaceuticals, Inc. et al. v. Mylan Technologies Inc. et al.*, C.A. No. 15-cv-328 (D. Del.); *Novartis Pharmaceuticals Corporation et al. v. Mylan Pharmaceuticals Inc. et al.*, C.A. No. 14-cv-777 (D. Del.); and *Endo Pharmaceuticals Inc. v. Mylan Technologies Inc. et al.*, C.A. No. 11-cv-220 (D. Del.).

48. Upon information and belief, Defendant Mylan N.V. is engaged in the business of challenging patents held by branded pharmaceutical companies, including in this Judicial District. Defendant Mylan N.V. has consented to jurisdiction and venue in this Court, and availed itself of the protections afforded by this Court, including by asserting counterclaims in this Court.

49. Upon information and belief, Defendant Mylan N.V. has substantial, continuous, and systematic contacts with the State of Delaware including Defendant Mylan N.V.'s engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

50. In addition, this Court has personal jurisdiction over Defendant Mylan N.V. by virtue of the fact that Defendant Mylan N.V. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, and intends a future course of conduct that includes acts of patent infringement in the State of Delaware, including acts of patent infringement with respect to Mylan's ANDA Product. These acts have led and will lead to foreseeable harm and injury to Noven, a Delaware corporation, in this Judicial District. For example, upon information and belief, upon receiving approval from the FDA, Defendant Mylan N.V. will make, use, import, sell, and/or offer for sale Mylan's ANDA

Product, throughout the United States, including in the State of Delaware, prior to the expiration of the patents-in-suit.

51. Upon information and belief, Defendant Mylan N.V., and/or its subsidiaries, affiliates or agents, intends to engage in the commercial manufacture and sale of Mylan's ANDA Product, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

52. Upon information and belief, Defendant Mylan N.V., and/or its subsidiaries, affiliates or agents, intends to place Mylan's ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in this Judicial District.

53. Upon information and belief, Defendant Mylan N.V. regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in this State, and/or derives substantial revenues from the services or products used or consumed in the State of Delaware.

54. Upon information and belief, Defendant Mylan N.V. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted claims and counterclaims in this jurisdiction, including, *inter alia*, in the matters of *Indivior Inc. et al. v. Mylan Technologies Inc. et al.*, C.A. No. 15-cv-1016 (D. Del.); *Noven Pharmaceuticals, Inc. v. Mylan Technologies Inc. et al.*, C.A. No. 15-cv-979 (D. Del.); and *Pfizer Inc. et al. v. Mylan Laboratories Ltd. et al.*, C.A. No. 15-cv-960 (D. Del.).

55. This Court has personal jurisdiction because, *inter alia*, Defendants, on information and belief: (1) have substantial, continuous, and systematic contacts with the State of Delaware; (2) intend to market, sell, and/or distribute Mylan's ANDA Product to the residents of

the State of Delaware; (3) maintain a broad distribution network within this State; and/or (4) enjoy substantial income from sales of its generic pharmaceutical products in this State.

56. Upon information and belief, Defendants are in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including Delaware.

57. Upon information and belief, Defendants operate as a unitary entity for the purposes of manufacturing, marketing, selling, and/or distribution of generic pharmaceutical products, as evidenced by common management headquartered in Pennsylvania. (Exhibit A, available at https://www.marketwatch.com/story/abbott-mylan-join-forces-to-dodge-us-taxes-2014-07-14, last accessed on December 7, 2017.)

58. Upon information and belief, Defendants operate as a unitary entity for the purposes of manufacturing, marketing, selling, and/or distribution of generic pharmaceutical products, as evidenced by Defendants sharing the same corporate website. (http://www.mylan.com, last accessed on November 8, 2017).

59. Defendants state on their corporate website that "In the United States, . . . Mylan products fill one out of every 13 prescriptions dispensed . . . Nearly 80% of Mylan's products sold in America are produced at a Mylan U.S. site . . . More generic drug applications [by Mylan were] approved by FDA over the last two years than any other company." (Available at http://www.mylan.com/en/company/business-segments, last accessed on November 8, 2017.)

60. Upon information and belief, Defendants MPI, MTI, Mylan Inc., and Mylan N.V. are alter egos of each other. Upon information and belief, Defendants MPI, MTI, Mylan Inc., and/or Mylan N.V. cooperate with each other in sale and marketing of generic pharmaceutical products and act as agents of one another. Upon information and belief, while Defendant MTI is

the ANDA holder for a number of Defendants' generic products, Defendant MPI is named on package inserts and labels of those generic products. (*See, e.g.*, Orange Book pages and labels for several of Mylan's generic products, attached herein as Exhibits B-M (showing MTI is the ANDA holder but packaging and/or label for Mylan's Xulane, Clonidine, Estradiol, Fentanyl, Lidocaine patch, and Nitroglycerine products all refer to Defendant MPI).).

61. Upon information and belief, Defendants participated in the preparation, development, and filing of ANDA No. 206685, and its underlying subject matter, with the intent to market, sell, and/or distribute Mylan's ANDA Product to the residents of the State of Delaware. Plaintiff's cause of action arose from Defendants' contact with the State of Delaware.

62. This Court therefore has personal jurisdiction over all Defendants.

VENUE

63. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

64. Upon information and belief, Defendants operate as a unitary entity for the purposes of manufacturing, marketing, selling, and/or distribution of generic pharmaceutical products, including Mylan's ANDA Product.

65. Upon information and belief, Defendants MPI, MTI, Mylan Inc., and Mylan N.V. are alter egos of each other. Upon information and belief, Defendants MPI, MTI, Mylan Inc., and/or Mylan N.V. cooperate with each other in sale and marketing of generic pharmaceutical products and act as agents of one another, including with respect to Mylan's ANDA Product.

66. Upon information and belief, Defendants' operations in the United States are spread out amongst 55 U.S. subsidiaries. (Exhibit N, which is Exhibit 21.1 to Mylan N.V.'s 2016 10-K filing, showing the Delaware entities highlighted in blue.) Upon information and

belief, at least 40 of 55 U.S. affiliates, subsidiaries, parents, alter egos, agents and/or other entities in the Mylan corporate family are incorporated in Delaware, all of which "reside" within this Judicial District. One such affiliate, subsidiary, parent, alter ego, agent and/or other entity in the Mylan corporate family is Delcor Asset Corporation, which is incorporated in Delaware, and upon information and belief is engaged in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and/or distributing Mylan pharmaceutical products throughout the United States, including Delaware. Also upon information and belief, the formalities of corporate separateness are not preserved between Defendants and one or more of such U.S. affiliates, parents, alter egos, agents and/or other entities that reside in the State of Delaware.

67. Upon information and belief, Defendants intend a future course of conduct that includes acts of patent infringement in the State of Delaware, including with respect to Mylan's ANDA Product. These acts have led and will lead to foreseeable harm and injury to Noven, a Delaware corporation, in this Judicial District. For example, upon information and belief, upon receiving approval from the FDA, Defendants will make, use, import, sell, and/or offer for sale Mylan's ANDA Product, throughout the United States, including in the State of Delaware, prior to the expiration of the patents-in-suit.

68. Upon information and belief, Defendant MPI is registered to do business in the State of Delaware, and has appointed an agent for service of process, Corporation Services Company located at 251 Little Falls Drive, Wilmington, DE 19808. Upon information and belief, Defendant MPI indicated on its certificate of registration in the State of Delaware that it intends to engage in "[p]harmaceutical manufacturing, distribution and sales" in Delaware.

Acorda Therapeutics v. Mylan Pharm. Inc., 817 F.3d 755, 763 (Fed. Cir. 2016) (citations omitted).

69. Defendants MTI and MPI are licensed in the State of Delaware as "Pharmacy – Wholesale" and "Distributor/Manufacturer," allowing distribution, and manufacture of controlled substances within this Judicial District.

70. Upon information and belief, a portion of Defendants' business is done in the State of Delaware. Upon information and belief, Defendants are in the business of bringing generic drugs to market, including filing Paragraph IV certifications, and triggering patent litigation, in which they challenge patents held by branded pharmaceutical companies, including in the State of Delaware.

71. Defendants have previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of Delaware, having asserted claims and counterclaims in this jurisdiction, in more than 100 Hatch-Waxman cases within the last ten years. (Exhibit O, Lex Machina report.) As such, a substantial portion of Defendants' business is done by hiring Delaware counsel, who act as Defendants' agents, and involves work from counsel's offices located in the State of Delaware and in the courtrooms located in the State of Delaware.

72. Defendants "leverage a broad network of local and global access channels that include physicians, institutions, governments, retailers and wholesalers," throughout the United States, including in the State of Delaware. (Available at http://www.mylan.com/en/company/business-segments, last accessed on November 8, 2017.)

73. Defendants state on their corporate website that "Hundreds of Mylan representatives call on thousands of physicians every day. Through these meetings, [they are]

better able to meet [physician] needs and deliver on [their] commitment to provide physicians and their patients with access to high quality medicine." (Available at http://www.mylan.com/en/company/business-segments, last accessed on November 8, 2017.)

74. Upon information and belief, Defendants call on physicians located in the State of Delaware. Upon information and belief, Defendants hire sales professionals who work in the State of Delaware. Upon information and belief, Defendants' hired sales professionals to call upon physicians and hospitals within this Judicial District. Upon information and belief, Defendants' hired sales professionals to provide physicians and hospitals with samples and product literature within the State of Delaware. Upon information and belief, Defendants make promotional payments to physicians in the State of Delaware. Defendants MPI and Mylan Inc. reported at least nine promotional payments to physicians in Delaware in 2016. (Exhibit P, MPI 2016 CMS Data.)

75. Defendants further state on their corporate website that "[their] institutional customers include a wide range of hospitals, long-term care facilities, correctional facilities, group purchasing organizations, integrated delivery networks and specialty pharmacies. [They] also work closely with many leading group purchasing organizations to ensure generic and brand name products are available to health care providers within the hospital environment." (Available at http://www.mylan.com/en/company/business-segments, last accessed on November 8, 2017.)

76. Defendants also provide the "Mylan On Location™" Program "that helps organizations better prepare for an emergency on their premises." (Available at http://www.mylan.com/en/company/business-segments, last accessed on November 8, 2017.)

Upon information and belief, Defendants provide the "Mylan On Location™" Program to hospitals and physicians in the State of Delaware.

77. Defendants also supply national pharmacies and provide them with a series of educational materials that "help[] pharmacies empower their customers with information and answers about common conditions." (Available at http://www.mylan.com/en/company/business-segments, last accessed on November 8, 2017.) Upon information and belief, Defendants supply such pharmacies within the State of Delaware.

78. Upon information and belief, Defendants tailor promotional activities for their generic products by specifically targeting the people of the State of Delaware. For example, Defendants state the following on their corporate website intended to specifically target sales in Delaware: (i) "Better health for a better Delaware"; (ii) In 2016, Mylan's generics saved Delaware $74 million."; (iii) "[Mylan] continue[s] to leverage [its] heritage as a generics manufacturer to help drive down Delaware's drug costs."; (iv) "Mylan is a leader in the fight against many of Delaware's most prevalent diseases." (Available at https://mylanbetterhealth.com/DE/#access_to_medicine, last accessed on November 8, 2017.)

79. Upon information and belief, McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health, Inc. are three major customers of Defendants' family of corporations, as evidenced by Mylan N.V.'s Annual Report 10-K for fiscal year ended on Dec. 31, 2016, at page 22. (Exhibit Q, available at https://www.sec.gov/Archives/edgar/data/1623613/000162361317000007/myl10k_20161231xdoc.htm, last accessed on December 6, 2017.) McKesson Corporation is a Delaware corporation with a registered office located at 2711 Centerville Road, Wilmington, DE 19808.

80. Upon information and belief, McKesson Corporation sells and/or distributes more than 450 drug products sold under Manufacturer Mylan Pharmaceuticals, throughout the United States, including in this Judicial District, as evidenced by the number of search hits for "Mylan" on McKesson Corporation's catalog. (Exhibit R, snapshot of search for Mylan products on McKesson online catalog, available at https://mms.mckesson.com/catalog?node=3235975&query=mylan, last accessed December 7, 2017.)

81. Venue is proper as to Defendant MTI because Defendant MTI has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement under 35 U.S.C. § 271(e)(2), intends a future course of conduct that includes acts of patent infringement in the State of Delaware, and on information and belief has a regular and established place of business in the State of Delaware, *inter alia*, through at least one or more affiliates, subsidiaries, parents, alter egos, agents and/or other entities in the Mylan corporate family who have a regular and established place of business in Delaware, through hired sales professionals and legal counsel who act as Defendants' agents and continue Defendants' business operations from locations within this District, and through its employees who conduct Mylan's business from various offices and other locations in the State of Delaware. Upon information and belief, Defendant MTI's hired sales professionals to provide samples and product literature to physicians and hospitals within this District. Upon information and belief, Defendant MTI makes promotional payments to physicians within this District. These acts have led and will lead to foreseeable harm and injury to Noven, a Delaware corporation, in this Judicial District. For example, upon information and belief, upon receiving approval from the FDA, Defendants will make, use, import, sell, and/or offer for sale Mylan's ANDA Product,

throughout the United States, including in the State of Delaware, prior to the expiration of the patents-in-suit.

82. Defendants have also sought to cause injury to Noven by filing petitions for *Inter Partes* Review ("IPR") before the Patent Trials and Appeals Board ("PTAB"), challenging the validity of the '900 and the '310 patents. Defendants' IPR petitions were filed on December 4, 2018, four days prior to Noven's filing of its Complaint for Patent Infringement (D.I. 1). Defendant MTI is identified as a real party-in-interest, pursuant to 37 C.F.R. § 42.8(b)(1), in both IPR petitions. (Exhibit S, which is *Mylan Technologies Inc. v. Noven Pharmaceuticals, Inc.* (hereinafter, "*Mylan '310 IPR*"), IPR2018-00173, Paper No. 2 at 20 (P.T.A.B. Dec. 4, 2017); Exhibit T, which is *Mylan Technologies Inc. v. Noven Pharmaceuticals, Inc.* (hereinafter, "*Mylan '900 IPR*"), IPR2018-00174, Paper No. 2 at 20 (P.T.A.B. Dec. 4, 2017).)

83. Venue is proper as to Defendant MPI because Defendant MPI has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, intends a future course of conduct that includes acts of patent infringement in the State of Delaware, and on information and belief has a regular and established place of business in the State of Delaware, *inter alia*, through at least one or more affiliates, subsidiaries, parents, alter egos, agents and/or other entities in the Mylan corporate family who have a regular and established place of business in Delaware, through hired sales professionals and legal counsel who act as Defendants' agents and continue Defendants' business operations from locations within this District, and through its employees who conduct Mylan's business from various offices and other locations in the State of Delaware. Upon information and belief, Defendant MPI's hired sales professionals to provide samples and product literature to physicians and hospitals within this District. Upon information and belief, Defendant MPI makes promotional

payments to physicians within this District. These acts have led and will lead to foreseeable harm and injury to Noven, a Delaware corporation, in this Judicial District. For example, upon information and belief, upon receiving approval from the FDA, Defendants will make, use, import, sell, and/or offer for sale Mylan's ANDA Product, throughout the United States, including in the State of Delaware, prior to the expiration of the patents-in-suit.

84. Defendants have also sought to cause injury to Noven by filing IPR petitions before the PTAB, challenging the validity of the '900 and the '310 patents. Defendants' IPR petitions were filed on December 4, 2018, four days prior to Noven's filing of its Complaint for Patent Infringement (D.I. 1). Defendant MPI is identified as a real party-in-interest, pursuant to 37 C.F.R. § 42.8(b)(1), in both IPR petitions. (Exhibit S, *Mylan '310 IPR*, Paper No. 2 at 20; Exhibit T, *Mylan '900 IPR*, Paper No. 2 at 20.)

85. Venue is proper as to Defendant Mylan Inc. because Defendant Mylan Inc. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, intends a future course of conduct that includes acts of patent infringement in the State of Delaware, and on information and belief has a regular and established place of business in the State of Delaware, *inter alia*, through at least one or more affiliates, subsidiaries, parents, alter egos, agents and/or other entities in the Mylan corporate family who have a regular and established place of business in Delaware, through hired sales professionals and legal counsel who act as Defendants' agents and continue Defendants' business operations from locations within this District, and through its employees who conduct Mylan's business from various offices and other locations in the State of Delaware. Upon information and belief, Defendant Mylan Inc.'s hired sales professionals to provide samples and product literature to physicians and hospitals within this District. Upon information and belief,

Defendant Mylan Inc. makes promotional payments to physicians within this District. These acts have led and will lead to foreseeable harm and injury to Noven, a Delaware corporation, in this Judicial District. For example, upon information and belief, upon receiving approval from the FDA, Defendants will make, use, import, sell, and/or offer for sale Mylan's ANDA Product, throughout the United States, including in the State of Delaware, prior to the expiration of the patents-in-suit.

86. Defendants have also sought to cause injury to Noven by filing IPR petitions before the PTAB, challenging the validity of the '900 and the '310 patents. Defendants' IPR petitions were filed on December 4, 2018, four days prior to Noven's filing of its Complaint for Patent Infringement (D.I. 1). Defendants MTI and MPI, each of which are wholly owned subsidiaries of Mylan Inc., are identified as real parties-in-interest, pursuant to 37 C.F.R. § 42.8(b)(1), in both IPR petitions. (Exhibit S, *Mylan '310 IPR*, Paper No. 2 at 20; Exhibit T, *Mylan '900 IPR*, Paper No. 2 at 20.)

87. Venue is proper as to Defendant Mylan N.V. because Defendant Mylan N.V. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, intends a future course of conduct that includes acts of patent infringement in the State of Delaware, and on information and belief has a regular and established place of business in the State of Delaware, *inter alia*, through at least one or more affiliates, subsidiaries, parents, alter egos, agents and/or other entities in the Mylan corporate family who have a regular and established place of business in Delaware, through hired sales professionals and legal counsel who act as Defendants' agents and continue Defendants' business operations from locations within this District, and through its employees who conduct Mylan's business from various offices and other locations in the State of Delaware. Upon

information and belief, Defendant Mylan N.V.'s hired sales professionals to provide samples and product literature to physicians and hospitals within this District. Upon information and belief, Defendant Mylan N.V. makes promotional payments to physicians within this District. These acts have led and will lead to foreseeable harm and injury to Noven, a Delaware Corporation, in this Judicial District. For example, upon information and belief, upon receiving approval from the FDA, Defendants will make, use, import, sell, and/or offer for sale Mylan's ANDA Product, throughout the United States, including in the State of Delaware, prior to the expiration of the patents-in-suit.

88. Defendants have also sought to cause injury to Noven by filing IPR petitions before the PTAB, challenging the validity of the '900 and the '310 patents. Defendants' IPR petitions were filed on December 4, 2018, four days prior to Noven's filing of its Complaint for Patent Infringement (D.I. 1). Defendant Mylan N.V. is identified as a real party-in-interest, pursuant to 37 C.F.R. § 42.8(b)(1), in both IPR petitions. (Exhibit S, *Mylan '310 IPR*, Paper No. 2 at 20; Exhibit T, *Mylan '900 IPR*, Paper No. 2 at 20.)

89. Venue is also proper as to alien defendant Mylan N.V. under 28 U.S.C. § 1391(c)(3).

90. Venue is proper as to all Defendants.

MINIVELLE®

91. Plaintiff Noven Pharmaceuticals, Inc. is the holder of New Drug Application ("NDA") No. 203752 for the manufacture and sale of estradiol transdermal system, 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day, and sells the product in the United States under the registered trademark Minivelle®.

92. The FDA approved NDA No. 203752 for the 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day dosage strengths on October 29, 2012, and the 0.025 mg/day dosage strength on September 23, 2014.

93. Plaintiff Noven Pharmaceuticals, Inc. sells and distributes Minivelle® throughout the United States pursuant to NDA No. 203752.

94. Minivelle® is indicated for the treatment of moderate to severe vasomotor symptoms (also known as "hot flashes") due to menopause and for the prevention of post-menopausal osteoporosis. A copy of the September 23, 2014 Minivelle® Label is attached as Exhibit U.

PATENTS-IN-SUIT

95. The '900 patent, entitled "Transdermal Estrogen Device and Delivery" was duly and legally issued by the United States Patent and Trademark Office on August 15, 2017. Noven is the owner of all right, title, and interest in and to the '900 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A certified copy of the '900 patent is attached as Exhibit V.

96. Pursuant to Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(1) ("FFD&C Act") and corresponding FDA regulations, Noven has submitted information concerning the '900 patent to the FDA in connection with NDA No. 203752, identifying it 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." The '900 patent has been listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Minivelle® and methods for using it.

97. Claim 1 of the ’900 patent is directed, *inter alia*, to a method for administering estradiol, comprising applying to the skin or mucosa of a subject in need thereof a monolithic transdermal drug delivery system consisting of (i) a backing layer and (ii) a single adhesive polymer matrix layer defining an active surface area and comprising an adhesive polymer matrix comprising estradiol as the only drug, wherein the polymer matrix has a coat weight of greater than about 10 mg/cm^2 and includes greater than 0.156 mg/cm^2 estradiol, and the system achieves an estradiol flux of from about 0.0125 to about 0.05 mg/cm^2/day, based on the active surface area.

98. The approved Minivelle® product labeling instructs medical personnel and/or patients to perform the steps of the claimed method of the ’900 patent.

99. The use of Minivelle® in accordance with its approved product labeling by medical personnel and/or patients necessarily results in the performance of each of the claimed method steps of the ’900 patent.

100. The ’310 patent, entitled “Transdermal Estrogen Device and Delivery” was duly and legally issued by the United States Patent and Trademark Office on August 8, 2017. Noven is the owner of all right, title, and interest in and to the ’310 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A certified copy of the ’310 patent is attached as Exhibit W.

101. Pursuant to FFD&C Act, 21 U.S.C. § 355(b)(1) and corresponding FDA regulations, Noven has submitted information concerning the ’310 patent to the FDA in connection with NDA No. 203752, identifying it 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." The '310 patent has been listed in the FDA's Orange Book as covering Minivelle® and methods for using it.

102. Claim 1 of the '310 patent is directed, *inter alia*, to a monolithic transdermal drug delivery system for estradiol, consisting of (i) a backing layer, (ii) a single adhesive polymer matrix layer defining an active surface area and, optionally, (iii) a release liner, wherein the single adhesive polymer matrix layer comprises an adhesive polymer matrix comprising estradiol as the only drug, wherein the adhesive polymer matrix layer has a coat weight of greater than about 10 mg/cm^2 and includes greater than 0.156 mg/cm^2 estradiol, and the system achieves an estradiol flux of from about 0.0125 to about 0.05 mg/cm^2/day, based on the active surface area.

103. The Minivelle® product and its approved labeling describe a product that embodies at least one claim of the '310 patent.

104. The '419 patent, entitled "Transdermal Estrogen Device and Delivery" was duly and legally issued by the United States Patent and Trademark Office on December 5, 2017. Noven is the owner of all right, title, and interest in and to the '419 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A certified copy of the '419 patent is attached as Exhibit X.

105. Pursuant to FFD&C Act, 21 U.S.C. § 355(b)(1) and corresponding FDA regulations, Noven has submitted information concerning the '419 patent to the FDA in connection with NDA No. 203752, identifying it 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." The '419 patent has been listed in the FDA's Orange Book as covering Minivelle® and methods for using it.

106. Claim 1 of the ’419 patent is directed, *inter alia*, to a monolithic transdermal drug delivery system for estradiol, consisting of (i) a backing layer, (ii) a single adhesive polymer matrix layer defining an active surface area and, optionally, (iii) a release liner, wherein the single adhesive polymer matrix layer comprises an adhesive polymer matrix comprising estradiol as the only drug, wherein the adhesive polymer matrix layer has a coat weight of greater than 10 mg/cm^2 and includes greater than 0.156 mg/cm^2 estradiol, and the system achieves an estradiol flux of from 0.0125 to about 0.05 mg/cm^2/day, based on the active surface area.

107. The Minivelle® product and its approved labeling describe a product that embodies at least one claim of the ’419 patent.

MYLAN’S ANDA PRODUCT

108. Upon information and belief, pursuant to FFD&C Act, 21 U.S.C. § 505(j), Defendants submitted ANDA No. 206685 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan’s ANDA Product within the United States prior to the expiration of the ’900, ’310, and ’419 patents.

109. Upon information and belief, Defendants’ ANDA No. 206685 identified Noven’s Minivelle® 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 ’900, ’310, and ’419 patents are invalid and/or not infringed by Mylan’s ANDA Product.

110. On or about November 3, 2017, Noven received a letter from Defendant MTI purporting to be a written notice that Defendants had filed ANDA No. 206685 seeking approval to market Mylan’s ANDA Product prior to the expiration of the ’900 and ’310 patents, pursuant to FFD&C Act 21 U.S.C. § 505(j)(2)(B)(iv) (the “First Paragraph IV notice letter”).

111. The First Paragraph IV notice letter provides the factual and legal bases for MTI's allegation that the '900 and '310 patents are invalid based on obviousness.

112. The First Paragraph IV notice letter did not contain any allegations of non-infringement of the '900 and '310 patents, and did not provide Noven with an Offer for Confidential Access ("OCA") to Mylan's ANDA No. 206685.

113. On or about January 24, 2018, Noven received a letter from Defendant MTI purporting to be a written notice that Defendants had filed ANDA No. 206685 seeking approval to market Mylan's ANDA Product prior to the expiration of the '419 patent, pursuant to FFD&C Act 21 U.S.C. § 505(j)(2)(B)(iv) (the "Second Paragraph IV notice letter").

114. The Second Paragraph IV notice letter provides the factual and legal bases for MTI's allegation that the '419 patent is invalid based on obviousness.

115. The Second Paragraph IV notice letter did not contain any allegations of non-infringement of the '419 patent.

116. Defendants' submission of ANDA No. 206685, including the Paragraph IV certifications, to the FDA constituted infringement of the '900, '310, and '419 patents under 35 U.S.C. § 271(e)(2). Moreover, Defendants' anticipated commercial manufacture, use, sale, offer for sale, and/or importation of Mylan's ANDA Product upon approval and before expiration of the '900, '310, and '419 patents will infringe at least claim 1 of the '900 patent, at least claim 1 of the '310 patent, and at least claim 1 of the '419 patent under 35 U.S.C. § 271(a), (b), and/or (c).

117. Noven commenced this action within 45 days of receiving Defendants' First Paragraph IV notice letter. Noven filed this First Amended Complaint within 45 days of receiving Defendants' Second Paragraph IV notice letter.

118. On information and belief, Defendants were first to file an ANDA for a generic copy of Minivelle®, with ANDA No. 206685 having been filed on August 18, 2014 for the 0.0375, 0.05, 0.075 and 0.1 mg/day dosage strengths. *See* Exhibit Y (May 5, 2015 press release stating that "Mylan believes it is the first company . . . to have filed a substantially complete ANDA containing a Paragraph IV certification for this product and expects to be eligible for 180 days of marketing exclusivity upon receiving final FDA approval."); Exhibit Z, at 20 (FDA Paragraph IV certification list indicating first ANDA for a generic copy of Minivelle® filed on August 18, 2014 for the 0.0375, 0.05, 0.075 and 0.1 mg/day dosage strengths).

119. In a 2017 publication, FDA estimated a median review time from receipt of ANDA to final approval of 36 months for FY2016 and FY2017. *See* Exhibit AA (Excerpt of FDA publication titled Justification for Estimates and Appropriations Committees at page 82).

120. On information and belief, FDA approval of ANDA No. 206685 is imminent given that nearly 40 months have passed since the August 18, 2014 filing date.

121. On information and belief, Defendants, and/or their subsidiaries, affiliates or agents, intend to engage in the commercial manufacture, use, and/or sale of Mylan's ANDA Product, upon imminent receipt of FDA approval, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

122. On information and belief, Defendants, and/or their subsidiaries, affiliates or agents, intend to place Mylan's ANDA Product, upon imminent receipt of FDA approval, into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in this Judicial District.

123. Defendants' anticipated commercial manufacture, use, sale, offer for sale, or importation of Mylan's ANDA Product, upon imminent receipt of FDA approval, will infringe the patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c).

124. Upon information and belief, Defendants collaborated with each other and/or participated in and/or directed activities related to the submission of ANDA No. 206685 and the development of Mylan's ANDA Product.

125. Upon information and belief, Defendant MTI was actively involved in preparing ANDA No. 206685, and/or intends to directly benefit from, and has a financial stake in the approval of ANDA No. 206685.

126. Upon information and belief, Defendant MPI was, is and will be involved in the manufacture of Mylan's ANDA Product.

127. Upon information and belief, Defendant MPI will be involved in the marketing of Mylan's ANDA Product upon imminent receipt of FDA approval.

128. Upon information and belief, Defendant MPI was actively involved in the development of Mylan's ANDA Product.

129. Upon information and belief, Defendant MTI will be involved in the sales, distribution and/or marketing of Mylan's ANDA Product upon imminent receipt of FDA approval.

130. Upon information and belief, Defendant MPI will be involved in the sales, distribution and/or marketing of Mylan's ANDA Product upon imminent receipt of FDA approval.

131. Upon information and belief, Defendant Mylan Inc. will be involved in the sales, distribution and/or marketing of Mylan's ANDA Product upon imminent receipt of FDA approval.

132. Upon information and belief, Defendant Mylan N.V. will be involved in the sales, distribution and/or marketing of Mylan's ANDA Product upon imminent receipt of FDA approval.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 9,730,900

133. Paragraphs 1-132 are incorporated by reference as though fully set forth herein.

134. Administration of Noven's Minivelle® Estradiol Transdermal System according to the approved Minivelle® product labeling satisfies at least claim 1 of the '900 patent.

135. Upon information and belief, Mylan's ANDA Product has the same use as Minivelle®, at least because Defendants' ANDA No. 206685 refers to and relies upon Plaintiff's NDA No. 203752 for Minivelle®.

136. Upon information and belief, the proposed product labeling for Mylan's ANDA Product is substantially the same as the approved product labeling for Minivelle®.

137. Upon information and belief, Mylan's ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Minivelle®.

138. Upon information and belief, Mylan's ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '900 patent.

139. Although FFD&C Act 21 U.S.C. § 355(j)(2)(A) permits ANDA filers such as Defendants to make a Paragraph IV certification on the basis that the listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted," the factual and legal basis provided by Defendants in its notice to Noven pursuant to

FFD&C Act 21 U.S.C. § 355(j)(B) contained only allegations of invalidity of the '900 patent and did not provide any factual or legal basis for non-infringement as to the '900 patent.

140. Defendants' submission of ANDA No. 206685 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Mylan's ANDA Product prior to the expiration of the '900 patent constitutes infringement of at least claim 1 of the '900 patent under 35 U.S.C. § 271(e)(2).

141. Upon information and belief, Defendants will infringe at least claim 1 of the '900 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Mylan's ANDA Product in the United States upon the FDA's approval of ANDA No. 206685.

142. Upon information and belief, Defendants will infringe at least claim 1 of the '900 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '900 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 206685.

143. Upon information and belief, the proposed product labeling for Mylan's ANDA will instruct medical personnel and/or patients to perform the steps of at least claim 1 of the '900 patent.

144. Upon information and belief, the use of Mylan's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '900 patent.

145. Upon information and belief, Defendants specifically intend to cause others, specifically for example, medical personnel and/or patients, to perform acts that Defendants know infringe at least claim 1 of the '900 patent.

146. Upon information and belief, Defendants will infringe at least claim 1 of the '900 patent under 35 U.S.C. § 271(c) by selling and offering to sell Mylan's ANDA Product in the United States, with knowledge of the '900 patent and that there is no substantial non-infringing use of Mylan's ANDA Product, upon the FDA's approval of ANDA No. 206685.

147. Upon information and belief, Defendants know that Mylan's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '900 patent.

148. Mylan's ANDA Product constitutes a material part of the invention covered by the claims of the '900 patent.

149. 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 Defendants' infringement of the '900 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

150. Upon information and belief, Defendants were aware of the '900 patent prior to submitting their Paragraph IV certification, 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 it would not be liable for infringing the '900 patent.

COUNT II – DECLARATORY JUDGMENT
INFRINGEMENT OF U.S. PATENT NO. 9,730,900

151. Noven repeats and realleges Paragraphs 1-150 above as if fully set forth herein.

152. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

153. There exists an actual case or controversy such that the Court may hear Noven's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

154. Upon information and belief, Defendants will infringe at least claim 1 of the '900 patent by engaging in the manufacture, use, sale, offer for sale, or importation of Mylan's ANDA Product within the United States, including the State of Delaware, prior to the expiration of the '900 patent upon imminent receipt of FDA approval.

155. Although FFD&C Act 21 U.S.C. § 355(j)(2)(A) permits ANDA filers such as Defendants to make a Paragraph IV certification on the basis that the listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted," the factual and legal basis provided by Defendants in its notice to Noven pursuant to FFD&C Act 21 U.S.C. § 355(j)(B) contained only allegations of invalidity of the '900 patent and did not provide any factual or legal basis for non-infringement as to the '900 patent.

156. Upon information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling at any time upon imminent receipt of FDA approval.

157. Upon information and belief, Defendants' anticipated manufacture, use, sale, offer for sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '900 patent will constitute direct, induced, and contributory infringement of at least claim 1 of the '900 patent under 35 U.S.C. §§ 271(a), (b), and (c).

158. Upon information and belief, by seeking approval to distribute Mylan's ANDA Product with its approved labeling, upon imminent receipt of FDA approval, Defendants

specifically intend to cause others, specifically, for example, medical professionals, to perform acts that Defendants know will infringe at least claim 1 of the ’900 patent.

159. Upon information and belief, unless enjoined by this Court, Defendants plan and intend to, and will actively induce infringement of at least claim 1 of the ’900 patent by launching Mylan’s ANDA Product upon imminent receipt of FDA approval.

160. Upon information and belief, Defendants know that Mylan’s ANDA Product and its approved labeling are specifically made or adapted for use in infringing one or more claims of the ’900 patent, and that Mylan’s ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use.

161. Noven will be irreparably harmed if Defendants are not enjoined from infringing the ’900 patent. Noven does not have an adequate remedy at law and Defendants’ acts will continue unless enjoined by this Court.

162. Noven is entitled to a declaratory judgment that Defendants’ anticipated manufacture, use, sale, offer to sell, or importation of Mylan’s ANDA Product prior to the expiration of the ’900 patent upon imminent receipt of FDA approval will constitute direct, induced, and contributory infringement of the ’900 patent.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 9,724,310

163. Noven repeats and realleges Paragraphs 1-162 above as if fully set forth herein.

164. Noven’s Minivelle® Estradiol Transdermal System satisfies at least claim 1 of the ’310 patent.

165. Upon information and belief, Mylan’s ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the ’310 patent.

166. Although FFD&C Act 21 U.S.C. § 355(j)(2)(A) permits ANDA filers such as Defendants to make a Paragraph IV certification on the basis that the listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted," the factual and legal basis provided by Defendants in its notice to Noven pursuant to FFD&C Act 21 U.S.C. § 355(j)(B) contained only allegations of invalidity of the '310 patent and did not provide any factual or legal basis for non-infringement as to the '310 patent.

167. Defendants' submission of ANDA No. 206685 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Mylan's ANDA Product prior to the expiration of the '310 patent constitutes infringement of at least claim 1 of the '310 patent under 35 U.S.C. § 271(e)(2).

168. Upon information and belief, Defendants will infringe at least claim 1 of the '310 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Mylan's ANDA Product in the United States upon the FDA's approval of ANDA No. 206685.

169. Upon information and belief, Defendants will infringe at least claim 1 of the '310 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '310 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 206685.

170. Upon information and belief, the use of Mylan's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '310 patent.

171. Upon information and belief, Defendants will infringe at least claim 1 of the '310 patent under 35 U.S.C. § 271(c) by selling and offering to sell Mylan's ANDA Product in the

United States, with knowledge of the '310 patent and that there is no substantial non-infringing use of Mylan's ANDA Product, upon the FDA's approval of ANDA No. 206685.

172. Upon information and belief, Defendants know that Mylan's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '310 patent.

173. Mylan's ANDA Product constitutes a material part of the invention covered by the claims of the '310 patent.

174. 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 Defendants' infringement of the '310 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

175. Upon information and belief, Defendants were aware of the '310 patent prior to submitting their Paragraph IV certification, 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 it would not be liable for infringing the '310 patent.

COUNT IV – DECLARATORY JUDGMENT
INFRINGEMENT OF U.S. PATENT NO. 9,724,310

176. Noven repeats and realleges Paragraphs 1-175 above as if fully set forth herein.

177. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

178. There exists an actual case or controversy such that the Court may hear Noven's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

179. Upon information and belief, Defendants will infringe at least claim 1 of the ’310 patent by engaging in the manufacture, use, sale, offer for sale, or importation of Mylan’s ANDA Product within the United States, including the State of Delaware, prior to the expiration of the ’310 patent upon imminent receipt of FDA approval.

180. Although FFD&C Act 21 U.S.C. § 355(j)(2)(A) permits ANDA filers such as Defendants to make a Paragraph IV certification on the basis that the listed patent “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted,” the factual and legal basis provided by Defendants in its notice to Noven pursuant to FFD&C Act 21 U.S.C. § 355(j)(B) contained only allegations of invalidity of the ’310 patent and did not provide any factual or legal basis for non-infringement as to the ’310 patent.

181. Upon information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan’s ANDA Product with its proposed labeling at any time upon imminent receipt of FDA approval.

182. Upon information and belief, Defendants’ anticipated manufacture, use, sale, offer for sale, and/or importation of Mylan’s ANDA Product prior to the expiration of the ’310 patent will constitute direct, induced, and contributory infringement of at least claim 1 of the ’310 patent under 35 U.S.C. §§ 271(a), (b), and (c).

183. Upon information and belief, by seeking approval to distribute Mylan’s ANDA Product with its approved labeling, upon imminent receipt of FDA approval, Defendants specifically intend to cause others, specifically, for example, medical professionals, to perform acts that Defendants know will infringe at least claim 1 of the ’310 patent.

184. Upon information and belief, unless enjoined by this Court, Defendants plan and intend to, and will actively induce infringement of at least claim 1 of the ’310 patent by launching Mylan’s ANDA Product upon imminent receipt of FDA approval.

185. Noven will be irreparably harmed if Defendants are not enjoined from infringing the ’310 patent. Noven does not have an adequate remedy at law and Defendants’ acts will continue unless enjoined by this Court.

186. Noven is entitled to a declaratory judgment that Defendants’ anticipated manufacture, use, sale, offer to sell, or importation of Mylan’s ANDA Product prior to the expiration of the ’310 patent upon imminent receipt of FDA approval will constitute direct, induced, and contributory infringement of the ’310 patent.

COUNT V – INFRINGEMENT OF U.S. PATENT NO. 9,833,419

187. Noven repeats and realleges Paragraphs 1-186 above as if fully set forth herein.

188. Noven’s Minivelle® Estradiol Transdermal System satisfies at least claim 1 of the ’419 patent.

189. Upon information and belief, Mylan’s ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the ’419 patent.

190. Although FFD&C Act 21 U.S.C. § 355(j)(2)(A) permits ANDA filers such as Defendants to make a Paragraph IV certification on the basis that the listed patent “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted,” the factual and legal basis provided by Defendants in its notice to Noven pursuant to FFD&C Act 21 U.S.C. § 355(j)(B) contained only allegations of invalidity of the ’419 patent and did not provide any factual or legal basis for non-infringement as to the ’419 patent.

191. Defendants' submission of ANDA No. 206685 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Mylan's ANDA Product prior to the expiration of the '419 patent constitutes infringement of at least claim 1 of the '419 patent under 35 U.S.C. § 271(e)(2).

192. Upon information and belief, Defendants will infringe at least claim 1 of the '419 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Mylan's ANDA Product in the United States upon the FDA's approval of ANDA No. 206685.

193. Upon information and belief, Defendants will infringe at least claim 1 of the '419 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '419 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 206685.

194. Upon information and belief, the use of Mylan's ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '419 patent.

195. Upon information and belief, Defendants will infringe at least claim 1 of the '419 patent under 35 U.S.C. § 271(c) by selling and offering to sell Mylan's ANDA Product in the United States, with knowledge of the '419 patent and that there is no substantial non-infringing use of Mylan's ANDA Product, upon the FDA's approval of ANDA No. 206685.

196. Upon information and belief, Defendants know that Mylan's ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '419 patent.

197. Mylan's ANDA Product constitutes a material part of the invention covered by the claims of the '419 patent.

198. 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 Defendants' infringement of the '419 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

199. Upon information and belief, Defendants were aware of the '419 patent prior to submitting their Paragraph IV certification, 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 it would not be liable for infringing the '419 patent.

COUNT VI – DECLARATORY JUDGMENT INFRINGEMENT OF U.S. PATENT NO. 9,833,419

200. Noven repeats and realleges Paragraphs 1-199 above as if fully set forth herein.

201. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

202. There exists an actual case or controversy such that the Court may hear Noven's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

203. Upon information and belief, Defendants will infringe at least claim 1 of the '419 patent by engaging in the manufacture, use, sale, offer for sale, or importation of Mylan's ANDA Product within the United States, including the State of Delaware, prior to the expiration of the '419 patent upon imminent receipt of FDA approval.

204. Although FFD&C Act 21 U.S.C. § 355(j)(2)(A) permits ANDA filers such as Defendants to make a Paragraph IV certification on the basis that the listed patent "is invalid or

will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted," the factual and legal basis provided by Defendants in its notice to Noven pursuant to FFD&C Act 21 U.S.C. § 355(j)(B) contained only allegations of invalidity of the '419 patent and did not provide any factual or legal basis for non-infringement as to the '419 patent.

205. Upon information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product with its proposed labeling at any time upon imminent receipt of FDA approval.

206. Upon information and belief, Defendants' anticipated manufacture, use, sale, offer for sale, and/or importation of Mylan's ANDA Product prior to the expiration of the '419 patent will constitute direct, induced, and contributory infringement of at least claim 1 of the '419 patent under 35 U.S.C. §§ 271(a), (b), and (c).

207. Upon information and belief, by seeking approval to distribute Mylan's ANDA Product with its approved labeling, upon imminent receipt of FDA approval, Defendants specifically intend to cause others, specifically, for example, medical professionals, to perform acts that Defendants know will infringe at least claim 1 of the '419 patent.

208. Upon information and belief, unless enjoined by this Court, Defendants plan and intend to, and will actively induce infringement of at least claim 1 of the '419 patent by launching Mylan's ANDA Product upon imminent receipt of FDA approval.

209. Noven will be irreparably harmed if Defendants are not enjoined from infringing the '419 patent. Noven does not have an adequate remedy at law and Defendants' acts will continue unless enjoined by this Court.

210. Noven is entitled to a declaratory judgment that Defendants' anticipated manufacture, use, sale, offer to sell, or importation of Mylan's ANDA Product prior to the expiration of the '419 patent upon imminent receipt of FDA approval will constitute direct, induced, and contributory infringement of the '419 patent.

PRAYER FOR RELIEF

WHEREFORE, Noven respectfully prays for:

A. A judgment that Defendants have infringed the '900, '310, and '419 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 206685 to the FDA, and that the commercial manufacture, use, sale, offer for sale, and/or importation of Mylan's ANDA Product before the expiration of the '900, '310, and '419 patents will constitute acts of infringement of the '900, '310, and '419patents;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 206685 shall be no earlier than the dates on which the '900, '310, and '419 patents expire, including any patent term and regulatory extensions;

C. A preliminary and permanent injunction under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283, enjoining Defendants, their officers, agents, servants employees, licensees, representatives, attorneys, and all other persons acting or attempting to act in active concert in participation with them or acting on their behalf, from engaging in the commercial manufacture, use, sale, offer to sell, and/or importation within the United States, of any pharmaceutical product covered by the '900, '310, and '419 patents;

D. A declaration under 28 U.S. C. § 2201 that if Defendants, their officers, agents, servants, employees, licensees, representatives, attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in

the commercial manufacture, use, sale, offer to sell, and/or importation within the United States, of Mylan's ANDA Product prior to the expiration of the '900, '310, and '419 patents, such acts will constitute direct and/or indirect infringement of the '900, '310, and '419 patents.

E. 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 appropriate;

F. 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

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

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February 26, 2018

CERTIFICATE OF SERVICE

I hereby certify that on February 26, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on February 26, 2018, upon the following in the manner indicated:

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