

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NOVEN PHARMACEUTICALS, INC.)	
)	
Plaintiff/Counterclaim-Defendant,)	
)	
v.)	C.A. No. 18-758-LPS
)	
ACTAVIS LABORATORIES UT, INC.,)	
)	
Defendant/Counterclaimant.)	
)	

**DEFENDANT ACTAVIS LABORATORIES UT, INC.'S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

ANSWER

Defendant Actavis Laboratories UT, Inc. (“Defendant” or “Actavis UT”), as its Answer to the numbered paragraphs in the Complaint of Plaintiff Noven Pharmaceuticals, Inc. (“Plaintiff” or “Noven”), responds and alleges as follows, based upon Actavis UT’s knowledge as to its own activities, and upon information and belief as to the activities of others:

THE PARTIES¹

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

Answer to 1: Actavis UT is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1, and therefore denies those allegations.

2. Upon information and belief, Actavis is a Delaware corporation having a place of business at 577 Chipeta Way, Salt Lake City, UT 84108.

Answer to 2: Admitted.

¹ The section headings in this Answer are provided solely for ease of reference, tracking those used in Noven’s Complaint, and do not constitute any part of Actavis UT’s Answer to the Complaint, or any form of admission by Actavis UT as to the truth of the matters asserted by Noven.

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

Answer to 3: Actavis UT admits that it is in the business of, among other things, developing certain generic pharmaceutical products. Actavis UT denies any remaining allegations in paragraph 3.

NATURE OF THE ACTION

4. 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.

Answer to 4: Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that this action purports to allege patent 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”) under the United States Patent Laws, Title 35, United States Code § 100 et seq., “and in particular under 35 U.S.C. § 271,” but Actavis UT denies that the Complaint states such a cause of action and/or that Actavis UT has committed or will commit any acts giving rise to such a cause of action. Actavis UT denies any remaining allegations in paragraph 4.

5. This action relates to Abbreviated New Drug Application (“ANDA”) Nos. 208893 and 206202, which Actavis filed or caused to be filed with the United States Food and Drug Administration (“FDA”) under Federal Food, Drug, and Cosmetic Act (“FFD&C Act”) § 505(j) (21 U.S.C. § 355(j)), for approval to market a generic copy of Noven’s Minivelle® product (Estradiol Transdermal System) in a dosage strength of 0.025 mg/day (ANDA No. 208893) (“Actavis’s 208893 ANDA Product”), as well as 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day dosage strengths (ANDA No. 206202) (“Actavis’s 206202 ANDA Product”) (collectively, “Actavis’s ANDA Products”), throughout the United States.

Answer to 5: Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that this action purports to relate to Abbreviated New Drug Application (“ANDA”) Nos. 206202 and 208893. Actavis UT further

admits that it submitted ANDA No. 206202 under 21 U.S.C. §§ 355(j)(1) and (2)(A) to the United States Food and Drug Administration (“FDA”) for approval to manufacture, use, and/or sell Estradiol Transdermal System, USP, 0.025 mg/day. Actavis UT further admits that it submitted ANDA No. 208893 under 21 U.S.C. §§ 355(j)(1) and (2)(A) to FDA for approval to manufacture, use, and/or sell Estradiol Transdermal System, USP, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day. Actavis UT also admits that Minivelle® is sold in the United States. Actavis UT denies any remaining allegations in paragraph 5.

6. Actavis’s ANDA Nos. 208893 and 206202 are the subject of pending related actions, *Noven Pharms., Inc. v. Actavis Labs. UT, Inc.*, C.A. No. 15-249-LPS (D. Del.) and *Noven Pharms., Inc. v. Actavis Labs. UT, Inc.*, C.A. No. 16-465-LPS (D. Del.), which involve allegations by Noven that ANDA Nos. 208893 and 206202 infringe Noven’s U.S. Patent No. 8,231,906, the parent patent to the patents-in-suit. On December 22, 2017, the Court issued an Order in C.A. No. 15-249-LPS (D. Del.) finding that Actavis had failed to prove that the asserted claims of U.S. Patent No. 8,231,906 were invalid due to obviousness.

Answer to 6: Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that C.A. Nos. 15-249-LPS and 16-465-LPS purport to allege that ANDA Nos. 206202 and 208893, respectively, infringe U.S. Patent No. 8,231,906 (“the ’906 patent”), but Actavis UT denies that the Complaints in those cases state such a cause of action and/or that Actavis UT has committed or will commit any acts giving rise to such a cause of action. Actavis UT further admits that the Court issued an Order in C.A. No. 15-249-LPS on December 22, 2017. Actavis UT respectfully refers the Court to D.I. 249 in C.A. No. 15-249-LPS for details of the Order and denies any allegations to the extent they are inconsistent with or mischaracterize that Order. Actavis UT denies any remaining allegations in paragraph 6.

JURISDICTION AND VENUE

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

Answer to 7: Actavis UT admits that this action purports to allege patent infringement under the Patent Laws of the United States, including 35 U.S.C. § 271, but Actavis UT denies that the Complaint states such a cause of action and/or that Actavis UT has committed or will commit any acts giving rise to such a cause of action. Actavis UT denies any remaining allegations in paragraph 7.

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

Answer to 8: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that Noven asserts that the Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Actavis UT does not contest that this Court has subject matter jurisdiction over this action. Actavis UT denies any remaining allegations in paragraph 8.

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

Answer to 9: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that Noven purports to base venue on 28 U.S.C. §§ 1391 and 1400(b). Actavis UT does not contest venue in this District solely for purposes of this action. Actavis UT denies any remaining allegations in paragraph 9.

10. Actavis is incorporated and resides in the State of Delaware for purposes of 28 U.S.C. § 1400(b).

Answer to 10: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that it is incorporated in the state of Delaware. Actavis UT does not contest this Court's personal jurisdiction over it solely for purposes of this action. Actavis UT denies any remaining allegations in paragraph 10.

11. This Court has personal jurisdiction over Actavis because, *inter alia*, Actavis, on information and belief: (1) has substantial, continuous, and systematic contacts with the State of Delaware; (2) intends to market, sell, and/or distribute Actavis's ANDA Products to the residents

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

Answer to 11:Paragraph 11 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT does not contest this Court's personal jurisdiction over it solely for purposes of this action. Actavis UT denies any remaining allegations in paragraph 11.

12. In addition, this Court has personal jurisdiction over Actavis by virtue of the fact that Actavis has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, which has led to foreseeable harm and injury to Noven, which is incorporated in and exists under the laws of the State of Delaware.

Answer to 12:Paragraph 12 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT does not contest this Court's personal jurisdiction over it solely for purposes of this action. Actavis UT denies any remaining allegations in paragraph 12.

13. Upon information and belief, Actavis has purposefully availed itself of this forum by making, using, importing, selling or offering to sell pharmaceutical products in the State of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

Answer to 13:Paragraph 13 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT does not contest this Court's personal jurisdiction over it solely for purposes of this action. Actavis UT denies any remaining allegations in paragraph 13.

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

Answer to 14:Paragraph 14 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT does not contest this Court's personal

jurisdiction over it solely for purposes of this action. Actavis UT denies any remaining allegations in paragraph 14.

15. Upon information and belief, Actavis, and/or its subsidiaries, affiliates or agents, intends to engage in the commercial manufacture and sale of Actavis's ANDA Products, 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.

Answer to 15: Actavis UT admits that it submitted ANDA No. 206202 under 21 U.S.C. §§355(j)(1) and (2)(A) to FDA for approval to manufacture, use, and/or sell within the United States a generic Estradiol Transdermal System, USP, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day prior to the expiration of the patents-in-suit. Actavis UT admits that it submitted ANDA No. 208893 under 21 U.S.C. §§355(j)(1) and (2)(A) to FDA for approval to manufacture, use, and/or sell within the United States a generic Estradiol Transdermal System, USP, 0.025 mg/day prior to the expiration of the patents-in-suit. Actavis UT does not contest this Court's personal jurisdiction over it solely for purposes of this action. Actavis UT denies any remaining allegations in paragraph 15.

16. Upon information and belief, Actavis, and/or its subsidiaries, affiliates or agents, intends to place Actavis's ANDA Products 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.

Answer to 16: Actavis UT admits that it submitted ANDA No. 206202 under 21 U.S.C. §§355(j)(1) and (2)(A) to FDA for approval to manufacture, use, and/or sell within the United States a generic Estradiol Transdermal System, USP, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day prior to the expiration of the patents-in-suit. Actavis UT admits that it submitted ANDA No. 208893 under 21 U.S.C. §§355(j)(1) and (2)(A) to FDA for approval to manufacture, use, and/or sell within the United States a generic Estradiol Transdermal System, USP, 0.025 mg/day prior to the expiration of the patents-in-suit. Actavis UT does not contest this

Court's personal jurisdiction over it solely for purposes of this action. Actavis UT denies any remaining allegations in paragraph 16.

17. Upon information and belief, Actavis 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.

Answer to 17: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT does not contest this Court's personal jurisdiction over it solely for purposes of this action. Actavis UT denies any remaining allegations in paragraph 17.

18. Additionally, the business of Actavis involves challenging patents held by branded pharmaceutical companies, including in this Judicial District. Actavis has consented to jurisdiction and venue in this Court, and availed itself of the protections afforded by this Court, including by asserting claims and counterclaims in this Court.

Answer to 18: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT does not contest this Court's personal jurisdiction over it solely for purposes of this action. Actavis UT denies any remaining allegations in paragraph 18.

19. Actavis 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 *Actavis Labs. UT, Inc. v. Par Pharm., Inc.*, No. 15-0886 (D. Del.); *Noven Pharms., Inc. et al. v. Actavis Labs. UT, Inc.*, No. 15-249 (D. Del.); *Altergon SA et al. v. Actavis Labs. UT, Inc.*, No. 15-0883 (D. Del.); *LEO Pharma A/S et al. v. Actavis Labs. UT, Inc.*, No. 17-1752 (D. Del.); *Prostrakan, Inc. et al. v. Actavis Labs. UT, Inc.*, No. 16-0015 (D. Del.); *Shionogi Inc. et al. v. Actavis Labs. UT, Inc.*, No. 16-0606 (D. Del.); *Indivior Inc. et al. v. Actavis Labs. UT, Inc.*, No. 18-0497 (D. Del.).

Answer to 19: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that it is a party in *Actavis Labs. UT, Inc. v. Par Pharm., Inc.*, No. 15-0886 (D. Del.); *Noven Pharms., Inc. et al. v. Actavis Labs. UT, Inc.*, No. 15-249 (D. Del.); *Altergon SA et al. v. Actavis Labs. UT, Inc.*, No. 15-0883 (D. Del.); *LEO*

Pharma A/S et al. v. Actavis Labs. UT, Inc., No. 17-1752 (D. Del.); *Prostrakan, Inc. et al. v. Actavis Labs. UT, Inc.*, No. 16-0015 (D. Del.); *Shionogi Inc. et al. v. Actavis Labs. UT, Inc.*, No. 16-0606 (D. Del.); *Indivior Inc. et al. v. Actavis Labs. UT, Inc.*, No. 18-0497 (D. Del.). Actavis UT further admits that it has asserted claims and counterclaims in this jurisdiction. Actavis UT does not contest this Court's personal jurisdiction over it solely for purposes of this action. Actavis UT denies any remaining allegations in paragraph 19.

20. Upon information and belief, Actavis holds a current and valid Delaware "Wholesale" pharmacy drug registration under License No. A4-0001263 (expires September 30, 2018).

Answer to 20: Actavis UT admits that it holds a current and valid Delaware License No. A4-0001263. Actavis UT further admits that Delaware License No. A4-0001263 is listed as a Pharmacy – Wholesale license type. Actavis UT further admits that Delaware License No. A4-0001263 expires on September 30, 2018. Actavis UT denies any remaining allegations in paragraph 20.

21. Upon information and belief, Actavis participated in the preparation, development, and filing of ANDA Nos. 208893 and 206202, and their underlying subject matter, with the intent to market, sell, and/or distribute Actavis's ANDA Products to the residents of the State of Delaware. Plaintiff's cause of action arose from Actavis's contact with the State of Delaware

Answer to 21: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that it submitted ANDA No. 206202 under 21 U.S.C. §§355(j)(1) and (2)(A) to FDA for approval to manufacture, use, and/or sell within the United States a generic Estradiol Transdermal System, USP, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day prior to the expiration of the patents-in-suit. Actavis UT admits that it submitted ANDA No. 208893 under 21 U.S.C. §§355(j)(1) and (2)(A) to FDA for approval to manufacture, use, and/or sell within the United States a generic Estradiol Transdermal System, USP, 0.025 mg/day prior to the expiration of the patents-in-suit. Actavis

UT denies that the Complaint states a valid cause of action and/or that Actavis UT has committed or will commit any acts giving rise to such a cause of action. Actavis UT does not contest this Court's personal jurisdiction over it solely for purposes of this action. Actavis UT denies any remaining allegations in paragraph 21.

MINIVELLE®

22. 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®.

Answer to 22: Actavis UT admits, on information and belief, that Noven is the holder of New Drug Application 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. Actavis UT further admits, on information and belief, that Noven sells a drug product under the name Minivelle®. Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 22 and therefore denies them.

23. 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.

Answer to 23: Actavis UT admits, on information and belief, that Noven is the holder of New Drug Application 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. Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 23 and therefore denies them.

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

Answer to 24: Actavis UT admits, on information and belief, that Noven is the holder of New Drug Application No. 203752. Actavis UT further admits, on information and belief, that

Noven sells a drug product under the name Minivelle®. Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 24 and therefore denies them.

25. 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 postmenopausal osteoporosis. A copy of the September 23, 2014 Minivelle® Label is attached as Exhibit A.

Answer to 25: Actavis UT admits that Exhibit A purports to be a copy of a Minivelle® Label. Actavis UT further admits that Exhibit A states that Minivelle is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause and for the prevention of postmenopausal osteoporosis. Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 25 and therefore denies them.

PATENTS-IN-SUIT

26. 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 B.

Answer to 26: Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that the title of the '900 patent is “Transdermal Estrogen Device and Delivery,” and that the '900 patent lists on its face an issue date of August 15, 2017. Actavis UT further admits that Exhibit B purports to be a copy of the '900 patent. Actavis UT lacks sufficient knowledge or information to admit or deny that 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, and therefore Actavis UT denies this allegation. Actavis UT denies any remaining allegations in paragraph 26.

27. Pursuant to FFD&C Act § 505(b)(1) (21 U.S.C. § 355(b)(1)) 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.

Answer to 27:Paragraph 27 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT admits that the ’900 patent is listed in FDA’s Orange Book in connection with the Minivelle® drug product. Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 27 and therefore denies them.

28. 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/cm² and includes greater than 0.156 mg/cm² estradiol, and the system achieves an estradiol flux of from about 0.0125 to about 0.05 mg/cm²/day, based on the active surface area.

Answer to 28:Paragraph 28 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT admits that the ’900 patent includes a claim 1 at column 15, lines 49-59. The language of claim 1 speaks for itself. Actavis UT denies any remaining allegations in paragraph 28.

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

Answer to 29:Paragraph 29 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT admits that Exhibit A purports to be a copy of a Minivelle® Label. Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 29 and therefore denies them.

30. 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.

Answer to 30: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that Exhibit A purports to be a copy of a Minivelle® Label. Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 30 and therefore denies them.

31. 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 C.

Answer to 31: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that the title of the '310 patent is "Transdermal Estrogen Device and Delivery," and that the '310 patent lists on its face an issue date of August 8, 2017. Actavis UT further admits that Exhibit C purports to be a copy of the '310 patent. Actavis UT lacks sufficient knowledge or information to admit or deny that 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, and therefore Actavis UT denies this allegation. Actavis UT denies any remaining allegations in paragraph 31.

32. Pursuant to FFD&C Act § 505(b)(1) (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.

Answer to 32: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that the '310 patent is listed in FDA's Orange Book in connection with the Minivelle® drug product. Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 32 and therefore denies them.

33. 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/cm² and includes greater than 0.156 mg/cm² estradiol, and the system achieves an estradiol flux of from about 0.0125 to about 0.05 mg/cm²/day, based on the active surface area.

Answer to 33: Paragraph 33 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT admits that the '310 patent includes a claim 1 at column 15, line 50 through column 16, line 3. The language of claim 1 speaks for itself. Actavis UT denies any remaining allegations in paragraph 33.

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

Answer to 34: Paragraph 34 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT admits that Exhibit A purports to be a copy of a Minivelle® Label. Actavis UT denies any remaining allegations in paragraph 34.

35. 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 D.

Answer to 35: Paragraph 35 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT admits that the title of the '419 patent is "Transdermal Estrogen Device and Delivery," and that the '419 patent lists on its face an issue date of December 5, 2017. Actavis UT further admits that Exhibit D purports to be a copy of the '419 patent. Actavis UT lacks sufficient knowledge or information to admit or deny that 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, and therefore Actavis UT denies this allegation. Actavis UT denies any remaining allegations in paragraph 35.

36. Pursuant to FFD&C Act § 505(b)(1) (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.

Answer to 36: Paragraph 36 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT admits that the '419 patent is listed in FDA's Orange Book in connection with the Minivelle® drug product. Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 36 and therefore denies them.

37. 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/cm² and includes greater than 0.156 mg/cm² estradiol, and the system achieves an estradiol flux of from 0.0125 to about 0.05 mg/cm²/day, based on the active surface area.

Answer to 37: Paragraph 37 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT admits that the '419 patent includes a claim 1 at column 15, lines 44-54. The language of claim 1 speaks for itself. Actavis UT denies any remaining allegations in paragraph 37.

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

Answer to 38: Paragraph 38 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT admits that Exhibit A purports to be a copy of a Minivelle® Label. Actavis UT denies any remaining allegations in paragraph 38.

ACTAVIS'S ANDA PRODUCTS

39. Upon information and belief, pursuant to FFD&C Act § 505(j) (21 U.S.C. 355(j)), Actavis submitted ANDA Nos. 208893 and 206202 to the FDA seeking approval in each to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's

ANDA Products within the United States prior to the expiration of the '900, '310, and '419 patents..

Answer to 39: Paragraph 39 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that it submitted ANDA No. 206202 under 21 U.S.C. §§355(j)(1) and (2)(A) to FDA for approval to manufacture, use, and/or sell within the United States a generic Estradiol Transdermal System, USP, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day prior to the expiration of the patents-in-suit. Actavis UT admits that it submitted ANDA No. 208893 under 21 U.S.C. §§355(j)(1) and (2)(A) to FDA for approval to manufacture, use, and/or sell within the United States a generic Estradiol Transdermal System, USP, 0.025 mg/day prior to the expiration of the patents-in-suit. Actavis UT denies any remaining allegations in paragraph 39.

40. Upon information and belief, Actavis's ANDA Nos. 208893 and 206202 each identified Noven's Minivelle® product and each included a written certification, as required by the FFD&C Act § 505(j)(2)(A)(vii)(IV) (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 or otherwise will not be infringed by Actavis's ANDA Products.

Answer to 40: Actavis UT admits that ANDA Nos. 206202 and 208893 identified Noven's Minivelle® product and included a written certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that certified to FDA that in the opinion of Actavis UT, and to the best of Actavis UT's knowledge, the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in ANDA Nos. 206202 and 208893. Actavis UT denies any remaining allegations in paragraph 40.

41. On or about February 27, 2018, Noven received a letter from Actavis purporting to be a written notice that Actavis had filed ANDA Nos. 208893 and 206202 seeking approval to market Actavis's ANDA Products prior to the expiration of the '900, '310, and '419 patents, pursuant to FFD&C Act § 505(j)(2)(B)(iv) (21 U.S.C. § 355(j)(2)(B)(iv)) (the "Paragraph IV notice letter"). The Paragraph IV notice letter included notice of Actavis's allegations that the '900, '310, and '419 patents are not valid, unenforceable, or will not be infringed by Actavis's ANDA Products.

Answer to 41: Actavis UT admits that on February 27, 2018, it sent to Noven a notice letter pursuant to 21 U.S.C. § 505(j)(2)(B)(iv) identifying the filing of ANDA Nos. 206202 and 208893, seeking approval to manufacture, use, and/or sell within the United States a generic Estradiol Transdermal System, USP, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day and 0.025 mg/day, respectively, prior to the expiration of the patents-in-suit. Actavis UT further admits that the notice letter included notice of Actavis UT's certification to FDA that in the opinion of Actavis UT, and to the best of Actavis UT's knowledge, the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in ANDA Nos. 206202 and 208893. Actavis UT denies any remaining allegations in paragraph 41.

42. Actavis's submission of ANDA No. 208893, including the Paragraph IV certification, to the FDA constituted infringement of the '900, '310, and '419 patents under 35 U.S.C. § 271(e)(2).

Answer to 42: Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 42.

43. Actavis's submission of ANDA No. 206202, including the Paragraph IV certification, to the FDA constituted infringement of the '900, '310, and '419 patents under 35 U.S.C. § 271(e)(2).

Answer to 43: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 43.

44. Actavis's anticipated commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's ANDA Products 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 under 35 U.S.C. § 271(a), (b), and/or (c).

Answer to 44: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 44.

COUNT I – INFRINGEMENT OF PATENT NO. 9,730,900
BY ACTAVIS'S 208893 ANDA PRODUCT

45. Paragraphs 1-44 are incorporated by reference as though fully set forth herein.

Answer to 45: Actavis UT repeats and realleges the responses in paragraphs 1-44 of this Answer, as set forth above, and incorporates them by reference as if fully set forth herein.

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

Answer to 46: Paragraph 46 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 46 and therefore denies them.

47. Upon information and belief, Actavis's 208893 ANDA Product has the same use as Minivelle®, at least because Actavis's ANDA No. 208893 refers to and relies upon Plaintiff's NDA No. 203752 for Minivelle®.

Answer to 47: Paragraph 47 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that ANDA No. 208893 refers to and relies upon Minivelle®. Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 47 and therefore denies them.

48. Upon information and belief, the proposed product labeling for Actavis's 208893 ANDA Product is substantially the same as the approved product labeling for Minivelle®.

Answer to 48: Paragraph 48 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 48 and therefore denies them.

49. Upon information and belief, Actavis's 208893 ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Minivelle®.

Answer to 49: Paragraph 49 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 49 and therefore denies them.

50. Upon information and belief, Actavis's 208893 ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '900 patent.

Answer to 50: Paragraph 50 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 50.

51. Actavis's submission of ANDA No. 208893 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Actavis's 208893 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).

Answer to 51: Paragraph 51 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 51.

52. Upon information and belief, Actavis 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 Actavis's 208893 ANDA Product in the United States upon the FDA's approval of ANDA No. 208893.

Answer to 52: Paragraph 52 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 52.

53. Upon information and belief, Actavis 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. 208893.

Answer to 53: Paragraph 53 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 53.

54. Upon information and belief, the proposed product labeling for Actavis's 208893 ANDA Product will instruct medical personnel and/or patients to perform the steps of at least claim 1 of the '900 patent.

Answer to 54: Paragraph 54 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 54.

55. Upon information and belief, the use of Actavis's 208893 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.

Answer to 55: Paragraph 55 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 55.

56. Upon information and belief, Actavis specifically intends to cause others, specifically for example, medical personnel and/or patients, to perform acts that Actavis knows infringe at least claim 1 of the '900 patent.

Answer to 56: Paragraph 56 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 56.

57. Upon information and belief, Actavis will infringe at least claim 1 of the '900 patent under 35 U.S.C. § 271(c) by selling and offering to sell Actavis's 208893 ANDA Product in the United States, with knowledge of the '900 patent and that there is no substantial noninfringing use of Actavis's 208893 ANDA Product, upon the FDA's approval of ANDA No. 208893.

Answer to 57: Paragraph 57 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 57.

58. Upon information and belief, Actavis knows that Actavis's 208893 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.

Answer to 58: Paragraph 58 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 58.

59. Actavis's 208893 ANDA Product constitutes a material part of the invention covered by the claims of the '900 patent.

Answer to 59: Paragraph 59 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 59.

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

Answer to 60: Actavis UT denies the allegations in paragraph 60.

61. Upon information and belief, Actavis was aware of the '900 patent prior to Actavis submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in FFD&C Act § 505 (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..

Answer to 61: Actavis UT admits that it had knowledge of the '900 patent prior to filing ANDA No. 208893, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95. Actavis UT denies any remaining allegations in paragraph 61.

COUNT II – INFRINGEMENT OF PATENT NO. 9,724,310

BY ACTAVIS'S 208893 ANDA PRODUCT

62. Paragraphs 1-61 are incorporated by reference as though fully set forth herein.

Answer to 62: Actavis UT repeats and realleges the responses in paragraphs 1-61 of this Answer, as set forth above, and incorporates them by reference as if fully set forth herein.

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

Answer to 63: Paragraph 63 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 63 and therefore denies them.

64. Upon information and belief, Actavis's 208893 ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '310 patent.

Answer to 64: Paragraph 64 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 64.

65. Actavis's submission of ANDA No. 208893 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Actavis's 208893 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).

Answer to 65: Paragraph 65 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 65.

66. Upon information and belief, Actavis 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 Actavis's 208893 ANDA Product in the United States upon the FDA's approval of ANDA No. 208893.

Answer to 66: Paragraph 66 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 66.

67. Upon information and belief, Actavis 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. 208893.

Answer to 67: Paragraph 67 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 67.

68. Upon information and belief, the use of Actavis's 208893 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.

Answer to 68: Paragraph 68 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 68.

69. Upon information and belief, Actavis will infringe at least claim 1 of the '310 patent under 35 U.S.C. § 271(c) by selling and offering to sell Actavis's 208893 ANDA Product in the United States, with knowledge of the '310 patent and that there is no substantial noninfringing use of Actavis's 208893 ANDA Product, upon the FDA's approval of ANDA No. 208893.

Answer to 69: Paragraph 69 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 69.

70. Upon information and belief, Actavis knows that Actavis's 208893 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.

Answer to 70: Paragraph 70 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 70.

71. Actavis's 208893 ANDA Product constitutes a material part of the invention covered by the claims of the '310 patent.

Answer to 71: Paragraph 71 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 71.

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

Answer to 72: Actavis UT denies the allegations in paragraph 72.

73. Upon information and belief, Actavis was aware of the '310 patent prior to Actavis submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in FFD&C Act § 505 (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.

Answer to 73: Actavis UT admits that it had knowledge of the '310 patent prior to filing ANDA No. 208893, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95. Actavis UT denies any remaining allegations in paragraph 73.

COUNT III – INFRINGEMENT OF PATENT NO. 9,833,419

BY ACTAVIS'S 208893 ANDA PRODUCT

74. Paragraphs 1-73 are incorporated by reference as though fully set forth herein.

Answer to 74: Actavis UT repeats and realleges the responses in paragraphs 1-73 of this Answer, as set forth above, and incorporates them by reference as if fully set forth herein.

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

Answer to 75: Paragraph 75 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 75 and therefore denies them.

76. Upon information and belief, Actavis's 208893 ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '419 patent.

Answer to 76: Paragraph 76 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 76.

77. Actavis's submission of ANDA No. 208893 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Actavis's 208893 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).

Answer to 77: Paragraph 77 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 77.

78. Upon information and belief, Actavis 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 Actavis's 208893 ANDA Product in the United States upon the FDA's approval of ANDA No. 208893.

Answer to 78: Paragraph 78 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 78.

79. Upon information and belief, Actavis 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. 208893.

Answer to 79: Paragraph 79 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 79.

80. Upon information and belief, the use of Actavis's 208893 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.

Answer to 80: Paragraph 80 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 80.

81. Upon information and belief, Actavis will infringe at least claim 1 of the '419 patent under 35 U.S.C. § 271(c) by selling and offering to sell Actavis's 208893 ANDA Product in the United States, with knowledge of the '419 patent and that there is no substantial noninfringing use of Actavis's 208893 ANDA Product, upon the FDA's approval of ANDA No. 208893.

Answer to 81: Paragraph 81 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 81.

82. Upon information and belief, Actavis knows that Actavis's 208893 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.

Answer to 82: Paragraph 82 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 82.

83. Actavis's 208893 ANDA Product constitutes a material part of the invention covered by the claims of the '419 patent.

Answer to 83: Paragraph 83 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 83.

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

Answer to 84: Actavis UT denies the allegations in paragraph 84.

85. Upon information and belief, Actavis was aware of the '419 patent prior to Actavis submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in FFD&C Act § 505 (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.

Answer to 85: Actavis UT admits that it had knowledge of the '419 patent prior to filing ANDA No. 208893, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95. Actavis UT denies any remaining allegations in paragraph 85.

COUNT IV – INFRINGEMENT OF PATENT NO. 9,730,900
BY ACTAVIS'S 206202 ANDA PRODUCT

86. Paragraphs 1-85 are incorporated by reference as though fully set forth herein.

Answer to 86: Actavis UT repeats and realleges the responses in paragraphs 1-85 of this Answer, as set forth above, and incorporates them by reference as if fully set forth herein.

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

Answer to 87: Paragraph 87 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 87 and therefore denies them.

88. Upon information and belief, Actavis's 202602 ANDA Product has the same use as Minivelle®, at least because Actavis's ANDA No. 202602 refers to and relies upon Plaintiff's NDA No. 203752 for Minivelle®.

Answer to 88: Paragraph 88 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT admits that ANDA No. 202602 refers to and relies upon Minivelle®. Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 88 and therefore denies them.

89. Upon information and belief, the proposed product labeling for Actavis's 202602 ANDA Product is substantially the same as the approved product labeling for Minivelle®.

Answer to 89: Paragraph 89 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 89 and therefore denies them.

90. Upon information and belief, Actavis's 202602 ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Minivelle®.

Answer to 90: Paragraph 90 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 90 and therefore denies them.

91. Upon information and belief, Actavis's 202602 ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '900 patent.

Answer to 91: Paragraph 91 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 91.

92. Actavis's submission of ANDA No. 202602 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Actavis's 202602 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).

Answer to 92: Paragraph 92 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 92.

93. Upon information and belief, Actavis 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 Actavis's 202602 ANDA Product in the United States upon the FDA's approval of ANDA No. 202602.

Answer to 93: Paragraph 93 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 93.

94. Upon information and belief, Actavis 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. 202602.

Answer to 94: Paragraph 94 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 94.

95. Upon information and belief, the proposed product labeling for Actavis's 202602 ANDA Product will instruct medical personnel and/or patients to perform the steps of at least claim 1 of the '900 patent.

Answer to 95: Paragraph 95 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 95.

96. Upon information and belief, the use of Actavis's 202602 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.

Answer to 96: Paragraph 96 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 96.

97. Upon information and belief, Actavis specifically intends to cause others, specifically for example, medical personnel and/or patients, to perform acts that Actavis knows infringe at least claim 1 of the '900 patent.

Answer to 97: Paragraph 97 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 97.

98. Upon information and belief, Actavis will infringe at least claim 1 of the '900 patent under 35 U.S.C. § 271(c) by selling and offering to sell Actavis's 202602 ANDA Product in the United States, with knowledge of the '900 patent and that there is no substantial noninfringing use of Actavis's 202602 ANDA Product, upon the FDA's approval of ANDA No. 202602.

Answer to 98: Paragraph 98 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 98.

99. Upon information and belief, Actavis knows that Actavis's 202602 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.

Answer to 99: Paragraph 99 contains legal conclusions to which no answer is required.

To the extent an answer is required, Actavis UT denies the allegations in paragraph 99.

100. Actavis's 202602 ANDA Product constitutes a material part of the invention covered by the claims of the '900 patent.

Answer to 100: Paragraph 100 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 100.

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

Answer to 101: Actavis UT denies the allegations in paragraph 101.

102. Upon information and belief, Actavis was aware of the '900 patent prior to Actavis submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in FFD&C Act § 505 (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..

Answer to 102: Actavis UT admits that it had knowledge of the '900 patent prior to filing ANDA No. 202602, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95. Actavis UT denies any remaining allegations in paragraph 102.

COUNT V – INFRINGEMENT OF PATENT NO. 9,724,310

BY ACTAVIS'S 206202 ANDA PRODUCT

103. Paragraphs 1-102 are incorporated by reference as though fully set forth herein.

Answer to 103: Actavis UT repeats and realleges the responses in paragraphs 1-102 of this Answer, as set forth above, and incorporates them by reference as if fully set forth herein.

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

Answer to 104: Paragraph 104 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 104 and therefore denies them.

105. Upon information and belief, Actavis's 206202 ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '310 patent.

Answer to 105: Paragraph 105 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 105.

106. Actavis's submission of ANDA No. 206202 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Actavis's 206202 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).

Answer to 106: Paragraph 106 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 106.

107. Upon information and belief, Actavis 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 Actavis's 206202 ANDA Product in the United States upon the FDA's approval of ANDA No. 206202.

Answer to 107: Paragraph 107 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 107.

108. Upon information and belief, Actavis 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. 206202.

Answer to 108: Paragraph 108 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 108.

109. Upon information and belief, the use of Actavis's 206202 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.

Answer to 109: Paragraph 109 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 109.

110. Upon information and belief, Actavis will infringe at least claim 1 of the '310 patent under 35 U.S.C. § 271(c) by selling and offering to sell Actavis's 206202 ANDA Product in the United States, with knowledge of the '310 patent and that there is no substantial noninfringing use of Actavis's 206202 ANDA Product, upon the FDA's approval of ANDA No. 206202.

Answer to 110: Paragraph 110 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 110.

111. Upon information and belief, Actavis knows that Actavis's 206202 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.

Answer to 111: Paragraph 111 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 111.

112. Actavis's 206202 ANDA Product constitutes a material part of the invention covered by the claims of the '310 patent.

Answer to 112: Paragraph 112 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 112.

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

Answer to 113: Actavis UT denies the allegations in paragraph 113.

114. Upon information and belief, Actavis was aware of the '310 patent prior to Actavis submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in FFD&C Act § 505 (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.

Answer to 114: Actavis UT admits that it had knowledge of the '310 patent prior to filing ANDA No. 206202, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95. Actavis UT denies any remaining allegations in paragraph 114.

COUNT VI – INFRINGEMENT OF PATENT NO. 9,833,419

BY ACTAVIS'S 202602 ANDA PRODUCT

115. Paragraphs 1-114 are incorporated by reference as though fully set forth herein.

Answer to 115: Actavis UT repeats and realleges the responses in paragraphs 1-114 of this Answer, as set forth above, and incorporates them by reference as if fully set forth herein.

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

Answer to 116: Paragraph 116 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 116 and therefore denies them.

117. Upon information and belief, Actavis's 206202 ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '419 patent.

Answer to 117: Paragraph 117 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 117.

118. Actavis's submission of ANDA No. 206202 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Actavis's

206202 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).

Answer to 118: Paragraph 118 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 118.

119. Upon information and belief, Actavis 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 Actavis's 206202 ANDA Product in the United States upon the FDA's approval of ANDA No. 206202.

Answer to 119: Paragraph 119 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 119.

120. Upon information and belief, Actavis 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. 2206202 08893.

Answer to 120: Paragraph 120 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 120.

121. Upon information and belief, the use of Actavis's 206202 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.

Answer to 121: Paragraph 121 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 121.

122. Upon information and belief, Actavis will infringe at least claim 1 of the '419 patent under 35 U.S.C. § 271(c) by selling and offering to sell Actavis's 206202 ANDA Product in the United States, with knowledge of the '419 patent and that there is no substantial noninfringing use of Actavis's 206202 ANDA Product, upon the FDA's approval of ANDA No. 206202.

Answer to 122: Paragraph 122 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 122.

123. Upon information and belief, Actavis knows that Actavis's 206202 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.

Answer to 123: Paragraph 123 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 123.

124. Actavis's 206202 ANDA Product constitutes a material part of the invention covered by the claims of the '419 patent.

Answer to 124: Paragraph 124 contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis UT denies the allegations in paragraph 124.

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

Answer to 125: Actavis UT denies the allegations in paragraph 125.

126. Upon information and belief, Actavis was aware of the '419 patent prior to Actavis submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in FFD&C Act § 505 (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.

Answer to 126: Actavis UT admits that it had knowledge of the '419 patent prior to filing ANDA No. 206202, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95. Actavis UT denies any remaining allegations in paragraph 126.

* * *

Actavis UT denies any remaining allegations not expressly admitted or responded to herein. Actavis UT further denies that Noven is entitled to the relief requested in paragraphs A-J of the Prayer for Relief or to any relief whatsoever. Actavis UT respectfully requests that the Court: (a) dismiss the Complaint with prejudice; (b) deny all relief requested by Noven; (c) enter judgment in favor of Actavis UT; (d) award Actavis UT the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (e) award Actavis UT such further relief as the Court deems just and appropriate.

AFFIRMATIVE DEFENSES

127. Without prejudice to the denials set forth in its Answer, without admitting any averments of the Complaint not otherwise admitted, and without any admission as to the burden of proof, Actavis UT states the following defenses to the allegations of the Complaint.

FIRST AFFIRMATIVE DEFENSE

128. The purported claims for relief in the Complaint are barred for failure to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

129. The manufacture, use, sale, offer for sale, or importation of the product described in ANDA No. 202602 has not infringed, does not infringe, and would not infringe, if marketed, any valid and enforceable claim of the '900 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

THIRD AFFIRMATIVE DEFENSE

130. The manufacture, use, sale, offer for sale, or importation of the product described in ANDA No. 208893 has not infringed, does not infringe, and would not infringe, if marketed,

any valid and enforceable claim of the '900 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE

131. The manufacture, use, sale, offer for sale, or importation of the product described in ANDA No. 202602 has not infringed, does not infringe, and would not infringe, if marketed, any valid and enforceable claim of the '310 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE

132. The manufacture, use, sale, offer for sale, or importation of the product described in ANDA No. 208893 has not infringed, does not infringe, and would not infringe, if marketed, any valid and enforceable claim of the '310 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

SIXTH AFFIRMATIVE DEFENSE

133. The manufacture, use, sale, offer for sale, or importation of the product described in ANDA No. 202602 has not infringed, does not infringe, and would not infringe, if marketed, any valid and enforceable claim of the '419 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

SEVENTH AFFIRMATIVE DEFENSE

134. The manufacture, use, sale, offer for sale, or importation of the product described in ANDA No. 208893 has not infringed, does not infringe, and would not infringe, if marketed, any valid and enforceable claim of the '419 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

EIGHTH AFFIRMATIVE DEFENSE

135. The '900 patent and the claims thereof are invalid under one or more provisions of the U.S. Code, including but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 282, and/or the doctrine of obvious-type double patenting.

NINTH AFFIRMATIVE DEFENSE

136. The '310 patent and the claims thereof are invalid under one or more provisions of the U.S. Code, including but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 282, and/or the doctrine of obvious-type double patenting.

TENTH AFFIRMATIVE DEFENSE

137. The '419 patent and the claims thereof are invalid under one or more provisions of the U.S. Code, including but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, 282, and/or the doctrine of obvious-type double patenting.

ELEVENTH AFFIRMATIVE DEFENSE

138. Noven's infringement claims of Counts I and IV are barred as a result of prosecution history estoppel, prosecution history disclaimer, and/or due to statements or amendments made during prosecution of the application which issued as the '900 patent, or related patents and applications, or during any other proceedings in the U.S. Patent and Trademark Office or in court.

TWELFTH AFFIRMATIVE DEFENSE

139. Noven's infringement claims of Counts II and V are barred as a result of prosecution history estoppel, prosecution history disclaimer, and/or due to statements or amendments made during prosecution of the application which issued as the '310 patent, or related patents and applications, or during any other proceedings in the U.S. Patent and Trademark Office or in court.

THIRTEENTH AFFIRMATIVE DEFENSE

140. Noven's infringement claims of Counts III and VI are barred as a result of prosecution history estoppel, prosecution history disclaimer, and/or due to statements or amendments made during prosecution of the application which issued as the '419 patent, or related patents and applications, or during any other proceedings in the U.S. Patent and Trademark Office or in court.

FOURTEENTH AFFIRMATIVE DEFENSE

141. By operation of 35 U.S.C. § 288, Noven is precluded from recovering costs in connection with this action.

FIFTEENTH AFFIRMATIVE DEFENSE

142. Actavis UT reserves the right to assert any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant/Counterclaimant Actavis Laboratories UT, Inc. ("Actavis UT"), as its Counterclaims against Plaintiff/Counterclaim-Defendant Noven Pharmaceuticals, Inc. ("Noven"), alleges as follows, based upon Actavis UT's knowledge as to its own activities, and upon information and belief as to the activities of others:

JURISDICTION AND VENUE

1. This is an action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, the Federal Food, Drug, and Cosmetic Act, and the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, based upon an actual controversy between the parties to declare that Actavis UT is free to continue to seek approval of its Abbreviated New Drug Application ("ANDA") Nos. 206202 and 208893 (collectively, "Actavis UT ANDAs"), and upon approval by the U.S. Food and Drug Administration ("FDA"), to manufacture, use, market, sell, and offer

to sell Estradiol Transdermal System, USP, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day and 0.1 mg/day, as described in ANDA No. 206202 and Estradiol Transdermal System, USP, 0.025 mg/day, as described in ANDA No. 208893, in the United States.

2. This Court has jurisdiction over the subject matter of these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, 21 U.S.C. § 355(j)(5)(C)(i)(II) and/or 35 U.S.C. § 271(e)(5).

3. This Court has personal jurisdiction over Noven because Noven commenced and continues to maintain this action against Actavis UT in this judicial district. In addition, Noven has previously availed itself of the rights and benefits of Delaware law and this Court by initiating numerous actions in this judicial district, including *Noven Pharmaceuticals, Inc. v. Actavis Laboratories UT, Inc.*, C.A. No. 1:15-cv-249-LPS (D. Del.) and *Noven Pharms., Inc. v. Actavis Labs. UT, Inc.*, C.A. No. 16-465-LPS (D. Del.), cases concerning U.S. Patent No. 8,231,906, and *Noven Pharmaceuticals, Inc. v. Mylan Technologies, Inc., et al.*, C.A. No. 1:17-cv-1777-LPS (D. Del.), *Noven Pharmaceuticals, Inc. v. Alvogen Pine Brook LLC, et al.*, C.A. No. 1:17-cv-01429-LPS (D. Del.), and *Noven Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC*, C.A. No. 1:18-cv-00699-LPS (D. Del.), cases concerning U.S. Patent Nos. 9,730,900 (“the ’900 patent”), 9,724,310 (“the ’310 patent”), and 9,833,419 (“the ’419 patent”).

4. Venue is proper under 28 U.S.C. §§ 1391 and 1400, by Noven’s choice of forum.

PARTIES

5. Counterclaimant Actavis Laboratories UT, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 577 Chipeta Way, Salt Lake City, Utah 84108.

6. Counterclaim-Defendant Noven Pharmaceuticals, Inc. purports to be a Delaware corporation with a principal place of business at 11960 S.W. 144th Street, Miami, Florida 33186.

FACTUAL BACKGROUND

7. Actavis UT filed an ANDA, assigned number 206202, with FDA seeking approval to engage in the commercial manufacture, use, or sale of Estradiol Transdermal System, USP, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day and 0.1 mg/day, as described in ANDA No. 206202 (“ANDA 202602 Products”). Actavis UT amended ANDA No. 206202 to contain a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) indicating that the ’900, ’310, and ’419 patents (collectively, “patents-in-suit”) are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the ANDA 206202 Products.

8. Actavis UT filed an ANDA, assigned number 208893, with FDA seeking approval to engage in the commercial manufacture, use, or sale of Estradiol Transdermal System, USP, 0.025 mg/day, as described in ANDA No. 208893 (“ANDA 208893 Products”). Actavis UT amended ANDA No. 208893 to contain a Paragraph IV Certification indicating that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the ANDA 208893 Products.

9. By letter dated February 27, 2018, Actavis UT provided notice to Noven with respect to the ANDA 202602 Products and the ANDA 208893 Products (collectively, “ANDA Products”) and the patents-in-suit under 21 U.S.C. § 355(j)(2)(B)(ii) (“Notice Letter”).

10. Noven filed a Complaint on May 17, 2018, seeking, *inter alia*, a judgment that Actavis UT infringed one or more claims of the patents-in-suit by filing a Paragraph IV Certification as to the patents-in-suit in ANDA Nos. 206202 and 208893.

11. Actavis UT seeks a declaratory judgment that the claims of the patents-in-suit are not infringed and/or are invalid.

FIRST COUNTERCLAIM
Declaratory Judgment of
Noninfringement of U.S. Patent No. 9,730,900

12. Actavis UT incorporates by reference and realleges each of the allegations set forth in paragraphs 1-11 of these Counterclaims.

13. A present, genuine and justiciable controversy exists between Actavis UT and Noven regarding, *inter alia*, whether the manufacture, use, sale, offer for sale, or importation of the ANDA Products would infringe any valid and enforceable claim of the '900 patent.

14. Because Noven maintains and Actavis UT denies that the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Products would directly and/or indirectly infringe any valid and enforceable claim of the '900 patent, either literally or under the doctrine of equivalents, a declaration of rights between the parties is both appropriate and necessary.

15. Neither the filing of the Actavis UT ANDAs nor the manufacture, use, sale, offer for sale, or importation of the ANDA Products would infringe directly and/or indirectly any valid and enforceable claim of the '900 patent, either literally or under the doctrine of equivalents.

16. A declaration that neither the filing of Actavis UT ANDAs nor the manufacture, use, sale, offer for sale, or importation of the ANDA Products would infringe any valid and enforceable claim of the '900 patent is appropriate and warranted.

SECOND COUNTERCLAIM

**Declaratory Judgment of
Noninfringement of U.S. Patent No 9,724,310**

17. Actavis UT incorporates by reference and realleges each of the allegations set forth in paragraphs 1-16 of these Counterclaims.

18. A present, genuine and justiciable controversy exists between Actavis UT and Noven regarding, *inter alia*, whether the manufacture, use, sale, offer for sale, or importation of the ANDA Products would infringe any valid and enforceable claim of the '310 patent.

19. Because Noven maintains and Actavis UT denies that the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Products would directly and/or indirectly infringe any valid and enforceable claim of the '310 patent, either literally or under the doctrine of equivalents, a declaration of rights between the parties is both appropriate and necessary.

20. Neither the filing of the Actavis UT ANDAs nor the manufacture, use, sale, offer for sale, or importation of the ANDA Products would infringe directly and/or indirectly any valid and enforceable claim of the '310 patent, either literally or under the doctrine of equivalents.

21. A declaration that neither the filing of Actavis UT ANDAs nor the manufacture, use, sale, offer for sale, or importation of the ANDA Products would infringe any valid and enforceable claim of the '310 patent is appropriate and warranted.

THIRD COUNTERCLAIM

**Declaratory Judgment of
Noninfringement of U.S. Patent No. 9,833,419**

22. Actavis UT incorporates by reference and realleges each of the allegations set forth in paragraphs 1-21 of these Counterclaims.

23. A present, genuine and justiciable controversy exists between Actavis UT and Noven regarding, *inter alia*, whether the manufacture, use, sale, offer for sale, or importation of the ANDA Products would infringe any valid and enforceable claim of the '419 patent.

24. Because Noven maintains and Actavis UT denies that the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Products would directly and/or indirectly infringe any valid and enforceable claim of the '419 patent, either literally or under the doctrine of equivalents, a declaration of rights between the parties is both appropriate and necessary.

25. Neither the filing of the Actavis UT ANDAs nor the manufacture, use, sale, offer for sale, or importation of the ANDA Products would infringe directly and/or indirectly any valid and enforceable claim of the '419 patent, either literally or under the doctrine of equivalents.

26. A declaration that neither the filing of Actavis UT ANDAs nor the manufacture, use, sale, offer for sale, or importation of the ANDA Products would infringe any valid and enforceable claim of the '419 patent is appropriate and warranted.

FOURTH COUNTERCLAIM

**Declaratory Judgment of
Invalidity of U.S. Patent No. 9,730,900**

27. Actavis UT incorporates by reference and realleges each of the allegations set forth in paragraphs 1-26 of these Counterclaims.

28. A present, genuine and justiciable controversy exists between Actavis UT and Noven regarding, *inter alia*, the validity of the '900 patent and the claims thereof.

29. Because Noven maintains and Actavis UT denies that the '900 patent and the claims thereof are valid and enforceable, a declaration of rights between the parties is both appropriate and necessary.

30. The '900 patent and the claims thereof are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting.

31. Based at least upon the reasons and facts set forth in the Notice Letter, the subject matter claimed in the '900 patent fails to comply with 35 U.S.C. § 103.

32. The '900 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

33. The alleged invention of the '900 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '900 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '900 patent and would have had a reasonable expectation of success in doing so.

34. The subject matter claimed in the '900 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

35. Based at least upon the reasons and facts set forth in the Notice Letter, the subject matter claimed in the '900 patent fails to comply with 35 U.S.C. § 112.

36. The specification of the '900 patent does not enable a person of ordinary skill in the art to make and use the claimed invention for the full scope of the claims without undue experimentation.

37. A declaration that the '900 patent and the claims thereof are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112, 282, and/or the doctrine of obviousness-type double patenting, is appropriate and warranted.

FIFTH COUNTERCLAIM
Declaratory Judgment of
Invalidity of U.S. Patent No. 9,724,310

38. Actavis UT incorporates by reference and realleges each of the allegations set forth in paragraphs 1-37 of these Counterclaims.

39. A present, genuine and justiciable controversy exists between Actavis UT and Noven regarding, *inter alia*, the validity of the '310 patent and the claims thereof.

40. Because Noven maintains and Actavis UT denies that the '310 patent and the claims thereof are valid and enforceable, a declaration of rights between the parties is both appropriate and necessary.

41. The '310 patent and the claims thereof are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting.

42. Based at least upon the reasons and facts set forth in the Notice Letter, the subject matter claimed in the '310 patent fails to comply with 35 U.S.C. § 103.

43. The '310 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

44. The alleged invention of the '310 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '310 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been

motivated to combine the teachings of the prior art to achieve the alleged invention of the '310 patent and would have had a reasonable expectation of success in doing so.

45. The subject matter claimed in the '310 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

46. Based at least upon the reasons and facts set forth in the Notice Letter, the subject matter claimed in the '310 patent fails to comply with 35 U.S.C. § 112.

47. The specification of the '310 patent does not enable a person of ordinary skill in the art to make and use the claimed invention for the full scope of the claims without undue experimentation.

48. A declaration that the '310 patent and the claims thereof are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112, 282, and/or the doctrine of obviousness-type double patenting, is appropriate and warranted.

SIXTH COUNTERCLAIM
Declaratory Judgment of
Invalidity of U.S. Patent No. 9,833,419

49. Actavis UT incorporates by reference and realleges each of the allegations set forth in paragraphs 1-48 of these Counterclaims.

50. A present, genuine and justiciable controversy exists between Actavis UT and Noven regarding, *inter alia*, the validity of the '419 patent and the claims thereof.

51. Because Noven maintains and Actavis UT denies that the '419 patent and the claims thereof are valid and enforceable, a declaration of rights between the parties is both appropriate and necessary.

52. The '419 patent and the claims thereof are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting.

53. Based at least upon the reasons and facts set forth in the Notice Letter, the subject matter claimed in the '419 patent fails to comply with 35 U.S.C. § 103.

54. The '419 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

55. The alleged invention of the '419 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '419 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '419 patent and would have had a reasonable expectation of success in doing so.

56. The subject matter claimed in the '419 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

57. Based at least upon the reasons and facts set forth in the Notice Letter, the subject matter claimed in the '419 patent fails to comply with 35 U.S.C. § 112.

58. The specification of the '419 patent does not enable a person of ordinary skill in the art to make and use the claimed invention for the full scope of the claims without undue experimentation.

59. A declaration that the '419 patent and the claims thereof are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112, 282, and/or the doctrine of obviousness-type double patenting, is appropriate and warranted.

PRAYER FOR RELIEF

WHEREFORE, Actavis UT respectfully requests that the Court enter judgment as follows:

- a. That the Complaint be dismissed and that all relief requested by Noven therein be denied;
- b. That Actavis UT and the ANDA Products have not infringed, are not infringing, and will not infringe, directly and/or indirectly, any valid and enforceable claim of the patents-in-suit, that Actavis UT has a lawful right to proceed with ANDA Nos. 206202 and 208893 and to obtain FDA's approval of ANDA Nos. 206202 and 208893 and to manufacture, market, offer for sale, and sell the ANDA Products upon approval of ANDA No. 206202 and 208893;
- c. That each claim of the patents-in-suit is invalid;
- d. That any applicable 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii) be shortened to expire immediately;
- e. That Noven and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive notice thereof, be preliminarily and permanently enjoined from initiating infringement litigation against, or threatening Actavis UT or any parties associated therewith (including Actavis UT's customers) or charging any of them either orally or

in writing with infringement, or inducement of infringement, or contributory infringement of the patents-in-suit;

- f. That this is an exceptional case under 35 U.S.C. § 285, and therefore that Actavis UT is entitled to an award of attorneys' fees, costs, and expenses in this action; and
- g. That Actavis UT be awarded such other further relief as this Court may deem just and proper.

OF COUNSEL:

James K. Stronski
Jacob Z. Zambrzycki
Anne Elise Herold Li
Preetha Chakrabarti
CROWELL & MORING LLP
590 Madison Avenue, 20th Floor
New York, NY 10022-2524
(212) 223-4000

Chiemi D. Suzuki
CROWELL & MORING LLP
515 South Flower St., 40th Floor
Los Angeles, CA 90071-2201
(213) 622-4750

Craig P. Lytle
CROWELL & MORING LLP
1001 Pennsylvania Avenue NW
Washington, DC 20004-2595
(202) 624-2500

Dated: June 8, 2018

/s/ Steven J. Fineman

Steven J. Fineman (#4025)
Fineman@rlf.com
Katharine L. Mowery (#5629)
Mowery@rlf.com
RICHARDS, LAYTON & FINGER P.A.
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 651-7700

*Attorneys for Defendant/Counterclaimant
Actavis Laboratories UT, Inc.*