IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACTAVIS LABORATORIES UT, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. _____
	)	
PAR PHARMACEUTICAL, INC.,	)	
	)	
Defendant.	)	
	)	
	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Actavis Laboratories UT, Inc. ("Actavis"), files this Complaint for patent infringement against Defendant Par Pharmaceutical, Inc. ("Par") under 35 U.S.C. §§ 271(e)(2), (a), (b), and (c). This patent action concerns the pharmaceutical drug product Gelnique® (oxybutynin chloride) 10% gel. Actavis hereby states as follows:

JURISDICTION AND PARTIES

1. Actavis Laboratories UT, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 577 Chipeta Way, Salt Lake City, UT 84108. Actavis manufactures and sells, through an affiliate, a 10% strength of oxybutynin gel in the United States under the brand name Gelnique® (oxybutynin chloride) 10% gel.

2. On information and belief, Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, has a registered agent for service of process in Delaware, and has a principal place of business at 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

3. On information and belief, Par is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

4. On information and belief, Par is registered with the Delaware Board of Pharmacy as "Distributer/Manufacturer CSR" (License No. DM-0009385) and "Pharmacy-Wholesale" with (License No. A4-0002001).

5. On information and belief, Par derives substantial revenue from the sale of its products in Delaware and throughout the United States.

6. On information and belief, Par conducts marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

7. Par has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Par has filed suit for patent infringement and has filed counterclaims for declaratory judgment. *See, e.g., Par Pharmaceutical, Inc. et al. v. TWi Pharmaceuticals, Inc. et al.*, 1:15-cv-00710-SLR (D. Del.); *Par Pharmaceutical, Inc. et al. v. Breckenridge Pharmaceutical Inc.*, 1:15-cv-00486-SLR (D. Del.); *Par Pharmaceutical, Inc. v. Novartis Pharmaceuticals Corporation et al.*, 1:14-cv-00843-RGA (D. Del.); *Par Pharmaceutical, Inc. et al. v. Breckenridge Pharmaceutical Inc.*, 1:13-cv-01114-SLR-SRF (D. Del.).

8. As set forth in paragraphs 2-7 above, this Court has personal jurisdiction over Par, by virtue of, among other things: (1) its incorporation in the State of Delaware; (2) its sale and distribution of generic drugs in Delaware; (3) its registration to do business in Delaware, including its appointment of a registered agent in Delaware for the receipt of service of process;

(4) its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff Actavis, which is a Delaware corporation; and (5) its purposeful availment of this forum for the purpose of litigating prior patent disputes.

9. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq*. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT
(Infringement of the '694 Patent Under 35 U.S.C. § 271(e)(2))

10. Actavis realleges and incorporates by reference paragraphs 1-9.

11. United States Patent No. 7,029,694 ("the '694 patent"), titled "Compositions and Methods for Transdermal Oxybutynin Therapy," was duly and legally issued to inventors Charles D. Ebert and Steven W. Sanders by the United States Patent and Trademark Office ("PTO") on April 18, 2006. The '694 patent is currently assigned to Plaintiff. A true and correct copy of the '694 patent is attached as Exhibit A.

12. Actavis holds New Drug Application ("NDA") No. 22204, which is directed to the use of Gelnique® 10% gel in the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. The FDA approved NDA No. 22204 on January 27, 2009. The '694 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for NDA No. 22204.

13. On information and belief, Par filed, or caused to be filed, ANDA No. 207329 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial

manufacture, use, and sale of Oxybutynin Chloride Gel, 10% ("Par's Generic Oxybutynin Product") in the United States before the expiration of the '694 patent.

14. On information and belief, ANDA No. 207329 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the claims of the '694 patent "are invalid, unenforceable, and/or will not be infringed" by Par's Generic Oxybutynin Product.

15. Par sent, or caused to be sent, to Actavis, a letter dated August 18, 2015 ("Par's Notice Letter") notifying Actavis that Par had submitted ANDA No. 207329, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Par's Notice Letter alleges invalidity of claims of the '694 patent, but does not present any unenforceability or noninfringement defenses with regard to the '694 patent.

16. On information and belief, Par seeks approval for the commercial manufacture, use, and sale of at least one formulation of Par's Generic Oxybutynin Product that, if approved, would infringe one or more claims of the '694 patent.

17. On information and belief, Par seeks approval of at least one indication for Par's Generic Oxybutynin Product that is claimed in the '694 patent.

18. Under 35 U.S.C. § 271(e)(2)(A), Par infringed one or more claims of the '694 patent, in violation of Actavis's patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market—before the expiration date of the '694 patent—Par's Generic Oxybutynin Product. On information and belief, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Par's Generic Oxybutynin Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '694 patent. On information and belief, the manufacture, use, offer for sale, or sale

within the United States, or importation into the United States, of Par's Generic Oxybutynin Product would contribute to or induce the direct infringement of one or more claims of the '694 patent by users of Par's Generic Oxybutynin Product.

19. On information and belief, Par has knowledge of the '694 patent and has filed ANDA No. 207329 seeking authorization to commercially manufacture, use, offer for sale, and sell Par's Generic Oxybutynin Product in the United States. On information and belief, if the FDA approves ANDA No. 207329, physicians, health care providers, and/or patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '694 patent.

20. On information and belief, Par knows and intends that physicians, health care providers, and/or patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par, and will therefore induce infringement of one or more claims of the '694 patent, with the requisite intent.

21. On information and belief, if the FDA approves ANDA No. 207329, Par will sell or offer to sell its Generic Oxybutynin Product specifically labeled for use in practicing one or more claims of the '694 patent, wherein Par's Generic Oxybutynin Product is a material part of the claimed invention, wherein Par knows that physicians will prescribe and patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par in practicing one or more claims of the '694 patent, and wherein Par's Generic Oxybutynin Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Par will thus contribute to the infringement of one or more claims of the '694 patent.

22. Actavis will be substantially and irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Actavis has no adequate remedy at law.

COUNT II FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '694 Patent Under 35 U.S.C. § 271(a), (b), and/or (c))

23. Actavis realleges and incorporates by reference paragraphs 1-22.

24. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

25. Par sent, or caused to be sent, to Actavis, Par's Notice Letter notifying Actavis that Par had submitted ANDA No. 207329, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Par's Notice Letter alleges invalidity of claims of the '694 patent, but does not raise any unenforceability or noninfringement defenses with regard to the '694 patent.

26. On information and belief, if the FDA approves Par's Generic Oxybutynin Product for use and sale in the United States, Par would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '694 patent under 35 U.S.C. § 271(a), in violation of Actavis's patent rights by making, using, offering to sell, and/or selling within the United States, and/or importing into the United States, Par's Generic Oxybutynin Product.

27. On information and belief, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Par's Generic Oxybutynin Product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '694 patent, under 35 U.S.C. § 271(b) and/or (c), in violation of Actavis's patent rights.

28. On information and belief, Par has knowledge of the '694 patent and has filed ANDA No. 207329 seeking authorization to commercially manufacture, use, offer for sale, and

sell Par's Generic Oxybutynin Product in the United States. On information and belief, if the FDA approves ANDA No. 207329, physicians, health care providers, and/or patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '694 patent under 35 U.S.C. § 271(a), in violation of Actavis's patent rights.

29. On information and belief, Par knows and intends that physicians, health care providers, and/or patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par, and will therefore induce infringement of one or more claims of the '694 patent under 35 U.S.C. § 271(b).

30. On information and belief, if the FDA approves ANDA No. 207329, Par will sell or offer to sell its Generic Oxybutynin Product specifically labeled for use in practicing one or more claims of the '694 patent, wherein Par's Generic Oxybutynin Product is a material part of the invention claimed in the '694 patent, wherein Par knows that physicians will prescribe and patients will use Par's Generic Oxybutynin Product for practicing one or more claims in the '694 patent, and wherein Par's Generic Oxybutynin Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Par will thus contribute to the infringement of the '694 patent under 35 U.S.C. § 271(c).

31. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Actavis and Par as to liability for the infringement of the '694 patent claims. Par's actions have created in Actavis a reasonable apprehension of irreparable harm and loss resulting from Par's threatened imminent actions.

COUNT III FOR PATENT INFRINGEMENT
(Infringement of the '483 Patent Under 35 U.S.C. § 271(e)(2))

32. Actavis realleges and incorporates by reference paragraphs 1-31.

33. United States Patent No. 7,179,483 ("the '483 patent"), titled "Compositions and Methods for Transdermal Oxybutynin Therapy," was duly and legally issued to inventors Charles D. Ebert and Steven W. Sanders by the PTO on February 20, 2007. The '483 patent is currently assigned to Plaintiff Actavis. A true and correct copy of the '483 patent is attached as Exhibit B.

34. Actavis holds NDA No. 22204, which is directed to the use of Gelnique® 10% gel in the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. The FDA approved NDA No. 22204 on January 27, 2009. The '483 patent is listed in the Orange Book for NDA No. 22204.

35. On information and belief, Par filed, or caused to be filed, ANDA No. 207329 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Par's Generic Oxybutynin Product in the United States before the expiration of the '483 patent.

36. On information and belief, ANDA No. 207329 contains a Paragraph IV certification alleging that the claims of the '483 patent are "invalid, unenforceable, and/or will not be infringed" by Par's Generic Oxybutynin Product.

37. Par sent, or caused to be sent, to Actavis, Par's Notice Letter notifying Actavis that Par had submitted ANDA No. 207329, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Par's Notice Letter alleges invalidity of claims of the '483 patent, but does not raise any unenforceability or noninfringement defenses with regard to the '483 patent.

38. On information and belief, Par seeks approval for the commercial manufacture, use, and sale of at least one formulation of Par's Generic Oxybutynin Product that, if approved, would infringe one or more claims of the '483 patent.

39. On information and belief, Par seeks approval of at least one indication for Par's Generic Oxybutynin Product that is claimed in the '483 patent.

40. Under 35 U.S.C. § 271(e)(2)(A), Par infringed one or more claims of the '483 patent, in violation of Actavis's patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market—before the expiration date of the '483 patent—Par's Generic Oxybutynin Product. On information and belief, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Par's Generic Oxybutynin Product would contribute to or induce the direct infringement of one or more claims of the '483 patent by users of Par's Generic Oxybutynin Product.

41. On information and belief, Par has knowledge of the '483 patent and has filed ANDA No. 207329 seeking authorization to commercially manufacture, use, offer for sale, and sell Par's Generic Oxybutynin Product in the United States. On information and belief, if the FDA approves ANDA No. 207329, physicians, health care providers, and/or patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '483 patent.

42. On information and belief, Par knows and intends that physicians, health care providers, and/or patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par, and will therefore induce infringement of one or more claims of the '483 patent, with the requisite intent.

43. On information and belief, if the FDA approves ANDA No. 207329, Par will sell or offer to sell its Generic Oxybutynin Product specifically labeled for use in practicing one or more claims of the '483 patent, wherein Par's Generic Oxybutynin Product is a material part of

the claimed invention, wherein Par knows that physicians will prescribe and patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par in practicing one or more claims of the '483 patent, and wherein Par's Generic Oxybutynin Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Par will thus contribute to the infringement of one or more claims of the '483 patent.

44. Actavis will be substantially and irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Actavis has no adequate remedy at law.

COUNT IV FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '483 Patent Under 35 U.S.C. § 271(b) and/or (c))

45. Actavis realleges and incorporates by reference paragraphs 1-44.

46. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

47. Par sent, or caused to be sent, to Actavis, Par's Notice Letter notifying Actavis that Par had submitted ANDA No. 207329, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Par's Notice Letter alleges invalidity of claims of the '483 patent, but does not raise any unenforceability or noninfringement defenses with regard to the '483 patent.

48. On information and belief, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Par's Generic Oxybutynin Product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '483 patent, under 35 U.S.C. § 271(b) and/or (c), in violation of Actavis's patent rights.

49. On information and belief, Par has knowledge of the ’483 patent and has filed ANDA No. 207329 seeking authorization to commercially manufacture, use, offer for sale, and sell Par’s Generic Oxybutynin Product in the United States. On information and belief, if the FDA approves ANDA No. 207329, physicians, health care providers, and/or patients will use Par’s Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the ’483 patent under 35 U.S.C. § 271(a), in violation of Actavis’s patent rights.

50. On information and belief, Par knows and intends that physicians, health care providers, and/or patients will use Par’s Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par, and will therefore induce infringement of one or more claims of the ’483 patent under 35 U.S.C. § 271(b).

51. On information and belief, if the FDA approves ANDA No. 207329, Par will sell or offer to sell its Generic Oxybutynin Product specifically labeled for use in practicing one or more claims of the ’483 patent, wherein Par’s Generic Oxybutynin Product is a material part of the invention claimed in the ’483 patent, wherein Par knows that physicians will prescribe and patients will use Par’s Generic Oxybutynin Product for practicing one or more claims in the ’483 patent, and wherein Par’s Generic Oxybutynin Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Par will thus contribute to the infringement of the ’483 patent under 35 U.S.C. § 271(c).

52. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Actavis and Par as to liability for the infringement of the ’483 patent claims. Par’s actions have created in Actavis a reasonable apprehension of irreparable harm and loss resulting from Par’s threatened imminent actions.

COUNT V FOR PATENT INFRINGEMENT
(Infringement of the '662 Patent Under 35 U.S.C. § 271(e)(2))

53. Actavis realleges and incorporates by reference paragraphs 1-52.

54. United States Patent No. 8,241,662 ("the '662 patent"), titled "Unoccluded Topical Oxybutynin Gel Composition and Methods for Transdermal Oxybutynin Therapy," was duly and legally issued to inventors Charles D. Ebert and Steven W. Sanders by the PTO on August 14, 2012. The '662 patent is currently assigned to Plaintiff Actavis. A true and correct copy of the '662 patent is attached as Exhibit C.

55. Actavis holds NDA No. 22204, which is directed to the use of Gelnique® 10% gel in the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. The FDA approved NDA No. 22204 on January 27, 2009. The '662 patent is listed in the Orange Book for NDA No. 22204.

56. On information and belief, Par filed, or caused to be filed, ANDA No. 207329 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Par's Generic Oxybutynin Product in the United States before the expiration of the '662 patent.

57. On information and belief, ANDA No. 207329 contains a Paragraph IV certification alleging that the claims of the '662 patent are "invalid, unenforceable, and/or will not be infringed" by Par's Generic Oxybutynin Product.

58. Par sent, or caused to be sent, to Actavis, Par's Notice Letter notifying Actavis that Par had submitted ANDA No. 207329, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Par's Notice Letter alleges invalidity of claims of the '662 patent, but does not raise any unenforceability or noninfringement defenses with regard to the '662 patent.

59. On information and belief, Par seeks approval for the commercial manufacture, use, and sale of at least one formulation of Par's Generic Oxybutynin Product that, if approved, would infringe one or more claims of the '662 patent.

60. On information and belief, Par seeks approval of at least one indication for Par's Generic Oxybutynin Product that is claimed in the '662 patent.

61. Under 35 U.S.C. § 271(e)(2)(A), Par infringed one or more claims of the '662 patent, in violation of Actavis's patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market—before the expiration date of the '662 patent—Par's Generic Oxybutynin Product. On information and belief, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Par's Generic Oxybutynin Product would contribute to or induce the direct infringement of one or more claims of the '662 patent by users of Par's Generic Oxybutynin Product.

62. On information and belief, Par has knowledge of the '662 patent and has filed ANDA No. 207329 seeking authorization to commercially manufacture, use, offer for sale, and sell Par's Generic Oxybutynin Product in the United States. On information and belief, if the FDA approves ANDA No. 207329, physicians, health care providers, and/or patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '662 patent.

63. On information and belief, Par knows and intends that physicians, health care providers, and/or patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par, and will therefore induce infringement of one or more claims of the '662 patent, with the requisite intent.

64. On information and belief, if the FDA approves ANDA No. 207329, Par will sell or offer to sell its Generic Oxybutynin Product specifically labeled for use in practicing one or more claims of the ’662 patent, wherein Par’s Generic Oxybutynin Product is a material part of the claimed invention, wherein Par knows that physicians will prescribe and patients will use Par’s Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par in practicing one or more claims of the ’662 patent, and wherein Par’s Generic Oxybutynin Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Par will thus contribute to the infringement of one or more claims of the ’662 patent.

65. Actavis will be substantially and irreparably harmed by Par’s infringing activities unless those activities are enjoined by this Court. Actavis has no adequate remedy at law.

COUNT VI FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the ’662 Patent Under 35 U.S.C. § 271 (b) and/or (c))

66. Actavis realleges and incorporates by reference paragraphs 1-65.

67. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

68. Par sent, or caused to be sent, to Actavis, Par’s Notice Letter notifying Actavis that Par had submitted ANDA No. 207329, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Par’s Notice Letter alleges invalidity of claims of the ’662 patent, but does not raise any unenforceability or noninfringement defenses with regard to the ’662 patent.

69. On information and belief, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Par’s Generic Oxybutynin Product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more

claims of the ’662 patent, under 35 U.S.C. § 271(b) and/or (c), in violation of Actavis’s patent rights.

70. On information and belief, Par has knowledge of the ’662 patent and has filed ANDA No. 207329 seeking authorization to commercially manufacture, use, offer for sale, and sell Par’s Generic Oxybutynin Product in the United States. On information and belief, if the FDA approves ANDA No. 207329, physicians, health care providers, and/or patients will use Par’s Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the ’662 patent under 35 U.S.C. § 271(a), in violation of Actavis’s patent rights.

71. On information and belief, Par knows and intends that physicians, health care providers, and/or patients will use Par’s Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par, and will therefore induce infringement of one or more claims of the ’662 patent under 35 U.S.C. § 271(b).

72. On information and belief, if the FDA approves ANDA No. 207329, Par will sell or offer to sell its Generic Oxybutynin Product specifically labeled for use in practicing one or more claims of the ’662 patent, wherein Par’s Generic Oxybutynin Product is a material part of the invention claimed in the ’662 patent, wherein Par knows that physicians will prescribe and patients will use Par’s Generic Oxybutynin Product for practicing one or more claims in the ’662 patent, and wherein Par’s Generic Oxybutynin Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Par will thus contribute to the infringement of the ’662 patent under 35 U.S.C. § 271(c).

73. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Actavis and Par as to liability for the infringement of the ’662

patent claims. Par's actions have created in Actavis a reasonable apprehension of irreparable harm and loss resulting from Par's threatened imminent actions.

COUNT VII FOR PATENT INFRINGEMENT
(Infringement of the '392 Patent Under 35 U.S.C. § 271(e)(2))

74. Actavis realleges and incorporates by reference paragraphs 1-73.

75. United States Patent No. 8,920,392 ("the '392 patent"), titled "Method for Treating Overactive Bladders and a Device for Storage and Administration of Topical Oxybutynin Compositions," was duly and legally issued to inventors Scott Gochnour, Venkatesh Subramanyan, and Michael W. Kimball by the PTO on December 30, 2014. The '392 patent is currently assigned to Plaintiff Actavis. A true and correct copy of the '392 patent is attached as Exhibit D.

76. Actavis holds NDA No. 22204, which is directed to the use of Gelnique® 10% gel in the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. The FDA approved NDA No. 22204 on January 27, 2009. The '392 patent is listed in the Orange Book for NDA No. 22204.

77. On information and belief, Par filed, or caused to be filed, ANDA No. 207329 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of Par's Generic Oxybutynin Product in the United States before the expiration of the '392 patent.

78. On information and belief, ANDA No. 207329 contains a Paragraph IV certification alleging that the claims of the '392 patent are "invalid, unenforceable, and/or will not be infringed" by Par's Generic Oxybutynin Product.

79. Par sent, or caused to be sent, to Actavis, Par's Notice Letter notifying Actavis that Par had submitted ANDA No. 207329, and providing information pursuant to 21 U.S.C.

§ 355(j)(2)(B)(ii). Par's Notice Letter alleges invalidity of claims of the '392 patent, but does not raise any unenforceability or noninfringement defenses with regard to the '392 patent.

80. On information and belief, Par seeks approval for the commercial manufacture, use, and sale of at least one formulation of Par's Generic Oxybutynin Product that, if approved, would infringe one or more claims of the '392 patent.

81. On information and belief, Par seeks approval of at least one indication for Par's Generic Oxybutynin Product that is claimed in the '392 patent.

82. Under 35 U.S.C. § 271(e)(2)(A), Par infringed one or more claims of the '392 patent, in violation of Actavis's patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market—before the expiration date of the '392 patent—Par's Generic Oxybutynin Product. On information and belief, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Par's Generic Oxybutynin Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '392 patent. On information and belief, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Par's Generic Oxybutynin Product would contribute to or induce the direct infringement of one or more claims of the '392 patent by users of Par's Generic Oxybutynin Product.

83. On information and belief, Par has knowledge of the '392 patent and has filed ANDA No. 207329 seeking authorization to commercially manufacture, use, offer for sale, and sell Par's Generic Oxybutynin Product in the United States. On information and belief, if the FDA approves ANDA No. 207329, physicians, health care providers, and/or patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by

Par and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '392 patent.

84. On information and belief, Par knows and intends that physicians, health care providers, and/or patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par, and will therefore induce infringement of one or more claims of the '392 patent, with the requisite intent.

85. On information and belief, if the FDA approves ANDA No. 207329, Par will sell or offer to sell its Generic Oxybutynin Product specifically labeled for use in practicing one or more claims of the '392 patent, wherein Par's Generic Oxybutynin Product is a material part of the claimed invention, wherein Par knows that physicians will prescribe and patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par in practicing one or more claims of the '392 patent, and wherein Par's Generic Oxybutynin Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Par will thus contribute to the infringement of one or more claims of the '392 patent.

86. Actavis will be substantially and irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Actavis has no adequate remedy at law.

COUNT VIII FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '392 Patent Under 35 U.S.C. § 271(a), (b), and/or (c))

87. Actavis realleges and incorporates by reference paragraphs 1-86.

88. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

89. Par sent, or caused to be sent, to Actavis, Par's Notice Letter notifying Actavis that Par had submitted ANDA No. 207329, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Par's Notice Letter alleges invalidity of claims of the '392 patent, but does not raise any unenforceability or noninfringement defenses with regard to the '392 patent.

90. On information and belief, if the FDA approves Par's Generic Oxybutynin Product for use and sale in the United States, Par would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '392 patent under 35 U.S.C. § 271(a), in violation of Actavis's patent rights by making, using, offering to sell, and/or selling within the United States, and/or importing into the United States Par's Generic Oxybutynin Product.

91. On information and belief, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Par's Generic Oxybutynin Product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '392 patent, under 35 U.S.C. § 271(b) and/or (c), in violation of Actavis's patent rights.

92. On information and belief, Par has knowledge of the '392 patent and has filed ANDA No. 207329 seeking authorization to commercially manufacture, use, offer for sale, and sell Par's Generic Oxybutynin Product in the United States. On information and belief, if the FDA approves ANDA No. 207329, physicians, health care providers, and/or patients will use Par's Generic Oxybutynin Product in accordance with the instructions and/or label provided by Par and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '392 patent under 35 U.S.C. § 271(a), in violation of Actavis's patent rights.

93. On information and belief, Par knows and intends that physicians, health care providers, and/or patients will use Par's Generic Oxybutynin Product in accordance with the

instructions and/or label provided by Par, and will therefore induce infringement of one or more claims of the ’392 patent under 35 U.S.C. § 271(b).

94. On information and belief, if the FDA approves ANDA No. 207329, Par will sell or offer to sell its Generic Oxybutynin Product specifically labeled for use in practicing one or more claims of the ’392 patent, wherein Par’s Generic Oxybutynin Product is a material part of the invention claimed in the ’392 patent, wherein Par knows that physicians will prescribe and patients will use Par’s Generic Oxybutynin Product for practicing one or more claims in the ’392 patent, and wherein Par’s Generic Oxybutynin Product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Par will thus contribute to the infringement of the ’392 patent under 35 U.S.C. § 271(c).

95. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Actavis and Par as to liability for the infringement of the ’392 patent claims. Par’s actions have created in Actavis a reasonable apprehension of irreparable harm and loss resulting from Par’s threatened imminent actions.

PRAYER FOR RELIEF

Wherefore, Plaintiff Actavis prays for judgment against Defendant Par as follows:

a) declare that United States Patent Nos. 7,029,694; 7,179,483; 8,241,662; and 8,920,392 are valid;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Par infringed United States Patent Nos. 7,029,694; 7,179,483; 8,241,662; and 8,920,392 by submitting ANDA No. 207329 to the FDA to obtain approval to commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States, Par’s Generic Oxybutynin Product prior to the expiration of said patents;

c) declare that Par's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Par's Generic Oxybutynin Product prior to the expiration of United States Patent Nos. 7,029,694 and 8,920,392 would constitute infringement of one or more claims of said patents under 35 U.S.C. § 271 (a), (b), and/or (c); and that Par's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Par's Generic Oxybutynin Product prior to the expiration of United States Patent Nos. 7,179,483 and 8,241,662 would constitute infringement of one or more claims of said patents under 35 U.S.C. § 271 (b), and/or (c);

d) order that the effective date of any FDA approval of Par's Generic Oxybutynin Product shall be no earlier than the expiration date of United States Patent Nos. 7,029,694; 7,179,483; 8,241,662; and 8,920,392, including any exclusivities or extensions to which Actavis is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoin Par, and all persons acting in concert with Par, from seeking, obtaining, or maintaining final approval of ANDA No. 207329 until the expiration of United States Patent Nos. 7,029,694; 7,179,483; 8,241,662; and 8,920,392, including any exclusivities or extensions to which Actavis is or becomes entitled;

f) enjoin Par, and all persons acting in concert with Par, from commercially manufacturing, using, offering for sale, or selling Par's Generic Oxybutynin Product within the United States, or importing Par's Generic Oxybutynin Product into the United States, until the expiration of United States Patent Nos. 7,029,694; 7,179,483; 8,241,662; and 8,920,392, including any exclusivities or extensions to which Actavis is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(B);

g) enjoin Par, and all persons acting in concert with Par, from commercially manufacturing, using, offering for sale, or selling Par's Generic Oxybutynin Product within the United States, or importing Par's Generic Oxybutynin Product into the United States, until the expiration of United States Patent Nos. 7,029,694; 7,179,483; 8,241,662; and 8,920,392, including any exclusivities or extensions to which Actavis is or becomes entitled, in accordance with 35 U.S.C. § 283;

h) declare this to be an exceptional case and award Actavis its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4); and

i) grant Actavis such further and additional relief that this Court deems just and proper.

Dated: October 2, 2015

Respectfully submitted,

/s/ Francis DiGiovanni

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